A Randomized, Blinded Clinical Evaluation of a Novel Microwave Device for Treating Axillary Hyperhidrosis: The Dermatologic Reduction in Underarm Perspiration Study

Dee Anna Glaser, MD,* William P. Coleman, III, MD,† Larry K. Fan, MD,‡ Michael S. Kaminer, MD,§ Suzanne L. Kilmer, MD,¶ Robert Nossa, MD,** Stacy R. Smith, MD,†† and Kathryn F. O'Shaughnessy, PhD‡‡

BACKGROUND Duration of effect and effectiveness limit current options for treating axillary hyperhidrosis. A new microwave procedure for treatment of axillary hyperhidrosis has been tested.

STUDY DESIGN/MATERIALS AND METHODS Adults with primary axillary hyperhidrosis were enrolled in a randomized, sham-controlled, blinded study. Subjects were required to have a Hyperhidrosis Disease Severity Scale (HDSS) score of 3 or 4 and baseline sweat production greater than 50 mg/5 min. Procedures were administered using a proprietary microwave energy device that isolates and heats target tissue. Responders were defined as subjects reporting a HDSS score of 1 or 2. Subjects were followed for 6 months (sham group) or 12 months (active group).

RESULTS Thirty days after treatment, the active group had a responder rate of 89% (72/81), and the sham group had a responder rate of 54% (21/39) ($P < .001$). Treatment efficacy was stable from 3 months (74%) to 12 months (69%), when follow-up ended. Adverse events were generally mild, and all but one resolved over time.

CONCLUSIONS The procedure demonstrated statistically significant, long-term efficacy in sweat reduction. As with any new procedure, findings from this first investigational device study identified optimization strategies for the future.

This study was funded by Miramar Labs. Drs. Coleman, Glaser, and Kaminer are on the Scientific Advisory Board for Miramar Labs and have equity in the company.

Axillary hyperhidrosis (excessive underarm sweating) is a condition that can be a substantial burden, affecting work performance, relationships with other people, and self-esteem. One study that defined axillary hyperhidrosis as excessive or abnormal/unusual sweating found that 1.4% of the U.S. population met that definition.[1] A third-party survey found that 33% of the population reports that they sweat too much (in their underarms) (unpublished data). Duration of effect (e.g., topical antiperspirants, injections of botulinum toxin[2]) and complications and effectiveness (surgical interventions, sympathectomy[3,4]) limit current treatment options for axillary hyperhidrosis. Microwave devices, although not commonly used in dermatology, can be optimized to focus heat at the interface between the skin and subcutaneous tissue and cause irreversible thermolysis of apocrine and eccrine sweat glands that reside at that interface. In this study, a new early-generation

*Department of Dermatology, St. Louis University, St. Louis, Missouri; †Coleman Center for Cosmetic Dermatologic Surgery, Metairie, Louisiana; ‡7|7 Plastic Surgery, San Francisco, California; §SkinCare Physicians, Chestnut Hill, Massachusetts; ¶Laser and Skin Surgery Center of Northern California, Sacramento, California
**The Dermatology Group of Northern New Jersey, Verona, New Jersey; ††Division of Dermatology, University of California San Diego, San Diego, California; ‡‡Miramar Labs Inc., Sunnyvale, California*

ISSN: 1076-0512 • Dermatol Surg 2012;38:185–191 • DOI: 10.1111/j.1524-4725.2011.02250.x

microwave-based procedure for treatment of axillary hyperhidrosis was tested for long-term efficacy and safety.

Materials and Methods

Patients

One hundred twenty adults with primary axillary hyperhidrosis (PAH) were enrolled in a multicenter, randomized, sham-controlled study. Subjects were required to have a Hyperhidrosis Disease Severity Scale (HDSS)[5] score of 3 or 4 (barely tolerable or intolerable sweating) and to have baseline axillary sweat production of greater than 50 mg/5 min as measured by gravimetric readings. Subjects were excluded if they had ever had prior surgery for PAH or botulinum toxin injections to treat PAH within the past 12 months.

The study was conducted in accordance with the Declaration of Helsinki, and all subjects signed an institutional review board–approved informed consent before any study procedures.

Sweat Assessments

The primary method of assessing level of underarm sweat was subject-reported HDSS score. Table 1 provides the definition of each of the four possible categories. Gravimetric assessment of sweat was used as a secondary measure. Measurements were taken in a normal-temperature room with subjects at rest. Axillae were wiped with gauze or absorbent towels before the test, and a preweighed filter paper (Whatman #541, 90 mm, Maidstone, England) was placed in each axilla for 5 minutes, after which the difference in weight was calculated in milligrams.

Although not used for any study end points, the starch–iodine test was used in some treatment sessions to identify areas that still had active sweat glands. An alcohol-based iodine mixture was wiped on the skin of the axilla, and then corn starch was sprinkled on the area and gently brushed to create a thin uniform coating. Any sweat that appeared turned black (Figure 1). To protect study blinding, subjects wore an eye-mask during the starch–iodine test to preclude the possibility of seeing the extent of the sweat.

TABLE 1. Hyperhidrosis Disease Severity Scale Definition

Score	*How would you rate the severity of your hyperhidrosis?*
1	My underarm sweating is never noticeable and never interferes with my daily activities
2	My underarm sweating is tolerable but sometimes interferes with my daily activities
3	My underarm sweating is barely tolerable and frequently interferes with my daily activities
4	My underarm sweating is intolerable and always interferes with my daily activities

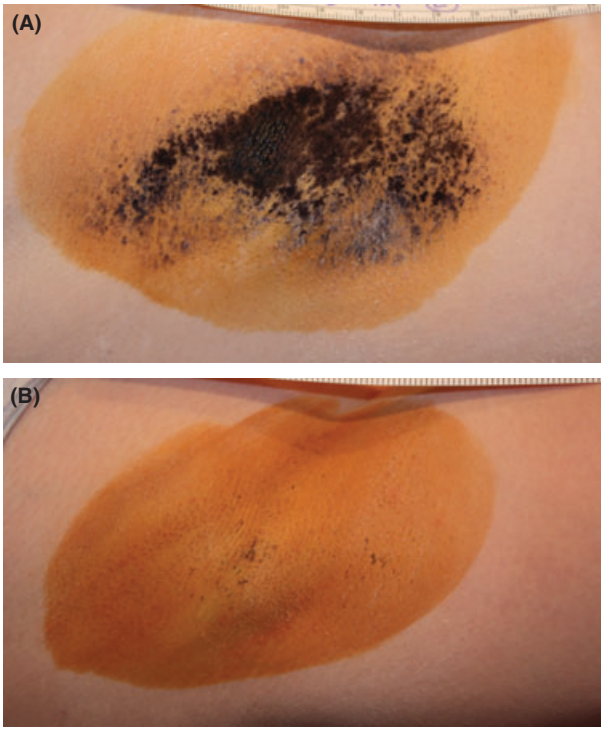


Figure 1. Photographs of starch–iodine tests of the left axilla of a subject who received treatment showing (A) baseline extent of sweating and (B) amount of sweat 12 months after treatment was complete.

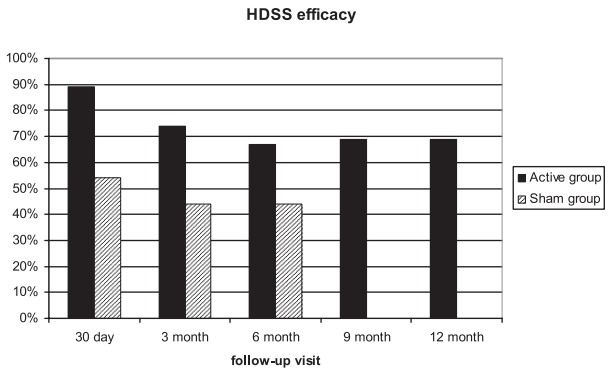


Figure 2. Hyperhidrosis Disease Severity Scale efficacy through the follow-up period. Sham subjects exited the study after the 6-month visit. The *P* value for the active-sham comparison was less than .05 for each visit.

Treatments

The study protocol was that subjects would typically undergo two procedure sessions, separated by approximately 2 weeks. Fewer procedure sessions were allowed if the subject's underarm sweat was eliminated with one session or if the subject declined further treatment. A third procedure session was allowed within a 30-day window if a subject still had a high level of sweating after two sessions. Procedures were put in place to protect blinding during the treatment period.

At the time of the first procedure session, subjects were randomized in a 2 to 1 ratio to a treatment group (n = 81) and sham group (n = 39). Each session included three steps: marking the axilla with a treatment template, injecting local anesthesia (1% lidocaine with 1:100,000 epinephrine) throughout the indicated area, and applying the microwave treatment. The microwave-based device included integrated vacuum and cooling (DTS G2 System; Miramar Labs, Sunnyvale, CA). Sham subjects experienced all steps of the procedure session, but microwave energy was not delivered.

In the first procedure session, the hair-bearing areas of both axillae were treated; 83% of subjects had a second procedure session approximately 2 weeks after the first session, as outlined in the protocol. The unblinded investigator determined the extent of the area to be treated based on a starch–iodine test and sweat assessments (active group) or a defined area based on axilla size (sham group). All sham group subjects had two procedure sessions. Eleven subjects (9%) had only one session. Four of these subjects had a reduction of sweat after the first session to a level that required no further treatment (i.e., HDSS = 1 or 2 and sweat measurements <50% of baseline and no visible areas to treat on the starch–iodine test). Two subjects declined further treatment because of pain during or after the treatment; five subjects had ongoing side effects (swelling, pustules, or blisters) at the time of the scheduled second treatment (2 weeks after the first) and so did not receive any more treatment. Ten subjects (8%) had a third procedure session approximately 30 days after the second procedure session when it was seen that they still had high levels of sweat production (HDSS = 3 or 4 or sweat measurements >50% of baseline).

Blinded study personnel administered HDSS questionnaires and gravimetric assessments at each follow-up visit. The timing for all follow-up visits was calculated relative to the last procedure session. Sham group subjects had follow-up visits at 30 days, 3 and 6 months and then exited the study. Active group subjects had follow-up visits at 30 days and 3, 6, 9, and 12 months after treatment. All subjects and study staff were unblinded at the end of the 6-month study visit.

Study Efficacy Measures

For the primary endpoint, responders were defined as subjects reporting a HDSS score of 1 or 2 at the 30-day follow-up visit. Secondary analyses included the same measure at the 6-month follow-up visit and calculating the proportion of subjects that achieved a 2-point or greater decline in HDSS. Gravimetric efficacy success was defined as a greater than 50% reduction in weighed sweat from baseline data (average of right and left values). A second analysis was also performed to

evaluate a 75% or greater reduction in weighed sweat.

Statistical Analysis

Statistical analysis was performed using SAS (Version 9.1, SAS Institute Inc., Cary, NC). The analysis used all 120 enrolled subjects (intention-to-treat population); the method of last observation carried forward was used to impute missing data from missed visits. Comparisons between the randomized groups for demographic characteristics and responder percentages were made using the Cochran-Mantel-Haenszel test stratified according to investigational site. Statistical hypothesis testing was two sided, with significance inferred at $\alpha = 0.05$.

Safety Assessments

The investigator rated Adverse events that subjects reported in severity and how likely it was that the event was related to the study device or procedure. The expected local sequelae in the treated area were categorized separately from the adverse events.

Results

Demographics for all enrolled subjects are shown in Table 2. There were no statistically significant differences between the subjects in the active group and the sham group, although there was a substantial difference in the proportion of subjects with a HDSS score of 3 between the sham group (67%) and the active group (51%). One hundred one of the 120 subjects completed the study as planned; 13 active group subjects (16%) and six sham group subjects (15%) exited the study early, none because of adverse events.

Efficacy

Hyperhidrosis Disease Severity Scale efficacy results are shown in Tables 3 and 4. The primary efficacy endpoint was met, with 89% of the active group and 54% of the sham group meeting the definition of responder at 30 days ($P < .001$). For all time points with data from both groups (through the 6-month visit), the HDSS efficacy for the active group was statistically significantly greater than the efficacy for the sham group. For the active group subjects, the efficacy results continued to be stable for 1 year after treatment (to the time of the last follow-up visit; see Figure 2).

TABLE 2. Subject Demographic Characteristics

	Active Group (n = *81*)	*Sham Group* (n = *39*)	*Total* (N = *120*)
Age			
Median	33	31	31
<30, *n* (%)	17 (44)	40 (49)	57 (48)
30–45, *n* (%)	15 (39)	32 (40)	47 (40)
≥ 45, *n* (%)	7 (18)	9 (11)	16 (13)
Sex, *n* (%)			
Male	13 (33)	38 (47)	51 (43)
Female	26 (67)	43 (53)	69 (58)
Race, *n* (%)			
White	33 (85)	68 (84)	101 (84)
African American	4 (10)	4 (4.9)	8 (6.7)
Other	2 (5.1)	8 (9.9)	10 (8.3)
Baseline Hyperhidrosis Disease Severity Scale score, *n* (%)			
3	41 (51)	26 (67)	77 (64)
4	40 (49)	13 (33)	53 (36)
Baseline gravimetric reading, mg/5 min, average	180.5	177.2	179.4

Percentages may not add up to 100% due to rounding.

The summary of results from the gravimetric assessment of sweat production can be seen in Table 5. A reduction of 50% or more in sweat at the 30-day follow-up visit was seen in 80% of the active group and 67% of the sham group ($P = .07$). There was a statistically significant difference when success was defined as a 75% or greater reduction in sweat; the active group efficacy was 62%, and the sham group efficacy was 39% ($P = .01$). At later time points, there was no statistically significant difference in gravimetrically measured sweat reduction between the two groups,

TABLE 3. Hyperhidrosis Disease Severity Scale (HDSS) Efficacy Results Through the 6-Month Follow-Up Visit, Comparing Responder Rate in the Active (n = 81) and Sham (n = 39) Groups

	30-Day Visit %			*3-Month Visit %*			*6-Month Visit %*		
Definition of Success	*Active Group*	*Sham Group*	P-*Value*	*Active Group*	*Sham Group*	P-*Value*	*Active Group*	*Sham Group*	P-*Value*
HDSS score 1 or 2	89	54	<.001	74	44	=.001	67	44	.02
HDSS score reduced by ≥2 points	67	13	<.001	57	13	<.001	47	13	<.001

TABLE 4. Hyperhidrosis Disease Severity Scale (HDSS) Efficacy Results Through the 12-Month Follow-Up Visit for the Active Group (n = 81)

Definition of Success	*30-Day Visit %*	*3-Month Visit %*	*6-Month Visit %*	*9-Month Visit %*	*12-Month Visit %*
HDSS = 1 or 2	89	74	67	69	69
HDSS reduces by ≥2	67	57	47	42	38

TABLE 5. Gravimetric Efficacy Results Through the 6 Month Follow-Up Visit, Comparing Responder Rate in the Active (n = 81) and Sham (n = 39) Groups

	30-Day Visit %			*3-Month Visit %*			*6-Month Visit %*		
Definition of Success, Reduction from Baseline	*Active Group*	*Sham Group*	P-*Value*	*Active Group*	*Sham Group*	P-*Value*	*Active Group*	*Sham Group*	P-*Value*
≥50%	80	67	.07	75	64	.20	63	59	.69
≥75%	62	39	.01	52	44	.34	41	36	.60

although the reduction was greater in the active group.

Safety

There were no procedure-related serious adverse events reported in the study for any subject. Procedure-related adverse events were generally mild. There were 45 procedure-related adverse events in 23 (28%) active group subjects and five (13%) sham group subjects. The types and frequency of adverse events are shown in Table 6 according to randomization group. The most frequently reported adverse event (9.9% of treated subjects) was altered sensation in a moderately sized area (average 12 cm length at onset) in the skin of the upper arm. This was reported as a change in sensitivity, tingling, or numbness and was most likely due to effects on cutaneous nerves. There was substantial variation in the duration of this mild effect, but all of these events resolved over time (median duration 25 days). A contributing factor to the longest-duration event was the subject's infrequent follow-up visits. For the other events shown in Table 6, all but one resolved with no permanent effects. As noted in Table 6, one subject with self-reported compensatory hyperhidrosis reported ongoing sweating of the face at study exit.

Post-treatment local sequelae that were common (>50% of subjects) were similar in the sham and active groups and included vacuum acquisition marks, tenderness or altered sensation in the treatment area, and soreness or discomfort.

TABLE 6. Procedure-Related Adverse Events in Each Study Group

Category	Total Events, n	Sham Group (N = 39) Events, n	Sham Group (N = 39) Subjects, n (%)	Sham Group (N = 39) Duration, Days, Mean (range)	Active Group (N = 81) Events, n	Active Group (N = 81) Subjects, n (%)	Active Group (N = 81) Duration, Days, Mean (range)
Altered sensation in treatment limb	10	1	1 (2.6)	79.0 (79–79)	9	8 (9.9)	67.4 (4–225)
Pain or soreness	8	2	2 (5.1)	3.5 (3–4)	6	5 (6.2)	21.8 (1–74)
Swelling in the treatment limb*	7	2	1 (2.6)	2.5 (2–3)	5	4 (4.9)	8.6 (2–20)
Blisters, burns, or ulcerations	5	0	0	–	5	4 (4.9)	28.2 (12–40)
Skin: rash, irritation, or dermatitis	4	0	0	–	4	4 (4.9)	27.0 (3–87)
Axillary bumps or nodules	4	2	1 (2.6)	11.0 (10–12)	2	2 (2.5)	30.0 (8–52)
Compensatory sweating	2	0	0	–	2	2 (2.5)	52†
Other	5	0	0	–	5	5 (6.2)	25.8 (2–46)
Total	45	7			38		

*This effect was rated as mild in all but one event, where the patient stayed in bed over a weekend, which required a severe severity rating.
†One subject reported ongoing, stable altered sweating of the face at study exit. No duration data were used.

Discussion

This study demonstrates a statistically significantly reduction in subject-reported sweat severity after treatment with a novel microwave device than in subjects who received a sham treatment. This endpoint, defined as reaching a HDSS score of 1 or 2, means that subjects' sweat level has no or little remaining interference in their daily life, a clinically meaningful result. The statistically significant difference occurred for all follow-up visits through 6 months. The active group followed to 12 months after treatment showed stable efficacy through their final follow-up visit. There is evidence in the literature[6] that sweat glands form only at the embryonic stage and that new sweat glands do not appear after birth. This suggests that a stable level of efficacy would continue.

The analysis of HDSS scores with a different criterion (requiring a $\geq$ 2 point drop in the HDSS scale) highlights that the randomization of the active and sham group yielded important differences in severity scores at baseline. A higher proportion of subjects enrolled in the sham group (67%) than of the active group (51%) had a baseline HDSS score of 3. This meant that more sham group subjects could achieve success in the primary efficacy measure by dropping a single point (from 3 to 2). By applying the more-stringent criterion of dropping two or more points to both groups, the result (67% for the active group and 13% for the sham group at the 30-day visit, a 54% difference) is statistically significant ($P < .001$). This analysis also allows a more-direct comparison with the published results on treatment with botulinum toxin A (where a 2-point change in HDSS score was required for success),[2] which showed similar results at the 30-day visit of 75% for the treatment group and 25% for the placebo group ($P < .001$), a difference of 50%. In the same study, the average duration of botulinum toxin effect was 6.7 months.

The results from the gravimetric assessment of sweat reduction did not show a statistically significant difference at all time points. Intrapatient variations of gravimetric testing have been noted previously[7,8]

and may have affected the ability to obtain accurate measurement of sweat reduction. The study design also did not include taking multiple baseline measurements to account for subjects being more nervous at the initial screening visit, potentially leading to higher baseline readings and a resulting reduction in the amount of weighed sweat at follow-up visits for all subjects, regardless of intervention. Furthermore, the room conditions (temperature and humidity) and the time of day were not strictly controlled. These effects could have contributed to gravimetric measurement variability.

The safety profile of the procedure demonstrated low risk for the subjects. The mechanism of action of the procedure causes noninvasive focused heating of the tissue at the depth of the sweat glands with resulting thermolysis of the sweat glands. As would be expected with this mechanism, most subjects experienced local edema and mild discomfort in the treated area, on average lasting 9 days and usually easily controlled with use of ice and nonprescription antiinflammatories. A small percentage (~5%) of subjects required prescription pain management after treatment. Some of the side effects were of long duration but resolved; they also generally were mild and did not affect subjects' daily activities.

This study also provided the opportunity to identify potential areas for improvement in the procedure and device. The second procedure session took place approximately 14 days after the first session. In retrospect, waiting longer between procedure sessions to allow postoperative fibrosis to set in may have given a better indication of areas that were missed or undertreated at the first procedure session. Also, some subjects experienced side effects that were not resolved in this short period, so they only received one treatment. Waiting longer would have allowed more-complete treatment. In addition, the study design used fixed energy delivery. Given the favorable safety results at this fixed setting, it is expected that using a higher dose at a second session might deliver a greater benefit with little risk.

Acknowledgments We would like to thank Naheed Abbasi, MD, Sandra Adsit, MD, Jeaneen Chappell, MD, William P Coleman IV, MD, Linda Coward, RN, Casey Croes, PA-C, Kathleen Keys, RN, Melanie Kingsley, MD, Jessie Maddox, MD, Judy Romero, RN, Rebecca Sprague, RN, FNP-C, and Shannon Welner, PA-C, for participating in this investigation. We would like to thank John Quiring, PhD, for his assistance in statistical analysis.

References

1. Strutton DR, Kowalski JW, Glaser DA, Stang PE. US Prevalence of hyperhidrosis and impact on individuals with axillary hyperhidrosis: results from national survey. J Am Acad Dermatol 2004;51:241–8.
2. Lowe NJ, Glaser DA, Eadie N, Daggett S, et al. Botulinum toxin type A in the treatment of primary axillary hyperhidrosis: a 52-week multicenter double-blind, randomized, placebo-controlled study of efficacy and safety. J Am Acad Dermatol 2007;56:604–11.
3. Darabaneanu S, Darabaneanu H-A, Niederberger U, Russo PA, et al. Long-term efficacy of subcutaneous sweat gland suction curettage for axillary hyperhidrosis: a prospective gravimetrically controlled study. Dermatol Surg 2008;34:1170–7.
4. Lawrence CM, Lonsdale Eccles AA. Selective sweat gland removal with minimal skin excision in the treatment of axillary hyperhidrosis: a retrospective clinical and historlogical review of 15 patients. Br J Dermatol 2006;155:115–8.
5. Kowalski JW, Eadie N, Dagget S, Lai P-Y. Validity and reliability of the Hyperhidrosis Disease Severity Scale (HDSS). J Am Acad Dermatol 2004;36:P51. Poster presented at the 62nd Annual Meeting of the American Academy of Dermatology; February 6-10, 2004; Washington, DC. Poster P198.
6. Li H-H, Zhou G, Fu X-B, Zhang Lei. Antigen expression of human sweat glands. J Cutan Pathol 2009;36:318–24.
7. Swartling C, Haver H, Lindberg M. Botulinum A toxin improves life quality in severe primary focal hyperhidrosis. Eur J Neurol 2001;8:247–52.
8. Solish N, Bertucci V, Dansereau A, et al. A comprehensive approach to the recognition, diagnosis, and severity-based treatment of focal hyperhidrosis: recommendations of the Canadian Hyperhidrosis Advisory Committee. Dermatol Surg 2007;33:908–23.

Address correspondence and reprint requests to: Dee Anna Glaser, MD, Department of Dermatology, St. Louis University, 1755 S. Grand Boulevard, St. Louis, MO 63104, or e-mail: glasermd@slu.edu

EMERGING INNOVATIONS IN AESTHETICS

From a device to treat excessive sweating to new technologies to support surgery, new developments proceed.

BY SUZANNE BRUCE, MD, SAM RIZK, MD, ADAM LUBER, BA AND GARY GOLDENBERG, MD

MICROWAVE TECHNOLOGY FOR EXCESSIVE SWEATING

A new device offers a long-term solution to excessive sweating.

By Suzanne Bruce, MD, FAAD

Although hyperhidrosis is estimated to affect three percent of the population, the International Hyperhidrosis Society maintains that roughly half of those affected are not formally diagnosed. Whether or not they have received a diagnosis of hyperhidrosis, patients affected by excessive sweating have had few treatment options that offer lasting efficacy. This has been disappointing for both the patients and providers, as the effects of excessive sweating can be seen in social, professional, and other areas of life.

A novel treatment for hyperhidrosis, the miraDry® system (Miramar Labs) delivers precisely controlled microwave energy non-invasively to sweat glands where accumulated energy results in thermolysis of the glands. The handpiece includes a continuous hydro-ceramic cooling system that protects the superficial dermis and keeps heat at the level of the sweat glands. Treatment results in permanent damage to sweat glands and long-term reduction in sweating.

When I heard about the miraDry technology at the American Society for Dermatologic Surgery Annual Meeting in November 2011, I thought it was a great option for people who suffer from hyperhidrosis. It offers a convenient and effective treatment for a relatively common patient concern. In studies reported by the company, patients reported an 82 percent reduction in sweat after a round of two treatments. Data show that damaged sweat glands do not regenerate, making microwave therapy a long-term solution to hyperhidrosis. We introduced the procedure into the practice in early 2012 and have seen good results and steadily increasing demand since then.

A WELCOME OPTION

Previously existing options for the treatment of hyperhidrosis include iontophoresis and botulinum toxin injections. Iontophoresis generally cannot be applied to the underarms, and results are typically short-term, requiring ongoing treatment for the patient. Botulinum toxin injections can be provided to the underarms as well as to the hands and feet, and they provide a reduction in sweating for several months. Effects are not permanent, however, and patients will inevitably require retreatment. Continuous treatments can become costly and inconvenient. Before offering miraDry, botulinum toxin was the only treatment for axillary hyperhidrosis we offered in our practice.

Over the past year, we have been pleased with the consistency in treatment outcomes. Results achieved with the miraDry system for axillary hyperhidrosis have been what we expected. We inform patients that they will need two to three treatments to achieve optimal results. The majority of our patients have had marked sweat reduction after two treatments; Only two or three patients have required a third treatment.

Patient response to treatment has been positive to date, with patients expressing satisfaction with the results of treatment. In fact, some patients have described treatment as "life changing."

MARKETING CONSIDERATIONS

There tends to be a stigma associated with hyperhidrosis. Patients may be reluctant to discuss the problem, especially if they don't know that treatment options exist. Therefore, marketing and patient education are important. At the same time, however, we have found that many patients with hyperhidrosis are researching the condition online and are aware of new treatment options; it's important to market so that such patients are aware that you offer treatment.

Along with brochures in our office, we have promoted miraDry on our website, in our e- and print newsletters, at our annual open house, and at seminars. For seminars, we typically incorporate discussion of hyperhidrosis and miraDry within presentations on other topics. Promoting a seminar solely for excessive sweating did not attract any people due to the highly personal nature of this condition. We are currently trying our first billboard advertisement.

With our current strategies in place, the volume of procedures has steadily increased since introduction. We are performing on average one procedure per day.

PRACTICAL CONSIDERATIONS

Beyond potential patient interest/demand and the positive outcomes associated with miraDry, another attractive system feature is its compact size and portability. The machine can roll from room-to-room so we keep it in a storage room when not in use. The lone consumable is the sterile, disposable BioTip.

We have had very few logistical challenges in incorporating miraDry into our practice. The time it takes to do the procedure is very consistent from patient-to-patient so scheduling is easy.

From a practical standpoint, we have found it beneficial to have patients pay up-front for the two procedures; the patient becomes mentally committed to undergoing both treatments, which are necessary for achieving an optimal response. We don't want our patients to have unrealistic expectations—expecting resolution of sweating from a single treatment.

NOVEL APPROACH, WIDESPREAD NEED

The population of patients dealing with excessive sweating may be large and underserved. While hyperhidrosis is a medical condition, it's important to note that excessive sweating can negatively influence an individual's quality of life with social, professional, and aesthetic ramifications. Certainly miraDry fits well into a general dermatology practice because we frequently see hyperhidrosis patients. At the same time, cosmetic practices are used to using technology like lasers and other energy-using devices, so this procedure also fits well in an aesthetic practice.

A PEARL FOR SUCCESSFUL INTEGRATION

Any time we introduce a new procedure we meet monthly for the first six months and then quarterly thereafter with our entire process team, including MD's/PA, representatives from the front and back office, our lead patient care coordinator, marketing director and our miraDry representative. At these meetings, we track our progress and address any issues that have arisen in any aspect of our service delivery system.

Suzanne Bruce, MD practices in Houston. She is a former Vice President of the Texas Dermatological Society and a former President of the Houston Dermatological Society.

A 21ST CENTURY APPROACH TO RHINOPLASTY: MARRIAGE OF FORM AND FUNCTION

A guide to the state of the art reveals why rhinoplasty is still the gold standard.

By Sam Rizk, MD, FACS

According to the American Academy of Facial Plastic and Reconstructive Surgery (AAFPRS.org), in 2012, rhinoplasty was the most popular surgical procedure performed on both men and women under the age of 35. Yet rhinoplasty is also among the most complex procedures to perform well because the surgeon must take into account not only aesthetics, but functional breathing considerations as well.

The nose is the most prominent feature on the human face: even a small change will affect a person's whole appearance in a big way. A beautiful nose is a natural one that complements and fits harmoniously with the other facial features. There is no universally ideal nose—only an ideal nose for one particular face. The consensus of opinion on the qualities of a beautiful nose has changed considerably over time. In nasal surgery, it is critical to achieve a natural result. Patients today do not want upturned noses, pointy tips, scooped-out bridges, or pinched nostrils that were commonplace in the 1980s. The modern concept in rhinoplasty is to preserve the overall characteristics of the original nose, and make small alterations to straighten or refine the shape and projection as the patient desires.

Every nose is unique since every face is different. Therefore an individualized approach is required to address each patient's unique goals. My main mission with nasal surgery is to create a natural looking nose that will stand the test of time, based on the structure of the cartilage and the overlying skin. A natural nose should be in harmony with the other features of the face, including the upper lip, chin, and cheeks. An important factor in achieving a natural result in rhinoplasty is to maintain good structural support.

I routinely combine treating the internal structures of the nose with cosmetic improvements. A deviated nasal septum, if significant (greater than 50 percent), can result in difficult breathing and may be treated with a septoplasty surgery. This can be done as an isolated procedure or combined with sinus surgery or cosmetic rhinoplasty surgery. Being able to restore a patient's ability to breathe, in addition to improving the appearance of the nose by rebuilding previously removed cartilage or bone, provides an additional benefit to the patient. Functional repair can be combined with an aesthetic approach simultaneously, without compromising either, which is what most patients desire.

A delicate framework of bone and cartilage supports the internal structure. Even a small miscalculation can lead to an unsatisfactory result. The determining factor in whether a patient's nose has good support is the inherent strength of the underlying cartilages. If the tip has good support, it can be refined by simply removing excess cartilage. Another important aspect of the nasal anatomy is skin thickness. Thicker skin can often present a greater challenge to achieve definition and to sculpt a newly refined shape. A bulbous tip is common with thicker-skinned patients, and it can appear larger and droopy with advanced age.

Local Procedural Approaches for Axillary Hyperhidrosis

Dee Anna Glaser, MD*, Timur A. Galperin, DO

KEYWORDS

• Hyperhidrosis • Liposuction-curettage • Microwave thermolysis • Minimally invasive • Surgery

KEY POINTS

- Surgical procedures can provide long-lasting relief from axillary hyperhidrosis.
- Local or tumescent anesthesia is most commonly used for local procedures of the axilla.
- Most of these procedures are limited to treating the axillary region of the body.
- Starch-iodine testing is valuable to identify the area of treatment, but the hair-bearing skin can be used as a landmark for treatment as well.
- Downtime is minimal, typically 2 to 6 days, depending on the procedure.

INTRODUCTION

When topical options for axillary hyperhidrosis (HH) have failed, botulinum toxin is an effective, safe, and well-tolerated, although temporary, treatment option. For long-lasting or permanent efficacy, some patients turn to local procedures, such as superficial liposuction or manual curettage, or more invasive local surgery. Local surgical treatment is divided into 3 categories: (1) excision of skin and glandular tissue, (2) curettage or liposuction procedures to remove the subcutaneous sweat glands, or (3) a combination of limited skin excision with glandular tissue removal.[1] Complete skin excision is performed infrequently, because improved minimally invasive surgical techniques have become effective with fewer long-term complications.[2] The nonresponder rate varies from 2% to 20% with minimally invasive surgery and is likely the result of inadequate mapping of the hyperhidrotic area or inadequate surgical technique.[2] Newer, minimally invasive treatments have become available, such as microwave energy thermolysis.

PATIENT EVALUATION OVERVIEW

A thorough HH history should be obtained from the patient, including age of onset of HH, location and symmetry of sweating, aggravating/alleviating factors, previous treatments for HH, family history of HH, and current medications that may exacerbate the condition. A physical examination should be performed to rule out a possible secondary cause of HH that needs to be treated. A starch-iodine test is then performed to identify the dimensions of the involved area for treatment. The Minor starch-iodine test is a cheap and

Disclosure: D.A. Glaser has served as advisor for Allergan, Galderma, Miramar Labs, and Unilever. She has been an investigator and received research grants from Allergan, Miramar Labs, and Ulthera. T.A. Galperin has nothing to disclose.

Department of Dermatology, Saint Louis University School of Medicine, 1402 South Grand Boulevard-ABI, St Louis, MO 63104, USA
* Corresponding author.
E-mail address: glasermd@slu.edu

Dermatol Clin 32 (2014) 533–540
http://dx.doi.org/10.1016/j.det.2014.06.014

simple procedure commonly used to detect focal areas of sweating. The affected area is first dried, then an iodine solution is brushed onto the skin and allowed to dry. A starch powder, such as corn starch, is peppered on top, and the area is observed for a few minutes. Purple-black dots develop when sweat interacts with the starch and iodine. If a positive starch-iodine test cannot be obtained, the hair-bearing portion of the axilla should be treated.

The amount of axillary sweating can be assessed using the patient-reported Hyperhidrosis Disease Severity Scale (HDSS) (**Table 1**). The HDSS can also be obtained during the postoperative period to assess treatment success. Gravimetric (weight-based) assessment is an objective measurement typically performed in research studies but is not practical for routine clinical use.

In addition, surgical risks need to be ascertained before considering which procedure may be best suited for the patient. Antiplatelet therapies and bleeding diathesis are relative contraindications. Patients with significant arthritis or previous injury to the shoulder area may limit access to the axillary vault for certain procedures, and pain in the area may limit the patient's ability to maintain proper arm position during surgery, even if good range of motion is present.

MANAGEMENT GOALS

The goals of therapy are to provide a permanent or long-lasting solution for axillary HH, with a minimally invasive procedure that is cost-effective, easily accessible, and has minimal side effects and downtime.

SURGICAL TREATMENT OPTIONS AND PROCEDURE

Excision

Surgical excision can either be a radical excision of the skin and glandular tissue (RSE) (ie, en bloc resection), or a limited skin excision with glandular tissue removal (LSE), such as the modified Shelley procedure. Surgical complication rates from RSE are high, and the procedure is rarely performed.[1] The relapse rate can vary. A study of 125 patients[3] undergoing LSE found a 12.8% relapse rate.

RSE can be performed via several different surgical techniques, each differing in the method of axillary skin removal and type of wound closure.[4] RSE can be performed under tumescent anesthesia, and the wounds sutured, generally requiring a subcutaneous drain for 1 to 2 days after treatment.[4]

Excessive sweating, as measured by gravimetric assessment, at 12 months after treatment is reduced by about 65%.[4] In studies, the average aesthetic outcome reported by patients was graded as moderate. Side effects of treatment include hematoma formation (20%), paresthesia (33.3%), focal alopecia (100%), and skin infection (13%).[4] Poor aesthetic outcomes, with scarring and skin retraction, which can lead to a decreased range of motion of the shoulder,[5] and long recovery times are 2 reasons that en bloc resections are rarely, if ever, performed.

With the skin-sparing technique (LSE), surgeons can perform the procedure on 1 axilla at a treatment session,[1,3] or both axillae can be treated simultaneously.[4] Antibiotic prophylaxis can be given an hour before the procedure, if deemed necessary. The area of maximal sweating is identified via the Minor starch-iodine test, and then, the axilla is anesthetized with lidocaine 1% and epinephrine 1:100,000[1] or tumescent anesthesia.[4] The elliptical area of maximal sweating, approximately 4 cm × 1 cm in diameter (horizontally), is excised down to the subcutaneous fat. The adjacent hair-bearing area of excessive sweating is undermined with Metzenbaum scissors to the affected edges, and the wound edges are everted to expose the 1-mm to 2-mm pink, papular sweat glands adhering to the dermis.[1] Sweat glands are cut out with curved scissors to defat the dermis, and the wound is closed with sutures. A subcutaneous drain is required for 1 to 2 days after treatment. A figure-of-eight dressing is applied for 10 days,[4] or a compression dressing for 24 hours.[3]

Excessive sweating, as measured by gravimetric assessment, at 12 months after treatment was reduced by a mean of 63% in 1 case series.[4] An early case series,[1] using a subjective, patient-assessed measure of sweat reduction after treatment, found a mean sweat reduction of 65%. The average aesthetic outcome reported by patients was graded as good,[4] 58.4% of patients

Table 1
HDSS

How Would You Rate the Severity of Your Hyperhidrosis?	
HDSS Score	**Definition**
1	Never noticeable, never interferes
2	Tolerable, sometimes interferes
3	Barely tolerable, frequently interferes
4	Intolerable and always interferes

were satisfied with treatment, and 82.4% would choose the same procedure again.[3] The mean amount of time to return to work is reported to vary from 4 to 8.8 days.[1,3]

Side effects and scarring are less prevalent than with en bloc excision. The mean scar length is 5 cm, and scar formation does not lead to functional impairment, compared with a scar length of 9.3 cm, and a relatively high prevalence of functional impairment in the RSE group.[3,4] Side effects include hematoma formation (18.2%), paresthesia (27.3%), focal alopecia (100%), seroma formation (27.3%), fibrotic bridles (27.3%), skin erosion (36.4%), skin infection (5.6%), hypertrophic scarring (13/99), and flap necrosis (18.2%).[3,4]

Liposuction

Because the eccrine glands are located at the superficial subcutaneous plane, liposuction procedures have been used to remove the sweat glands without having to excise tissue. Liposuction has been used safely, and with moderate long-term efficacy in axillary HH. Patients can receive antibiotic prophylaxis with ciprofloxacin 500 mg orally × 1 dose an hour before the procedure,[6] although most physicians do not pretreat with antibiotics. Like other procedures, a starch-iodine test is helpful to identify the area of HH. Two small incisions are made in the superior and inferior borders of the axilla to deliver tumescent anesthesia. Once the skin is visibly blanched, the suction cannula is used to superficially remove the subcutaneous fat. Physicians have a variety of cannulas to choose from (**Fig. 1**), but in general, the more aggressive cannulas provide greater reduction of sweat, although they may be associated with higher risks of adverse events.[6] The hole of the cannula is oriented toward the skin surface, and the sweat glands are scraped away from the underside of the dermis using a back-and-forth motion in a crisscross pattern.[7,8] Incisions are generally not closed, but are left open for drainage. A compression bandage can be applied for 24 hours.[6,7]

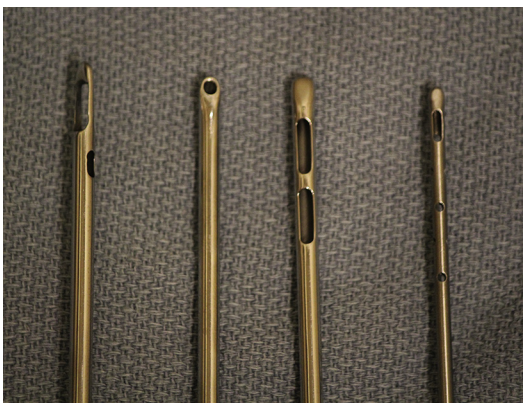


Fig. 1. Liposuction cannulas showing different configurations.

In 1 study comparing 3 different cannulas,[6] the investigators found a 44% and 49% reduction in sweating, obtained by gravimetric measurements, with a 1-hole and 3-hole cannula, respectively. The relapse rate with liposuction can be as high as 40% several months after treatment.[7] Side effects are minor and temporary. They include bruising, hematoma formation (43%), skin erosion (7%–14%), bridle formation (21%), paresthesia (43%–50%), and partial alopecia (14%).[6,8]

Liposuction-Curettage

Liposuction-curettage (LC) has been safely and effectively performed for many years. There are several different treatment techniques, which differ in their type and size of incisions, type of cannula and curette used, and the aggressiveness of the procedure. The experience of the surgeon is also an important factor. Tumescent anesthesia is administered, and small incisions are made into the central and upper inner axilla.[3,4,9] Alternatively, a modified technique can be used, in which 4 or 5 2-mm, evenly spaced, vertically oriented incisions are made using a punch biopsy instrument 1 cm beyond the lateral margin of the axilla, and 4 or 5 similarly sized and spaced incisions are made horizontally 1 cm beyond the inferior margin.[10] LC is performed using a liposuction device and a sharp, rasping-type cannula applied to the dermal-subcutaneous interface. Blunt cannulas may not remove sweat glands as proficiently as cannulas with curettage.[3,4,9] Back-and-forth strokes are performed with an upward tension, and the surgeon's thumb and forefinger provide pressure on the skin at either end of the cannula.[4,10]

Intraoperative indicators of sufficient LC include a complete elevation of the skin from subcutaneous fat, lividity of the skin, and no fat adhering to the dermis.[9,10] Incisions are closed with either Steri-Strips™ (3M, St. Paul, MN) or sutures but can be left open for better drainage. A compression bandage for 24 hours or a figure-of-eight dressing for 10 days is applied.[3,4]

Excessive sweating, as measured by gravimetric assessment, at 6 to 12 months after treatment, can be reduced by 60.4% to 69% in 89% to 93% of patients.[4,6,10] The mean HDSS score

of 3.05 decreased to 2.75 6 months after treatment, which was statistically significant.[10] The aesthetic outcome reported by patients was graded as either very good or good,[4] and 78.4% to 84% of patients were completely satisfied or satisfied with the procedure[3,4,9]; 94.6% of patients would choose the same procedure again.[3] The relapse rate is approximately 14.5%, and the mean amount of time to return to work was only 1.3 days.[3]

Side effects of treatment are mild and temporary, and include hematoma formation (20%–78.4%), paresthesia (11.8%–26.7%), focal alopecia (7.8%–60%), seroma formation (6.7%–13.7%), skin erosion (20%–32%), bridle formation (10.8%–53.3%), and flap necrosis (6.7%).[3,4,9] There is only a small risk of skin infection. Skin ulceration and full-thickness skin necrosis can occur with aggressive LC, without any added efficacy.[11] Scarring is minimal, with the average scar length of 1 cm, and without hypertrophy or functional impairment.[3,4]

The exact duration of efficacy of LC is difficult to ascertain, because past studies had many variations in surgical expertise, surgical techniques, methods of measuring efficacy, and no consistent follow-up of patients past 1 year.

Curettage

There are several different treatment techniques, which differ in their type and size of incisions, type of cannula and curette used, and the aggressiveness of the procedure. Tumescent anesthesia is used, followed by a 2-cm to 3-cm incision made caudally from the marked zone,[12] or 2 or 3 5-mm incisions can be made at the margins of the axillae.[13] The marked area is undermined using Metzenbaum scissors, and a sharp, gynecologic[12] or number 2 curette[13] is used within the dermis. After curettage, the wound is closed with subcutaneous and superficial sutures, and a suction drained is placed within the axilla until secretions are lower than 10 mL/d.[12] Conversely, with 2 or 3 small incisions, wounds can be closed with adhesive strips, and a compression bandage applied for 24 hours.[13]

At 6 months after treatment, 36.4% of patients had a very good outcome, and 29.9% of patients had a good outcome, based on subjective assessment.[12] Excessive sweating, as measured by gravimetric assessment, at a median 11 months after treatment can be reduced by more than 50% in 93% of patients[13]; 90.9% of patients would recommend the procedure to others.[12] The relapse rate with this procedure is approximately 29%.[13]

Side effects include infection (2.2%), epidermal necrosis (2.2%), hematoma formation (13.3%), a markedly visible scar (27%), paresthesia (33%), partial alopecia (44%), hyperpigmentation (33%), and skin ulceration (12%).[12,13]

MiraDry

The MiraDry device is a new, nonsurgical treatment that is cleared by the US Food and Drug Administration (FDA) for axillary HH. It uses microwave energy to destroy eccrine sweat glands. Microwave energy is preferentially absorbed by tissue with a high water content, such as the sweat glands. The microwave energy leads to rapid molecular rotation, which generates frictional heat and cellular thermolysis.[14,15]

The device consists of a console, a handpiece, and a single-use biotip (**Fig. 2**). The antennae, within the handpiece, focus microwave energy on to the dermal-adipose interface, regardless of skin thickness.[14,15] There is simultaneous cooling and monitoring of the skin temperature, during the energy cycle, to avert thermal transfer of heat into the epidermis. There are 5 energy settings, which regulate the duration and depth of heat to be delivered, and the vacuum system within the biotip helps to stabilize the skin during the treatment.[14]

A few days before the procedure, patients should shave their axillae, and 1 to 2 hours before the procedure, patients should take ibuprofen 800 mg to minimize posttreatment tenderness and edema. A starch-iodine test is performed to identify the area of prominent sweating, after this, the axillary vault is measured with a supplied grid. Alternatively, the hair-bearing skin can be treated. The grid measures the length and width of the vault in millimeters. A temporary template, fitting the specified measurements, is applied to the vault to identify the treatment zones and injection sites for anesthesia (**Fig. 3**).[14] The axillae are injected with lidocaine 1% and epinephrine 1:100,000, up to the maximum level of 7 mg/kg. The discomfort associated with lidocaine injection can be lessened by buffering the lidocaine with sodium bicarbonate.

The initial energy setting can be set to 1 (lowest), 2, or 3. We prefer to perform the initial treatment at level 3. The biotip automatically starts at the lowest energy setting in the upper inner axilla, where the skin is thinnest and the overlying nerves are closer to the skin surface. After the upper zones are treated, the energy level is automatically adjusted to the specified level for the remainder of treatment. Each zone takes approximately 45 seconds to treat (**Fig. 4**), and

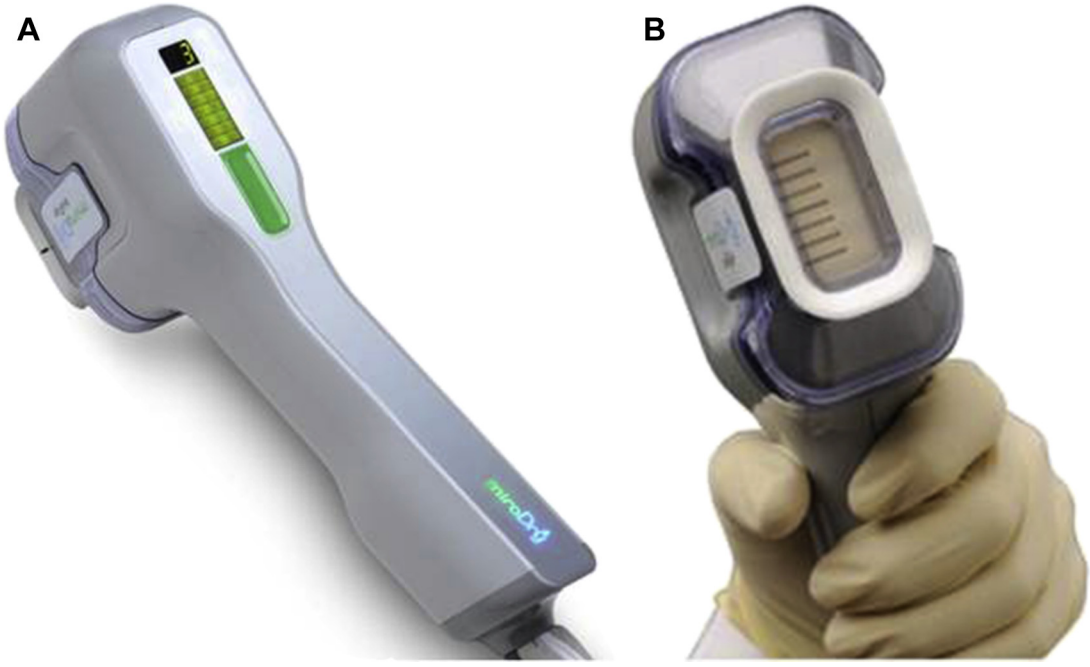


Fig. 2. (*A, B*) Handpiece and single-use biotip used for microwave thermolysis. (*Courtesy of* Miramar Labs, Santa Clara, CA; with permission.)

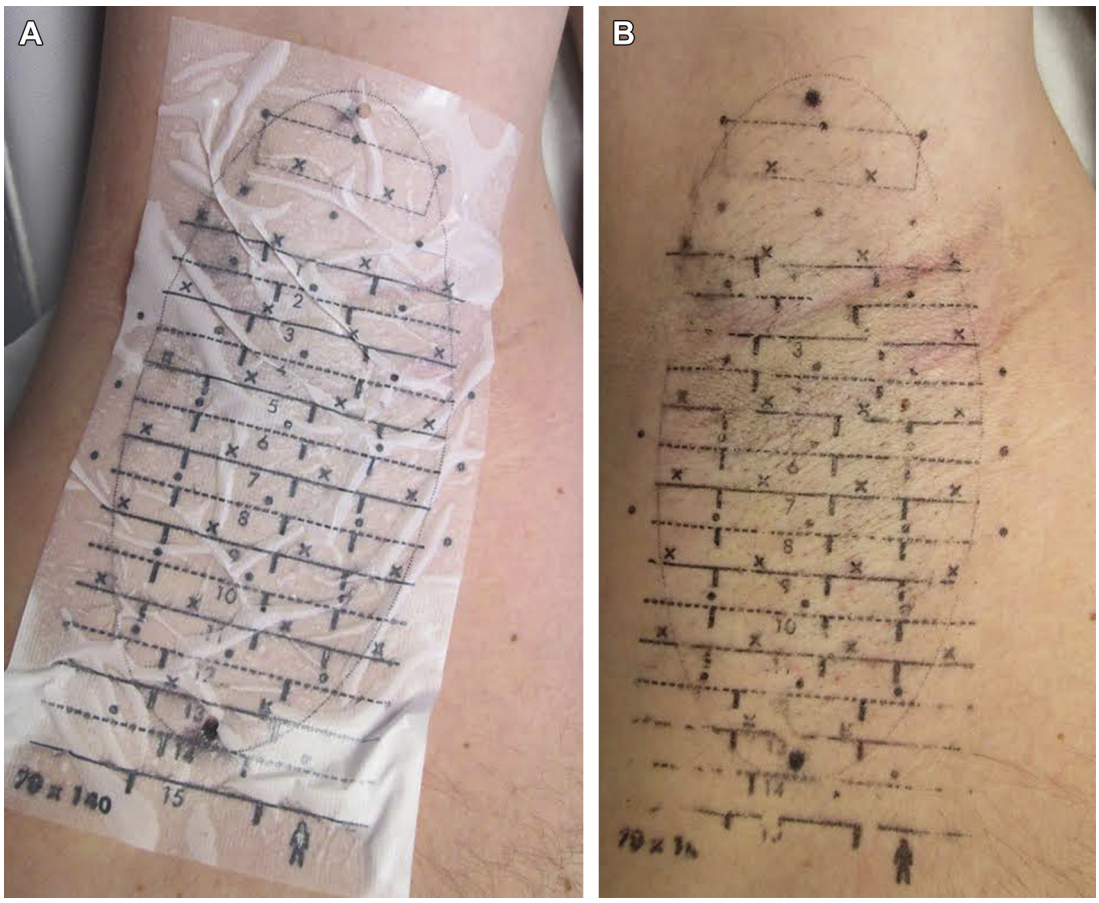


Fig. 3. (*A, B*) The appropriately sized template is placed onto the axillary vault. Alcohol is dabbed on to the tissue to transfer the template pattern to the axilla.

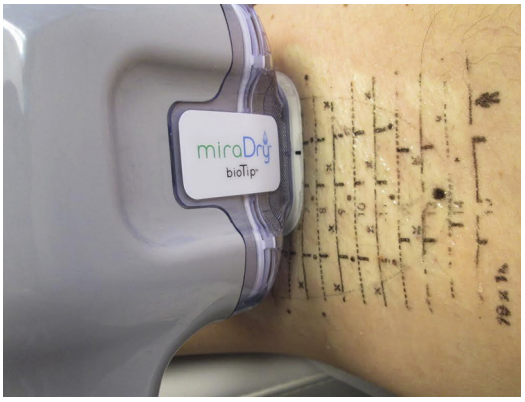


Fig. 4. As each zone is treated, cooling plates in the biotip cool the epidermis. (*Courtesy of* Miramar Labs, Santa Clara, CA; with permission.)

it takes 20 to 30 minutes per axilla, depending on the axilla size and energy level. After the treatment, patients are given an ice pack wrapped in gauze or a paper towel and instructed to keep it in place for 15 to 20 minutes at a time every 1 to 2 hours, for the first 48 hours after treatment. Patients are also instructed to continue nonsteroidal antiinflammatory agents such as ibuprofen 400 mg every 4 to 6 hours for the first 48 hours. Patients require 2 treatment sessions, with a second treatment performed 3 months after the initial one.[16] The treatment delay allows time for healing and fibrosis, which further reduces the number of eccrine and apocrine glands.[16,17] Rarely, a third treatment is performed to achieve the desired outcome.

MiraDry is effective in reducing excess sweating. From the baseline HDSS assessment, 94% of patients experienced a 1-point decrease in their HDSS score,[16] and 55% to 83.3% experienced a 2-point or greater decrease in their HDSS score at 12 months after treatment.[16,18] Based on gravimetric assessments, 90% of patients experienced a 50% or greater reduction in axillary sweating, with an average reduction of 81.7%.[16] At 12 months after treatment, 85.5% of patients were satisfied with their treatment outcome.[16]

Improvement of axillary odor has been noted by patients.[18] Lee and colleagues reported using the microwave device on 11 Asian patients: 3 with HH only, 3 with HH and osmidrosis, and 5 with osmidrosis alone. The HDSS scores improved in all patients with HH (1-point to 3-point decrease in the HDSS) and axillary odor improved in all patient with osmidrosis. The improvement in odor was subjective and rated on a 4-point scale, with a 1-point to 3-point decrease reported by the patients. The investigators have treated a limited number of patients whose main complaint is axillary body odor with the device, and patients have described improvement, but clearly more studies are needed.

Common and minor side effects include edema, redness from vacuum suction, and axillary tenderness/pain for several days' duration.[16] Altered sensation (numbness, tingling) in the upper arm or axilla can occur and lasts for approximately 5 weeks.[16,17] Less common side effects reported include blisters or burns at the treatment site, skin irritation/rash, axillary bumps, patchy alopecia, and mild compensatory sweating.[16,17] Patients can occasionally have edema outside the treatment area, and rarely, they can have temporary nerve injury.

EVALUATION OF OUTCOME, ADJUSTMENT OF TREATMENT, AND LONG-TERM RECOMMENDATIONS

To our knowledge, there are only a few randomized controlled trials comparing the efficacy of 2 procedures concurrently, which makes it difficult to assess the relative benefit of 1 procedure over another. A single randomized trial[4] compared the effectiveness, both histologically and gravimetrically, of RSE, LSE, and LC. The results showed that all 3 treatments had similar efficacy (minor differences were not statistically significant), but LC had the least amount of side effects, minimal scarring, and the least amount of down time. A randomized trial comparing LC versus curettage alone[19] found LC to be more effective, and with a similar side effect profile. Based on the available patient outcomes data, LC is the single best minimally invasive surgical treatment of axillary HH, in terms of efficacy, aesthetic outcome, and side effect profile.

The risk profile for RSE procedures does not justify their use, and procedures such as LC should be performed only by experienced surgeons, because the efficacy and safety of such procedures are operator dependent.

Since the initial advent of the invasive and minimally invasive surgical procedures for axillary HH, safer alternative treatments have become available, such as microwave thermolysis. When comparing the effectiveness, side effects, and patient satisfaction of the current procedural treatments for axillary HH (**Table 2**), microwave thermolysis may be the best available procedural treatment option, if the patient prefers a long-term solution.

Table 2
A comparison of the invasive and minimally invasive procedures for axillary HH

Procedure	Mean Reduction in HDSS	Mean Reduction with Gravimetric Measurements (%)	Mean Patient-Rated Satisfaction (%)	Mean Relapse Rate (%)	Common Side Effects (Mean %)	Less Common Side Effects (Mean %)
Liposuction	—	46.5	—	40	Bruising, hematoma formation (43), bridle formation (21), paresthesia (46.5)	Skin erosion (10.5), partial alopecia (14)
LC	0.30-point reduction	66	82.1 completely satisfied or satisfied	14.5	Paresthesia (19.8), hematoma (49.2), skin erosion (26.5), alopecia (33.9), bridle formation (29.3)	Flap necrosis (6.7), seroma formation (12.5), wound infection
Curettage	—	50	—	29	Hematoma (13.3), markedly visible scar (27), paresthesia (33), partial alopecia (44), hyperpigmentation (33)	Wound infection (2.2), epidermal necrosis (2.2), skin ulceration (12)
RSE	—	65.3	—	—	Hematoma (20), paresthesia (33.3), alopecia (100), large scar (100)	Wound infection (13)
LSE	—	62.9	58.4 satisfied	12.8	Hematoma (18.2), paresthesia (27.3), alopecia (100), seroma formation (27.3), bridle formation (27.3), skin erosion (36.4), flap necrosis (18.2)	Wound infection (5.6)
MiraDry	94 had a 1-point reduction	81.7	85.5 satisfied	—	Edema/erythema (90), paresthesia (65), patchy alopecia (26)	Blister formation (4.9), skin irritation (4.9), axillary bumps (2.5), mild compensatory sweating (2.5)

SUMMARY

Patients prefer treatments that are least invasive, require minimal downtime, and have good cosmetic results. Surgical treatments are effective at reducing excessive sweating, but require time for recovery after procedure, are operator dependent, and can have poor cosmetic outcomes. Treatment with microwave thermolysis is effective, minimally invasive, requires limited downtime, and has good cosmetic outcomes. Microwave thermolysis is the best minimally invasive procedural treatment of axillary HH and is FDA-cleared for such treatment. Other newer minimally invasive technologies are forthcoming, such as focused ultrasonography and fractional microneedle radiofrequency, which could prove to be efficacious as well.

REFERENCES

1. Lawrence CM, Lonsdale Eccles AA. Selective sweat gland removal with minimal skin excision in the treatment of axillary hyperhidrosis: a retrospective clinical and histological review of 15 patients. Br J Dermatol 2006;155(1):115–8. http://dx.doi.org/10.1111/j.1365-2133.2006.07320.x.
2. Bechara FG, Sand M, Altmeyer P. Characteristics of refractory sweating areas following minimally invasive surgery for axillary hyperhidrosis. Aesthetic Plast Surg 2008;33(3):308–11. http://dx.doi.org/10.1007/s00266-008-9261-4.
3. Wollina U, Köstler E, Schönlebe J, et al. Tumescent suction curettage versus minimal skin resection with subcutaneous curettage of sweat glands in axillary hyperhidrosis. Dermatol Surg 2008;34(5):709–16. http://dx.doi.org/10.1111/j.1524-4725.2008.34132.x.
4. Bechara FG, Sand M, Hoffmann K, et al. Histological and clinical findings in different surgical strategies for focal axillary hyperhidrosis: histologic and clinical findings. Dermatol Surg 2008;34(8):1001–9. http://dx.doi.org/10.1111/j.1524-4725.2008.34198.x.
5. Connolly M, de Berker D. Management of primary hyperhidrosis: a summary of the different treatment modalities. Am J Clin Dermatol 2003;4(10):681–97.
6. Bechara FG, Sand M, Sand D, et al. Surgical treatment of axillary hyperhidrosis: a study comparing liposuction cannulas with a suction-curettage cannula. Ann Plast Surg 2006;56(6):654–7. http://dx.doi.org/10.1097/01.sap.0000205771.40918.b3.
7. Lee MR, Ryman WJ. Liposuction for axillary hyperhidrosis. Australas J Dermatol 2005;46(2):76–9.
8. Swinehart JM. Treatment of axillary hyperhidrosis: combination of the starch-iodine test with the tumescent liposuction technique. Dermatol Surg 2000;26(4):392–6.
9. Bechara FG, Sand M, Tomi NS, et al. Repeat liposuction-curettage treatment of axillary hyperhidrosis is safe and effective. Br J Dermatol 2007;157(4):739–43. http://dx.doi.org/10.1111/j.1365-2133.2007.08092.x.
10. Ibrahim O, Kakar R, Bolotin D, et al. The comparative effectiveness of suction-curettage and onabotulinumtoxin-A injections for the treatment of primary focal axillary hyperhidrosis: a randomized control trial. J Am Acad Dermatol 2013;69(1):88–95. http://dx.doi.org/10.1016/j.jaad.2013.02.013.
11. Bechara FG, Sand M, Hoffmann K, et al. Aggressive shaving after combined liposuction and curettage for axillary hyperhidrosis leads to more complications without further benefit. Dermatol Surg 2008;34(7):952–3. http://dx.doi.org/10.1111/j.1524-4725.2008.34185.x.
12. Rompel R, Scholz S. Subcutaneous curettage vs. injection of botulinum toxin A for treatment of axillary hyperhidrosis. J Eur Acad Dermatol Venereol 2001;15(3):207–11.
13. Proebstle TM, Schneiders V, Knop J. Gravimetrically controlled efficacy of subcorial curettage: a prospective study for treatment of axillary hyperhidrosis. Dermatol Surg 2002;28(11):1022–6.
14. Jacob C. Treatment of hyperhidrosis with microwave technology. Semin Cutan Med Surg 2013;32(1):2–8.
15. Johnson JE, O'Shaughnessy KF, Kim S. Microwave thermolysis of sweat glands. Lasers Surg Med 2012;44(1):20–5. http://dx.doi.org/10.1002/lsm.21142.
16. Chih-Ho Hong H, Lupin M, O'Shaughnessy KF. Clinical evaluation of a microwave device for treating axillary hyperhidrosis. Dermatol Surg 2012;38(5):728–35. http://dx.doi.org/10.1111/j.1524-4725.2012.02375.x.
17. Glaser DA, Coleman WP, Fan LK, et al. A randomized, blinded clinical evaluation of a novel microwave device for treating axillary hyperhidrosis: the dermatologic reduction in underarm perspiration study. Dermatol Surg 2012;38(2):185–91. http://dx.doi.org/10.1111/j.1524-4725.2011.02250.x.
18. Lee SJ, Chang KY, Suh DH, et al. The efficacy of a microwave device for treating axillary hyperhidrosis and osmidrosis in Asians: a preliminary study. J Cosmet Laser Ther 2013;15(5):255–9. http://dx.doi.org/10.3109/14764172.2013.807114.
19. Tronstad C, Helsing P, Tønseth KA, et al. Tumescent suction curettage vs. curettage only for treatment of axillary hyperhidrosis evaluated by subjective and new objective methods. Acta Derm Venereol 2013;94(2):215–20. http://dx.doi.org/10.2340/00015555-1671.

Case Report

Histologic Assessment of Biopsy Samples Taken Before and After the miraDry Procedure Performed on a Patient with Axillary Hyperhidrosis

Nobuharu Kushikata, MD[1], Jinah Kim, MD, PhD[2], Steven Kim[3]
1. Sera Clinic, Tokyo, Japan
2. Departments of Pathology and Dermatology, Stanford, CA
3. Miramar Labs, Sunnyvale, CA

Introduction

Hyperhidrosis is defined as excessive sweating beyond what is physiologically required to regulate body temperature[1]. Although not life-threatening, hyperhidrosis has a significant impact on peoples' lives and is a condition which affects millions of people worldwide[2]. The negative impact on people's quality of life is comparable to many of the commonly recognized dermatologic disorders such as psoriasis, acne, and vitiligo[3].

Hyperhidrosis occurs in a number of different locations on the body, but the main areas of concern are the armpits (axillary), hands (palmar), and feet (plantar).

A new non-invasive, microwave-based device received FDA clearance in early 2011 for treating patients with primary axillary hyperhidrosis [miraDry System, Miramar Labs, Sunnyvale, CA]. This case study reviews the histologic findings of a patient who was treated with the miraDry system. The patient volunteered to allow biopsy samples to be taken at various timepoints before and after treatment.

Device Description

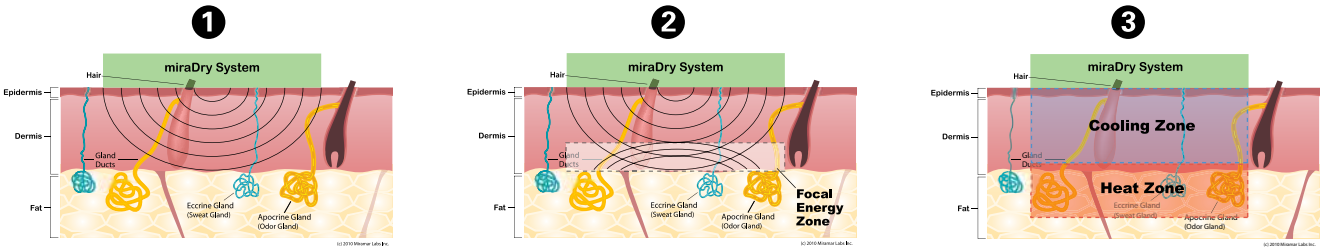
The miraDry system (Figure 1) utilizes microwave energy at 5.8 GHz to specifically heat the region of skin containing sweat glands to the point of causing thermolysis of the glands.

The miraDry system has an integrated hydro-ceramic cooling system which protects the superficial skin from thermal damage and a vacuum acquisition system to stabilize the target tissue during energy delivery.

The miraDry system automatically targets the dermal-hypodermal interface (Figure 2), where the majority of sweat glands reside in the axilla[4]. The eccrine glands are responsible for the wetness-producing sweat; the apocrine glands produce the substance that leads to odor. The system is designed to take advantage of the difference in microwave-related tissue properties of the dermis and subcutaneous tissue. Since the majority of the sweat glands reside at that interface, automatic targeting of that region, regardless of skin thickness, is a key feature of the miraDry system.

Figure 1.
miraDry System

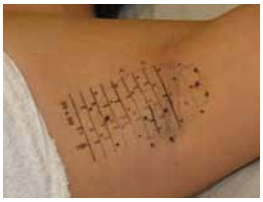
Figure 2.
miraDry System and mechanism of targeting the region where the sweat glands reside.



1 – Electromagnetic energy is delivered down into the skin from the external Handpiece.

2 – The energy reflects off of the dermal-hypodermal interface due to the abrupt change in microwave-related properties of the tissues.

3 – Surface cooling protects the dermis from thermal damage while allowing the thermal energy to spread within the target region.



Procedure Description

The miraDry procedure is performed in 3 steps.

Figure 3. Step 1 – Apply guidance template

The first step involves sizing the area to be treated and marking that area with the template system (Figure 3). The markings guide the user for anesthesia injection locations and placement of the Handpiece.

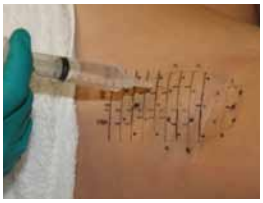


Figure 4. Step 2 – Deliver local anesthesia

The second step is the injection of local anesthesia (lidocaine) for pain management (Figure 4). Recommendations are provided for anesthesia delivery including injection site spacing, volume of anesthesia per injection site, and the depth of injection.

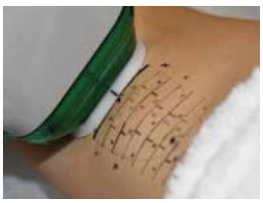


Figure 5. Step 3 – Place Handpiece on designated areas to deliver the therapy.

The third step is to apply the therapeutic energy by placing the Handpiece on the locations in each axilla (Figure 5). Multiple placements with the Handpiece are required to deliver therapy to the entire axilla. Typically, 2 procedures separated by a minimum of 3 months are necessary to get the optimal benefit. In the case reported here, the patient only received one procedure.

Case Description

The 37 year old male patient was enrolled in a study conducted by one of the authors (NK). The study was to evaluate the utility of the miraDry procedure in Japanese patients with axillary hyperhidrosis and/or osmidrosis. This patient presented with axillary hyperhidrosis as evidenced by both subjective patient evaluations and objective sweat measurements.

4mm cylindrical punch biopsies were taken from the left axilla before the procedure and at multiple timepoints after the procedure (nominally 10 days, 30 days, 60 days, 90 days, and 180 days ± 2 days). The samples were taken in a central location near each other, but not directly adjacent or overlapping (Figure 6). Residual hyper-pigmentation from the previous biopsies allowed accurate targeting of subsequent biopsies.

Biopsy samples were fixed in 10% neutral buffered formalin. Tissues were routinely processed in graded alcohols, cleared in xylene, embedded in paraffin, microtome sectioned at 5 microns, mounted on glass slides and stained with hematoxylin and eosin (H&E) for light microscopic evaluation. The histologic assessment was carried out by one of the authors (JK), who is a dermatopathologist.

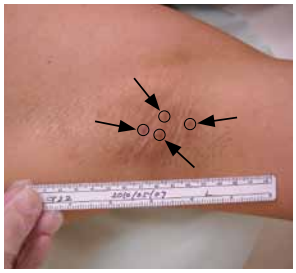


Figure 6. Arrows show the locations where biopsies were taken. The photo was taken before the 90 day follow-up.

Histologic Assessment

The pre-treatment "baseline" sample (Figure 7) demonstrated basketweave orthokeratosis overlying a normal appearing papillary and reticular dermis. The subcutis is abundant with normal appearing obulated apocrine glands, eccrine glands, and adipose tissue.

The biopsy sample taken at 10 days post-treatment is shown in Figure 8. Necrotic sweat glands and ducts are identified within the reticular dermis and subcutis. The necrotic glands and ducts are devoid of nuclei. A mild perivascular lymphohistiocytic infiltrate is present within the subcutis, which may be suggestive of inflammation and subsequent healing.

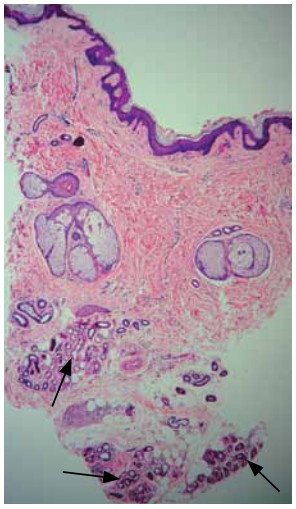


Figure 7. "Baseline" sample. Normal-appearing apocrine and eccrine glands are present in the subcutaneous tissue. Arrows point to some of the sweat gland lobules.

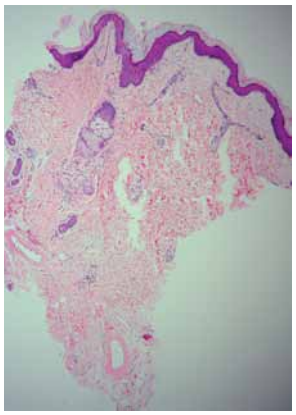


Figure 8. 10 days post-treatment sample.

The biopsy sample taken at 30 days post-treatment is shown in Figure 9. Unfortunately, the subcutis is not well-represented due to sampling. However, the sample is devoid of normal appearing sweat glands. The lower reticular dermis does show mildly atrophic eccrine gland with perieccrine fibrosis.

Figure 10 shows the biopsy sample taken at 60 days post-treatment. The reticular dermis and subcutaneous tissue is devoid of normal appearing sweat glands. Mild lymphohistiocytic infiltrate, periglandular fibrosis, and neovascularization are identified surrounding atrophic glands, suggestive of post-traumatic reactive changes.

Biopsy sample taken at 90 days post treatment is shown in Figure 11. This sample demonstrates similar findings to the prior time point (60 days). There are small foci of atrophic glandular lobules present within the subcutaneous tissue. An associated mild lymphohistiocytic infiltrate, periglandular fibrosis, and neovascularization are identified and surround the atrophic glands, suggestive of post-traumatic reactive changes.

The final biopsy sample, taken at 180 days post-treatment, is shown in Figure 12. In this specimen, a single well-formed sweat gland lobule is present in the subcutis. There is associated neovascularization and mild inflammatory infiltrate. The subcutaneous tissue contains minimal reactive changes associated with prior fat necrosis.

Discussion

The miraDry treatment uses microwave energy to non-invasively heat the region of the skin where sweat glands reside. The heat generated is enough to cause thermal necrosis of the sweat glands. This case study demonstrated that thermal injury that is sufficient to cause necrosis of sweat glands are indeed delivered by the miraDry system. There is a clear reduction of viable sweat gland structures when comparing the before treatment ("baseline") sample to any of the follow-up time point samples from this one patient. There was no significant histopathologic evidence of adverse effect on other cutaneous structures in this study.

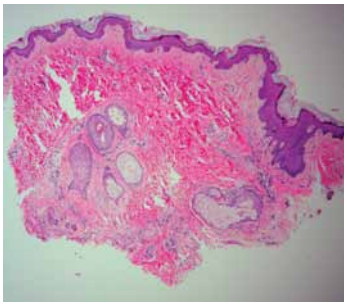


Figure 9.
30 days post-treatment sample.

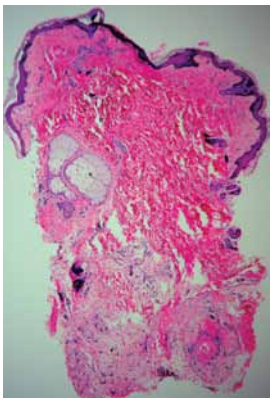


Figure 10.
60 days post-treatment sample.

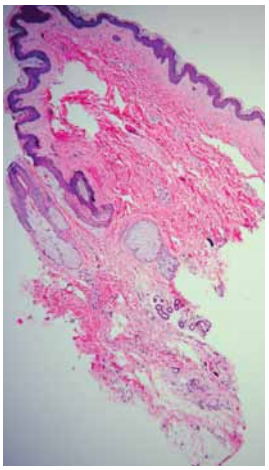


Figure 11.
90 days post-treatment sample.

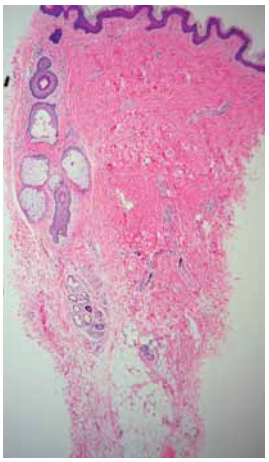


Figure 12.
180 days post-treatment sample.

References

1. Atkins JL and Butler P. Hyperhidrosis: a review of current management. Plast Reconstr Surg 2002; 110(1):222–228.
2. Strutton DR, Kowalski JW, Glaser DA, and Stang PE. US prevalence of hyperhidrosis and impact on individuals with axillary hyperhidrosis: Results from a national survey. J Am Acad Dermatol 2004; 51(2):241–248.
3. Basra M, Fenech R, Gatt R, Salek M, and Finlay A. The dermatology life quality index 1994–2007: a comprehensive review of validation data and clinical results. Br J Dermatol 2008; 159(5):997–1035.
4. Beer GM, Baumuller S, Zech N, Wyss P, Strasser D, Varga Z, Seifert B, Hafner J, and Mihic-Probst D. Immunohistochemical differentiation and localization analysis of sweat glands in the adult human axilla. Plast Reconstr Surg 2006; 117(6):2043–2049.

Lasers in Surgery and Medicine 44:20–25 (2012)

Microwave Thermolysis of Sweat Glands

Jessi E. Johnson, PhD, Kathryn F. O'Shaughnessy, PhD, and Steve Kim, MS*
Miramar Labs, Inc., Sunnyvale, California 94085

Background and Objectives: Hyperhidrosis is a condition that affects a large percentage of the population and has a significant impact on peoples' lives. This report presents a technical overview of a new noninvasive, microwave-based device for creating thermolysis of sweat glands. The fundamental principles of operation of the device are presented, as well as the design and optimization of the device to target the region where the sweat glands reside.
Materials and Methods: An applicator was designed that consists of an array of four waveguide antennas, a cooling system, and a vacuum acquisition system. Initially, the performance of the antenna array was optimized via computer simulation such that microwave absorption was maximized near the dermal/hypodermal interface. Subsequently, hardware was implemented and utilized in pre-clinical testing on a porcine model to optimize the thermal performance and analyze the ability of the system to create thermally affected zones of varying size yet centered on the target region.
Results: Computer simulation results demonstrated absorption profiles at a frequency of 5.8 GHz that had low amounts of absorption at the epidermis and maximal absorption at the dermal/hypodermal interface. The targeted zone was shown to be largely independent of skin thickness. Gross pathological and histological response from pre-clinical testing demonstrated the ability to generate thermally affected zones in the desired target region while providing protection to the upper skin layers.
Conclusions: The results demonstrate that microwave technology is well suited for targeting sweat glands while allowing for protection of both the upper skin layers and the structures beneath the subcutaneous fat. Promising initial results from simulation and pre-clinical testing demonstrate the potential of the device as a noninvasive solution for sweat gland thermolysis. Lasers Surg. Med. 44:20–25, 2012. © 2011 Wiley Periodicals, Inc.

Key words: dermatology; hyperhidrosis; eccrine glands; microwave; thermolysis; noninvasive

INTRODUCTION

Hyperhidrosis is defined as excessive sweating beyond what is physiologically required to regulate body temperature [1]. Although not life-threatening, hyperhidrosis has a significant impact on peoples' lives and is a condition which affects millions of people worldwide [2]. Its impact is comparable to many of the commonly recognized dermatologic disorders such as psoriasis, acne, and vitiligo [3].

A new noninvasive, microwave-based device has been developed to create thermolysis of sweat glands. This article will provide a technical overview of the device and present some of the device's fundamental principles of operation. A description of the target anatomy, basics of microwave-based therapeutic techniques, and the device configuration will be shown. Computer simulations utilized to design the microwave absorption pattern of the device will also be presented, followed by pre-clinical studies that assessed and optimized the location and size of thermally affected zones created by the device.

MATERIALS AND METHODS

Microwave Energy as a Thermal Treatment Modality

Microwave energy has been under investigation for decades as a modality for medical treatment. Early conceptual work for microwave-based thermal therapy has been reported as early as the 1930s [4,5] and practical hardware development and experimentation in this area began as early as 1946 [6]. Since this early work, research has been extensive and technology has been developed for use in medical fields such as oncology, urology, cardiology, and general surgery [4,7–12]. However, despite this work, microwave technology is less familiar to the medical community than other modalities such as lasers, radio frequency (RF), and ultrasound devices. A brief overview of some of the fundamental principles of microwave energy in relation to medical devices is presented below.

A microwave is typically defined as an electromagnetic signal having a frequency of between 300 MHz and 300 GHz, with a corresponding free-space wavelength of 1 m down to 1 mm [13]. This frequency range lends itself to coupling energy into the body utilizing radiated energy rather than coupling via direct contact or by capacitive (or inductive) coupling as utilized in RF devices [10]. Microwave-based therapeutic medical devices

The authors are all employees of Miramar Labs, Inc., the company developing the technology described in this work.

*Corresponding to: Steve Kim, MS, Miramar Labs, Inc., Sunnyvale, CA 94085. E-mail: skim@miramarlabs.com

Accepted 13 October 2011
Published online in Wiley Online Library (wileyonlinelibrary.com).
DOI 10.1002/lsm.21142

generally consist of an antenna that converts high frequency currents (produced by a microwave generator) into a propagating electromagnetic signal that is transmitted into the body to produce a desired absorption pattern in tissue. The absorption in tissue leads to the process of dielectric heating, a different phenomenon than generating heat via resistance to the flow of free electrons (as in RF devices). At a molecular level, microwave dielectric heating consists of the rapidly changing electric field induced by a microwave signal acting upon dipole moments within the water molecules present in tissue. Molecules are excited by the microwave field, resulting in frictional forces leading to heating [14].

Target Anatomy

It is generally accepted that there are two types of sweat glands that exist: eccrine and apocrine glands. The eccrine glands secrete a clear, nonodorous sweat, whose primary function is thermoregulation of body temperature; these glands are distributed all over the body. The apocrine glands secrete a milky sweat, where the bacterial breakdown of this sweat causes the unique body odor; these glands are primarily found in the axillae and genital region. Both of these glands reside near the dermal/hypodermal interface [15].

Device Configuration and Design

Figure 1 shows a diagram of the antenna array, cooling system components, and the tissue model utilized in the development of the microwave applicator. Microwave energy from a high-power generator is fed into a metal-plated waveguide structure via a coaxial probe as shown in the figure. The probe excites a propagating microwave signal in the waveguide which travels down the structure to an open face with no metal. This open face forms a radiating aperture that allows the transmission of energy out of the waveguide structure, through the cooling system and into tissue. The cooling system is formed from a circulating layer of water and a ceramic cooling plate and serves to prevent thermal damage to the superficial layers of the skin, while allowing therapeutic heat to develop in the deeper target tissue. The applicator also includes a vacuum acquisition system, which is represented in Figure 1 by the "lifted" configuration of the skin and fat regions. The vacuum system lifts the skin and underlying fat layers to achieve additional separation of the energy source from underlying fixed tissue structures and physically isolate the target region.

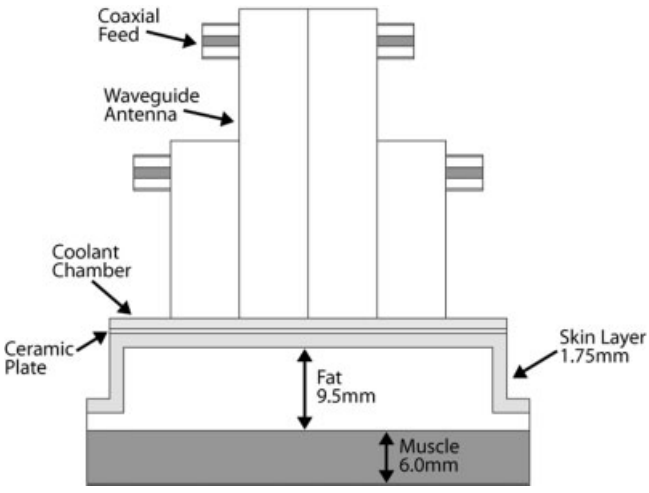


Fig. 1. Geometry of antenna array, cooling system, and tissue model utilized for this study.

The main design goal for this device was to achieve an optimal heating effect in the target tissue. The first step utilized electromagnetic computer simulations using the model described above to determine an optimal antenna geometry and frequency for maximizing microwave absorption near the target region. The computer modeling was followed by hardware implementation and preclinical testing to verify the design and determine optimal energy delivery parameters in terms of heating of the target region as well as protection of the epidermal and upper dermal regions. The details of the electromagnetic simulation and optimization are presented below.

Computer Simulation Setup

An industry-standard three-dimensional microwave simulation tool (CST Microwave Studio, CST of America, Inc., Boston, MA) was utilized to perform the optimization of the electromagnetic response of the system. The model included the four-channel waveguide array, the cooling system and the vacuum acquired tissue model as shown in Figure 1. Using the anatomy of the axilla as an example, the epidermal and dermal layers were modeled as a single 1.75 mm thick slab. The hypodermis was modeled as a 9.5 mm slab of adipose tissue, distended by vacuum, with a layer of underlying muscle tissue 6 mm thick. The microwave properties assumed for the various tissue types are shown in Table 1 for a frequency of 5.8 GHz. The tissue density properties were taken from [16] and are also shown in Table 1. In order to account for patient skin thickness variation, simulations were also conducted with 1.25 and 2.25 mm skin thicknesses. It is of note that the sweat glands themselves, which were shown in preliminary simulation investigations to have minimal affect on absorption pattern, were not explicitly included in the simulations.

As shown in Table 1, there are significant differences in the material properties of the dermal and underlying adipose tissue, with the relative permittivity and microwave conductivity being significantly larger in the dermal tissue. These differences result in two phenomena. The first is that a large reflection of the microwave energy will tend to occur at the dermal/hypodermal interface (in the same manner by which light reflects when striking a material with a different index of refraction than that it is propagating through). Secondly, the large difference in microwave conductivity (which is proportional to the amount of energy absorbed in a material for a given electric field strength) demonstrates that dermal tissue is

TABLE 1. Table of Tissue Properties (Data Taken From [16,25])

Tissue type	Relative permittivity ε_r	Conductivity σ (S/m)	Density ρ (kg/m^3)
Dermal/epidermal	38.62	4.34	1,010
Adipose	4.95	0.29	920
Muscle	49.5	5.44	1,040

The relative permittivity (ε_r) describes the velocity at which the microwave travels through each tissue type, with a large ε_r corresponding to a lower velocity. The conductivity is a measure of how well each tissue type absorbs microwave energy.

more readily subjected to absorption than the adipose layer. These phenomena were utilized to design an antenna geometry to target the region near the dermal/hypodermal interface, as described in further detail below.

Absorption (Specific Absorption Rate, or SAR) profiles were computed by the simulator and utilized to characterize the spatial absorption in tissue and assess the ability of the antennas to treat the target region effectively. SAR is a metric used for treatment zone estimations in microwave hyperthermia because the absorbed energy is converted into heat.

Pre-Clinical Testing

Although the computer simulation results provide accurate estimates of the microwave absorption, they do not account for thermal conduction effects. The constant temperature cooling system protects the superficial region of the skin by inhibiting upward thermal conduction from the peak microwave absorption region. The cooling parameters can also be designed such that the combination of direct microwave heating and thermal conduction creates an optimal therapeutic heating region in the deep dermis and adjacent subdermal tissue. The general concept of designing the combination of microwave absorption pattern and cooling system to create an optimal thermal profile is illustrated in Figure 2. Optimization of the thermal performance was achieved via pre-clinical studies, as described below.

Testing was performed on a porcine model at an Association for the Assessment and Accreditation of Laboratory Animal Care (AAALAC) accredited facility. The porcine model is commonly utilized for dermatological testing, having been used to test many modern laser systems [17–19], wound healing devices and drugs [20], and dermal abrasion systems [18]. It is also widely documented that porcine skin and human skin are similar in morphology and in physiology [21] and their microwave properties have also been shown to be similar [22–24]. The main limitation of the porcine model for this application is that eccrine glands are not present in the target tissue. However, the porcine model has apocrine glands that are similar in size to the human apocrine glands and are located near the dermal–hypodermal interface in the subcutaneous tissue. Since most of the human eccrine glands also reside at the same interface [15], they adequately model the presence of sweat glands for the optimization of thermal performance and provide confidence in the potential to achieve efficacy in humans.

The animal study was conducted in the following manner. The animals were anesthetized and a grid was created on the left and right flank surfaces. Each rectangular area of the grid was a test location for a single treatment. Utilizing a 15°C coolant temperature and an approximate 30 W antenna power per channel, microwave energy levels of 599, 630, and 756 J were utilized. Note that these energy levels represent the total energy spread over seven individual zones treated by a single applicator placement. The 756 J setting represented an example of excessive energy to test the limits of safety and was not considered a clinically viable setting. A minimum of six test locations

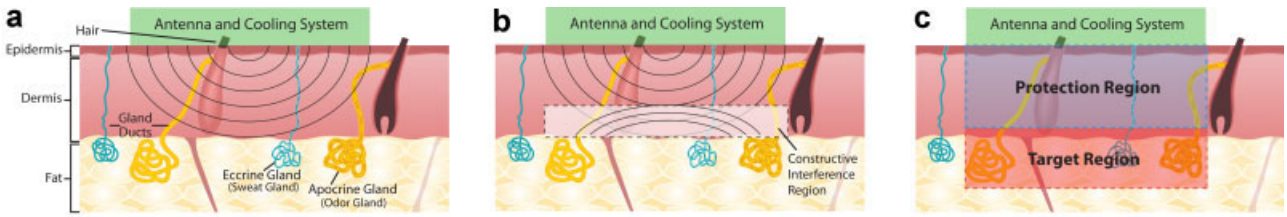


Fig. 2. Diagram demonstrating the basic method by which the sweat gland layer is targeted: (**a**) an incident signal is radiated by the antenna system through the epidermal and dermal layer, (**b**) a significant amount of reflection occurs at the dermal/hypodermal interface, resulting in constructive interference in the dermis near the interface, (**c**) the cooling system protects the epidermal/upper dermal layer and allows thermal conduction from the microwave absorption region to spread to the target zone.

were treated for every energy setting used. Animals were recovered and survived until time-points spanning 1–3 months. Gross pathological examination was utilized to assess the location and size of the thermally affected area, and histopathological analysis was conducted by a veterinary histopathologist to assess the local effects.

RESULTS

Computer Simulation Results

Figure 3 shows a plot of the normalized SAR profile in the plane perpendicular to the skin surface for the optimized design. As the figure shows, power is preferentially absorbed in the dermal layer in the region near the dermal/hypodermal interface. At the skin's surface the SAR is approximately 30% of the maximum, demonstrating the inherent protection of the epidermal and upper dermal layer achieved by the system independent of the cooling which further protects the superficial tissue. The peak SAR occurs in the dermal layer at a distance of 0.25 mm from the dermal/hypodermal interface and quickly drops when transitioning into the hypodermal region. Also, the peak SAR is less than 2% of maximum in the muscle layer, which demonstrates the ability of the system to focus the energy in the target region without causing significant absorption in the underlying structure.

As previously described, a range of skin thicknesses were subsequently simulated for the optimal antenna system geometry to assess the performance over variation in patient skin thickness. Normalized 1D SAR data were calculated and compared to the original result at 1.75 mm, as shown in Figure 4. The figure demonstrates that the peak absorption zone remains in the same location for all simulated skin thicknesses, with some variation in peak energy absorbed.

Pre-Clinical Testing Results

One month post-treatment gross pathological images from the study are shown in Figure 5, with part (a) of the figure showing a baseline untreated area and demonstrating the various tissue regions, and parts (b)–(d) of the figure showing the effects from energy delivery settings of 599, 630, and 756 J respectively. The figure demonstrates how the system was optimized to create a thermal effect consistently in the dermal/hypodermal interface and how the lesion size (range 1–3 mm thickness) was adjustable while still providing protection to the epidermal and upper dermal layers. Figure 6 (a) shows a histological image from the dosage study at the 1 month time-point for the 599 J setting. The majority of the dermal tissue has minimal to no histologic changes in the treatment zone. Inflammation and fibrosis were identified within the deep dermis and subdermal regions where the thermal energy was focused. The sample also shows an apocrine gland with inflammation, suggesting that it was subjected to a significant amount of thermal energy. Figure 6 (b) shows an untreated control sample for comparison. Figure 7 (a) shows another section that was treated at the 630 J setting. Again we notice a similar treatment zone. The boxed area in Figure 7 (a) is shown magnified in Figure 7 (b); the black arrows indicate the necrotic apocrine glands.

In terms of safety, protection of the epidermal and upper dermal layers was evident in the gross and histologic results. No evidence of skin effects such as skin necrosis, blisters, or hyper/hypopigmentation were found for any of the settings. There was a range of edema and erythema in the treatment area that was recorded at each follow-up time point, however these had resolved by the 3-month time-point for the clinically viable settings. The histologic changes were consistent across all of the energy settings; however the area of effect varied.

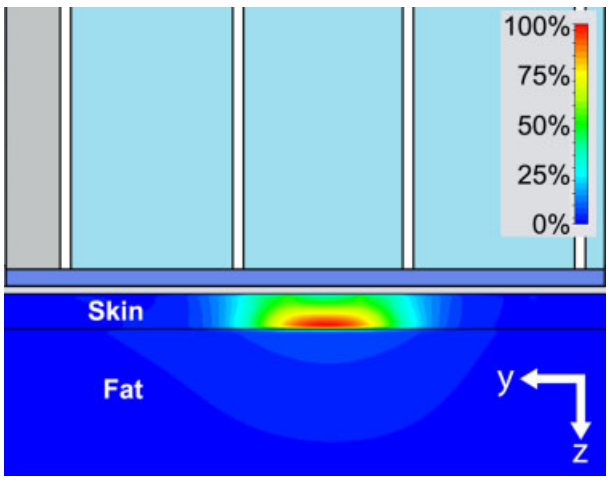


Fig. 3. SAR Plot for the optimized design, skin thickness = 1.75 mm, frequency = 5.8 GHz. The color scale represents the % of maximum SAR at a given point in the 3D model.

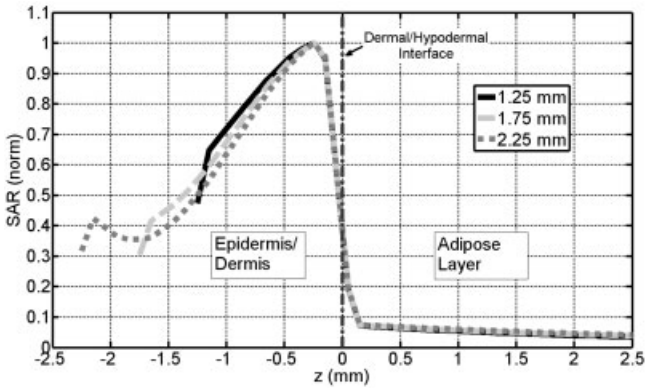


Fig. 4. 1D Normalized SAR profiles through center of waveguide antenna down into tissue, comparison of skin thickness models from 1.25 to 2.25 mm. Plot normalized such that $z = 0$ mm occurs at the dermal/hypodermal interface for each trace. Peak SAR values for each thickness were as follows: 1.25 mm = 1.6×10^5 W/kg, 1.75 mm = 1.2×10^5 W/kg, 2.25 mm = 9.0×10^4 W/kg.

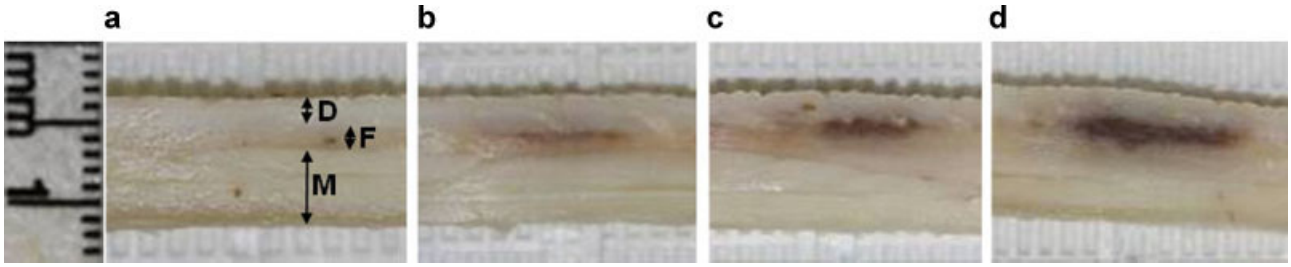


Fig. 5. Gross pathology examination 1 month posttreatment, for tissue treated at various energy levels in porcine model: (**a**) untreated, (**b**) 599 J, (**c**) 630 J, (**d**) 756 J. The dark region (localized hematoma) approximates the area affected by the energy. Note that the baseline untreated case shows the location of the dermal region (D) the fat layer (F) and muscle (M).

DISCUSSION

When delivering microwave energy into tissue, the difference in the dielectric properties between dermal and adipose tissue tend to generate a large amount of reflected energy at the dermal/hypodermal interface. The antenna system was designed to take advantage of this property such that this reflected signal travels back towards the waveguide antenna and creates an optimal interference pattern (i.e., standing wave pattern) with the initial incident signal. The result is constructive interference in the region near the dermal/hypodermal interface and destructive interference near the epidermal layer. The larger conductivity of the dermal tissue results in this constructive interference signal being absorbed mainly on the dermal side of the interface to produce the absorption profile shown in Figure 3.

A great advantage of utilizing the reflected signal to create an optimal interference pattern and corresponding absorption profile is that the reflection occurs at the dermal/hypodermal interface independently of the skin thickness. Thus, as demonstrated in Figure 4, changes in skin thickness do not affect the location of the targeted area. This principal highlights one of the inherent advantages of using this microwave technology for treating sweat glands.

The pre-clinical study showed that delivering energy with the system resulted in thermal injury to a well-defined area at the dermal/hypodermal interface where sweat glands reside. The results also demonstrate the ability of the system to create thermal zones of varying size while maintaining the desired safety profile. The high level of epidermal and upper-dermal protection achievable by the system is also attributable to the ability of the microwave energy to create a peak absorption zone that occurs below these layers. The gross pathological results were verified by the histology, which also clearly showed thermolysis of the apocrine glands.

CONCLUSION

A new noninvasive microwave device for treating sweat glands has been developed. This article has presented a technical overview of the fundamental principles of operation of this device and described how the microwave and thermal performance of the device were optimized for

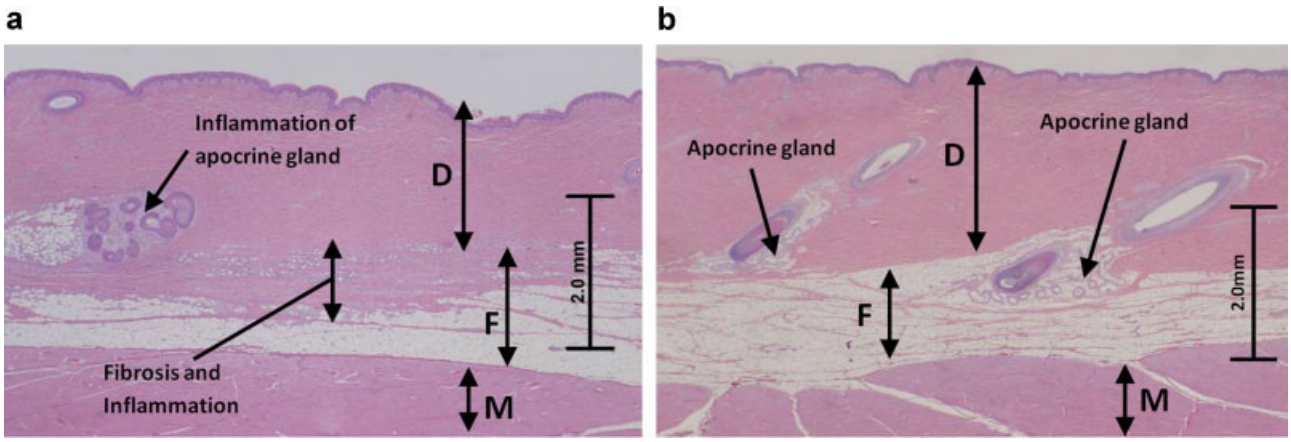


Fig. 6. H&E stained samples in porcine model: (**a**) treated with microwave device at 599 J, (**b**) untreated control. For both cases, dermal region is denoted with a (D), fat layer with an (F), and muscle with an (M).

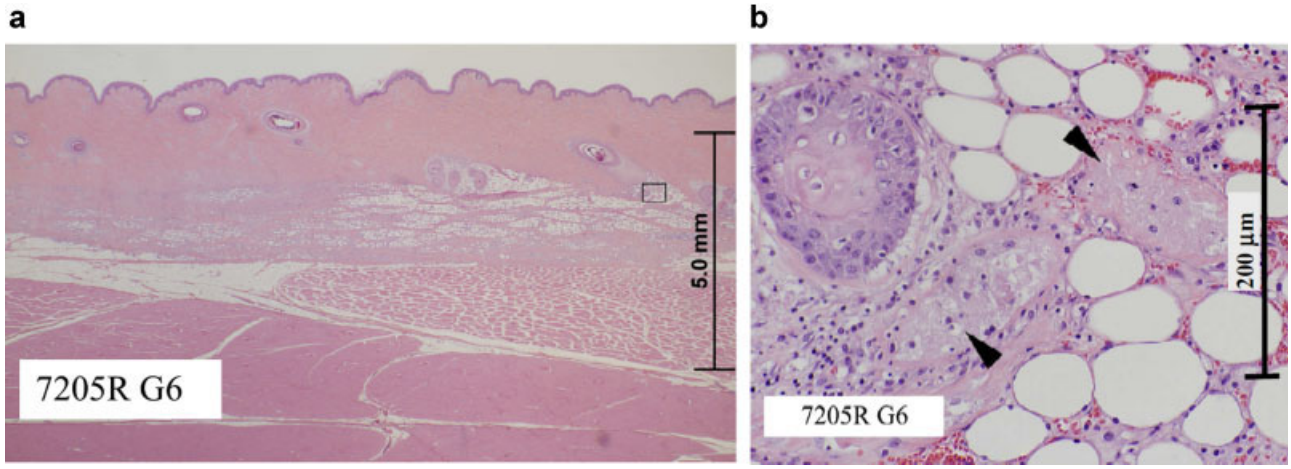


Fig. 7. H&E stained sample in porcine model: (**a**) treated with microwave device at 630 J, (**b**) magnification of part (a); the black arrows indicate the necrotic apocrine glands.

targeting the sweat glands. Clinical investigations of this device should be performed to demonstrate safety and efficacy for the specific indication of use.

REFERENCES

1. Atkins JL, Butler P. Hyperhidrosis: A review of current management. Plast Reconstr Surg 2002;110(1):222–228.
2. Strutton DR, Kowalski JW, Glaser DA, Stang PE. Us prevalence of hyperhidrosis and impact on individuals with axillary hyperhidrosis: Results from a national survey. J Am Acad Dermatol 2004;51(2):241–248.
3. Basra M, Fenech R, Gatt R, Salek M, Finlay A. The dermatology life quality index 1994–2007: A comprehensive review of validation data and clinical results. Br J Dermatol 2008; 159(5):997–1035.
4. Guy AW. Biophysics of high-frequency currents and electromagnetic radiation. In: Lehmann JF, editor. Therapeutic heat and cold, 4th edition. Baltimore, MD: Williams and Wilkins; 1990. pp 179–236.
5. Guy AW. History of biological effects and medical applications of microwave energy. IEEE Trans Microw Theory Tech 1984;32(9):1182–1200.
6. Krusen FH. Samuel hyde memorial lecture: Medical applications of microwave diathermy: Laboratory and clinical studies. Proc R Soc Med 1950;43(8):641.
7. Johnson JE, Neumann DG, Maccarini PF, Juang T, Stauffer PR, Turner P. Evaluation of a dual-arm Archimedean spiral array for microwave hyperthermia. Int J Hyperthermia 2006;22(6):475–490.
8. Rosen A, Greenspon AJ, Walinsky P. Microwaves treat heart disease. IEEE Microw Mag 2007;8(1):70–75.
9. Stauffer PR. Thermal therapy techniques for skin and superficial tissue disease. In: Ryan TP, editor. A critical review, matching the energy source to the clinical need. Bellingham, WA: SPIE Optical Engineering Press; 2000. pp 327–367.
10. Stauffer PR. Evolving technology for thermal therapy of cancer. Int J Hyperthermia 2005;21(8):731–744.
11. Sterzer F. Microwave medical devices. IEEE Microw Mag 2002;3(1):65–70.
12. Vander Vorst A, Rosen A, Kotsuka Y. RF/microwave interaction with biological tissues. Hoboken, NJ: John Wiley & Sons, Inc.; 2006.
13. Pozar DM. Microwave engineering, 2nd edition. New York, NY: John Wiley & Sons. Inc.; 1998.
14. Gabriel C, Gabriel S, Grant EH, Halstead BSJ, Mingos DMP. Dielectric parameters relevant to microwave dielectric heating. Chem Soc Rev 1998;27(3):213–224.
15. Beer GM, Baumuller S, Zech N, Wyss P, Strasser D, Varga Z, Seifert B, Hafner J, Mihic-Probst D. Immunohistochemical differentiation and localization analysis of sweat glands in the adult human axilla. Plast Reconstr Surg 2006;117(6): 2043–2049.
16. Gandhi OP, Lazzi G, Furse CM. Electromagnetic absorption in the human head and neck for mobile telephones at 835 and 1900 MHz. IEEE Trans Microw Theory Tech 1996; 44(10):1884–1897.
17. Ross EV, McKinlay JR, Sajben FP, Miller CH, Barnette DJ, Meehan KJ, Chhieng NP, Deavers MJ, Zelickson BD. Use of a novel erbium laser in a yucatan minipig: A study of residual thermal damage, ablation, and wound healing as a function of pulse duration. Lasers Surg Med 2002;30(2):93–100.
18. Ross EV, Naseef GS, McKinlay JR, Barnette DJ, Skrobal M, Grevelink J, Anderson R. Comparison of carbon dioxide laser, erbium: Yag laser, dermabrasion, and dermatome a study of thermal damage, wound contraction, and wound healing in a live pig model: Implications for skin. Resurfacing. J Am Acad Dermatol 2000;42(1):92–105.
19. Ross EV, Yashar SS, Naseef GS, Barnette DJ, Skrobal M, Grevelink J, Anderson R. A pilot study of in vivo immediate tissue contraction with CO_2 skin laser resurfacing in a live farm pig. Dermatol Surg 1999;25(11):851–856.
20. Sullivan TP, Eaglstein WH, Davis SC, Mertz P. The pig as a model for human wound healing. Wound Repair Regen 2001;9(2):66–76.
21. Vardaxis NJ, Brans TA, Boon ME, Kreis RW, Marres LM. Confocal laser scanning microscopy of porcine skin: Implications for human wound healing studies. J Anat 1997;190(04): 601–611.
22. Gabriel C, Gabriel S, Corthout E. The dielectric properties of biological tissues: I. Literature survey. Phys Med Biol 1996; 41(11):2231–2249.
23. Gabriel S, Lau RW, Gabriel C. The dielectric properties of biological tissues: II. Measurements in the frequency range 10 Hz to 20 GHz. Phys Med Biol 1996;41(11):2251–2269.
24. Peyman A, Gabriel C. Cole-cole parameters for the dielectric properties of porcine tissues as a function of age at microwave frequencies. Phys Med Biol 2010;55(15):N413–N419.
25. Gabriel S, Lau RW, Gabriel C. The dielectric properties of biological tissues: III. Parametric models for the dielectric spectrum of tissues. Phys Med Biol 1996;41(11):2271–2293.

Burcu Kim, MBBS
Naveen Somia, MBBS, PhD, FRACS
Department of Plastic and Reconstructive Surgery, Prince of Wales Hospital

Burcu Kim, MBBS
Naveen Somia, MBBS, PhD, FRACS
John Pereira, MBBS, BSc(Med), FRANZCR
Kurosh Parsi, MBBS, MSc(Med), PhD, FACP, FACD
Faculty of Medicine The University of New South Wales Sydney, Australia

John Pereira, MBBS, BSc(Med), FRANZCR
Kurosh Parsi, MBBS, MSc(Med), PhD, FACP, FACD
Department of Medical Imaging Prince of Wales and Sydney Children's Hospital Sydney, Australia

Kurosh Parsi, MBBS, MSc(Med), PhD, FACP, FACD
Department of Dermatology St Vincent's Hospital Sydney Australia

Long-term Efficacy and Quality of Life Assessment for Treatment of Axillary Hyperhidrosis With a Microwave Device

In a prior report,[1] we provided 1-year efficacy and safety data for subjects with axillary hyperhidrosis treated with a microwave technology. This letter provides 2-year follow-up data for a majority of those patients and a further exploration of the potential for quality of life improvement.

The original study enrolled 31 adult subjects with primary axillary hyperhidrosis in a single-group unblinded study at 2 centers. All subjects had Hyperhidrosis Disease Severity Scale (HDSS) ratings of 3 or 4 and a gravimetric sweat assessment of at least 50 mg per 5 minutes in each axilla. Baseline Dermatology Life Quality Index (DLQI) scores ranged from 1 to 28, with a mean of 11.8. The subjects were treated with a microwave-based device (miraDry System; Miramar Labs, Sunnyvale, CA). Nineteen of the original study group signed consent for a follow-on Web-based survey for a second year of follow-up that included the HDSS and DLQI questionnaires, and questions on odor reduction. At 1 year after treatment, all side effects (except underarm hair loss) had resolved in all patients who were active in the study. No patients noted any new side effects during the second year.

The results for baseline and each follow-up time point are shown in Table 1. The primary overall efficacy measure was the percentage of subjects who reduced their HDSS scores from 3 or 4 at baseline down to scores of 1 or 2 at the follow-up surveys. This remained greater than 90% and stable.

For the DLQI score, the average score across all patients at baseline was compared with the average score at the indicated follow-up time point, as well as the percentage of patients with at least a 5-point drop in DLQI. In addition, an analysis of the response to individual DLQI questions (percentage of subjects who responded that their activity was "very much" or "a lot" affected by their hyperhidrosis) identified those areas of daily activity that were most impacted by excessive sweat before the treatment: effect on clothing choices (84%), embarrassed or self-conscious (71%), prevented from work or studying (52%), and affected social or leisure activities (45%). After treatment, the percentages were between 0% and 11% and stable, as shown in Table 1.

An analysis for odor reduction was conducted by calculating the percentage of subjects who stated that

TABLE 1. Efficacy Results and Effect on Quality of Life, Measured at Each Visit

Efficacy Measure	*Baseline*	*30 days (n = 30)*	*3 months (n = 29)*	*6 months (n = 27)*	*12 months (n = 26)*	*15 months (n = 18)*	*18 months (n = 18)*	*21 months (n = 18)*	*24 months (n = 19)*
Percent of subjects with HDSS reduction to score of 1 or 2	NA	28/30 = 93.3%	28/29 = 96.6%	26/27 = 96.3%	26/26 = 100%	17/18 = 94.4%	18/18 = 100%	18/18 = 100%	19/19 = 100%
DLQI score (mean ± SD)	11.8 ± 6.4	1.87 ± 2.46	1.86 ± 3.56	1.81 ± 3.43	1.23 ± 1.53	2.00 ± 2.38	1.50 ± 1.72	1.44 ± 1.89	1.37 ± 1.54
Reduction of DLQI score* (mean ± SD)	NA	11.0 ± 4.8	10.7 ± 5.5	10.4 ± 5.94	11.2 ± 5.6	10.3 ± 4.79	11.2 ± 6.6	10.5 ± 5.9	11.4 ± 6.3
Reduction of DLQI by ≥5 points*	NA	25/25 = 100%	23/24 = 96%	21/22 = 95%	21/21 = 100%	13/13 = 100%	13/14 = 93%	13/13 = 100%	14/14 = 100%
DLQI—clothing	84%	10%	3%	7%	0%	0%	0%	0%	11%
DLQI—embarrassed or self-conscious	71%	7%	3%	7%	0%	0%	0%	0%	0%
DLQI—prevented work or studying	52%	0%	3%	0%	0%	0%	0%	0%	0%
DLQI—affected social or leisure	45%	0%	3%	4%	0%	0%	11%	0%	11%
Odor: % with "not a problem"	16%	80%	83%	81%	88%	83%	89%	89%	89%

*Only included patients who had a baseline DLQI of 5 or greater (excluded 5 patients).

their underarm odor was "not a problem" at the follow-up visits compared with baseline. At baseline, the percentage was 16%; after treatment, this ranged from 80% to 89% (Table 1).

A limitation to this data set is the smaller number of subjects who consented to the follow-on surveys and complied with survey completion—only 61% (19/31) of the treated patients completed the final survey. It is important to note that the majority of the discontinued patients, the 8 patients who declined to consent to the second year of follow-up, had a successful treatment effect at the end of the 1-year follow-up. Their DLQI scores were between 0 and 5; and all had HDSS scores of 1 or 2. Therefore, the cohort that continued into the second year is not biased by unsuccessful patients being excluded.

The effect has been shown to be durable and stable through 2 years of follow-up, and a substantial improvement on quality of life has been documented. This study confirms prior reports[2] regarding specific areas impacted by axillary hyperhidrosis. The tested device represents a new therapeutic option, providing long-term relief for patients suffering from axillary hyperhidrosis.

References

1. Hong HC-H, Lupin M, O'Shaughnessy KF. Clinical evaluation of a microwave device for treating axillary hyperhidrosis. Dermatol Surg 2012;38:728–35.

2. Solish N, Benohanian A, Kowalski JW. Canadian Dermatology Study Group on Health-Related Quality of Life in Primary Axillary Hyperhidrosis. Prospective open-label study of botulinum toxin type A in patients with axillary hyperhidrosis: effects on functional impairment and quality of life. Dermatol Surg 2005;31:405–13.

Clinical Evaluation of a Microwave Device for Treating Axillary Hyperhidrosis

H. Chih-Ho Hong, MD, FRCPC,* Mark Lupin, MD, FRCPC,* and Kathryn F. O'Shaughnessy, PhD†

BACKGROUND A third-generation microwave-based device has been developed to treat axillary hyperhidrosis by selectively heating the interface between the skin and underlying fat where the sweat glands reside.

MATERIALS AND METHODS Thirty-one (31) adults with primary axillary hyperhidrosis were enrolled. All subjects had one to three procedure sessions over a 6-month period to treat both axillae fully. Efficacy was assessed using the Hyperhidrosis Disease Severity Scale (HDSS), gravimetric weight of sweat, and the Dermatologic Life Quality Index (DLQI), a dermatology-specific quality-of-life scale. Subject safety was assessed at each visit. Subjects were followed for 12 months after all procedure sessions were complete.

RESULTS At the 12-month follow-up visit, 90.3% had HDSS scores of 1 or 2, 90.3% had at least a 50% reduction in axillary sweat from baseline, and 85.2% had a reduction of at least 5 points on the DLQI. All subjects experienced transient effects in the treatment area such as swelling, discomfort, and numbness. The most common adverse event (12 subjects) was the presence of altered sensation in the skin of the arm that resolved in all subjects.

CONCLUSION The device tested provided efficacious and durable treatment for axillary hyperhidrosis.

This study was funded by Miramar Labs. Kathryn O'Shaughnessy is an employee of Miramar Labs.

The prevalence of axillary hyperhidrosis in the United States has been estimated at 1.4%,[1] which amounted to more than 4.3 million people in 2011. Although there are several different treatment options,[2] only surgical modalities have been capable of conferring a permanent solution. A novel microwave device was developed[3] and has been cleared by the Food and Drug Administration as a noninvasive method to treat axillary hyperhidrosis. A prior randomized, blinded, multicenter study proved the efficacy of an earlier-generation device that implemented microwave technology.[4] The purpose of this present study was to evaluate a newer-generation device that delivers faster treatment times and to further assess efficacy and safety. This study was meant to provide information on device optimization, particularly with respect to energy levels, numbers of treatments, and timing of procedures.

Microwaves heat by physical rotation of dipole molecules. Because ionic water has a high dipole moment, and fat has a low dipole moment, there is relative selectivity to the water-rich dermis and sweat glands, with less absorption in the subcutaneous layer. Applying concurrent cooling to the upper dermis restricts the heat to a small zone near the interface, where the sweat glands are located. Although eccrine glands are the primary target in treatment of hyperhidrosis, this microwave device

*Department of Dermatology and Skin Science, University of British Columbia, Vancouver, British Columbia, Canada; †Miramar Labs, Inc., Sunnyvale, California

ISSN: 1076-0512 • Dermatol Surg 2012;38:728–735 • DOI: 10.1111/j.1524-4725.2012.02375.x

TABLE 1. Hyperhidrosis Disease Severity Scale (HDSS) Definition: How Would You Rate the Severity of Your Hyperhidrosis?

HDSS Score	*Definition*
1	My underarm sweating is never noticeable and never interferes with my daily activities
2	My underarm sweating is tolerable but sometimes interferes with my daily activities
3	My underarm sweating is barely tolerable and frequently interferes with my daily activities
4	My underarm sweating is intolerable and always interferes with my daily activities

can also affect the odor-related apocrine glands. In that respect, this study evaluated reduction of odor in addition to sweat reduction.

Materials and Methods

Patients

Thirty-one adults with primary axillary hyperhidrosis were enrolled in a single-group unblinded study at two centers. All subjects had primary axillary hyperhidrosis evidenced by Hyperhidrosis Disease Severity Scale (HDSS) ratings of 3 or 4 and a gravimetric sweat assessment of at least 50 mg in 5 minutes in each axilla. Subjects were excluded if they had had surgery for axillary hyperhidrosis or botulinum toxin injections in the axillae in the last 12 months.

The study was conducted in accordance with the Declaration of Helsinki, and all subjects signed an Ethics Committee–approved informed consent before any study procedures.

Sweat Assessments

The primary method for assessing subjects' level of underarm sweat was subject-reported HDSS score.[5] Table 1 provides the definition of each of the four possible scores. A gravimetric (weight) assessment of sweat was used as a secondary measure. Subjects were required to be at rest in a normal-temperature room. Their axillae were wiped before the test, a preweighed filter paper (Whatman #541, 90 mm, Maidstone, UK) was placed in each axilla for 5 minutes, the filter papers were weighed again, and the difference in weight was calculated in milligrams. A secondary assessment used the 10-question, validated Dermatology Life Quality Index (DLQI).[6] Also, although not used for any quantitative study assessments, a starch-iodine test was employed in some treatment sessions to identify areas that still had active sweat glands and at follow-up visits for a visual assessment of sweat. An alcohol-based iodine mixture was wiped on the skin of the axilla, and then corn starch was sprinkled on the area and gently brushed to create a thin uniform coating. Any sweat that appeared turned black (Figure 1). Histologic samples from punch biopsies at baseline and after treatment were obtained if subjects agreed.

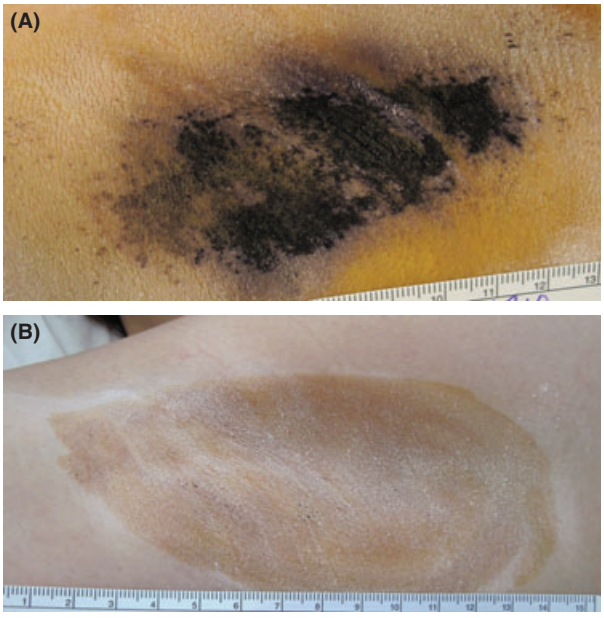


Figure 1. Starch-iodine photographs of the right axilla of subject at (A) baseline and (B) 6-month follow-up visit. Dark areas show active sweat glands. The subject had a Hyperhidrosis Disease Severity Scale (HDSS) score of 4 at baseline. At the 6-month visit, the HDSS score was 1, and the subject had a 91% reduction in sweat, as measured by the gravimetric assessment.

To obtain overall subject assessment of the procedure, patients were asked to choose a satisfaction rating that described their evaluation of the procedure from the following categories: very satisfied, somewhat satisfied, neutral, somewhat dissatisfied, and very dissatisfied.

Finally, although the primary investigation was of the effect of the procedure on wetness (sweat) production, subjects were asked to provide their perception of underarm odor at baseline and at follow-up visits, given that the mechanism of action of the device might affect the apocrine and the eccrine sweat glands. Subjects were asked to provide their rating of their underarm odor as not noticeable, slightly noticeable, somewhat noticeable, noticeable, or very noticeable.

Study Visit Schedule

Subjects attended a screening or baseline visit at which informed consent was obtained, and baseline sweat assessments were performed.

The treatment phase of the study started with the first procedure visit, at which the hair-bearing areas of both axillae were treated. As part of the procedure development, subsequent treatment phase visits were held approximately every 30 days for sweat assessments and safety evaluation; if the subject exhibited signs of sweat production (based on the answers to the subjective questionnaires or the starch-iodine test), another procedure session targeting the still-sweating areas was completed. At most, three procedure sessions were allowed, and all procedures had to be completed within a 6-month window.

Each procedure session included three steps: marking the axilla with a treatment template, injecting local anesthesia (1% lidocaine with 1:100 000 epinephrine) in a grid pattern throughout the indicated area, and applying the microwave treatment. The microwave-based device included integrated vacuum and cooling (miraDry System; Miramar Labs, Sunnyvale, CA) and allowed for a small range (±10%) of energy settings. Some variation in energy settings was explored to determine optimal parameters for the population being treated.

After all procedure sessions were complete, subjects attended follow-up visits at 30 days and 3, 6, and 12 months after their last procedure session.

Study Efficacy Measures

Efficacy of sweat reduction was measured using all sweat assessments (HDSS, gravimetric assessment, and DLQI) and patient satisfaction. The primary overall efficacy measure was the percentage of subjects that reduced their HDSS scores from 3 or 4 at baseline to 1 or 2 at the follow-up visits. As a secondary measure, gravimetric scores for each visit were obtained by taking the average of the readings from the right and left axillae; the percentage reduction was calculated by dividing the change in gravimetric score (from baseline) by the baseline gravimetric score. Efficacy was measured by calculating the percentage of subjects who achieved at least a 50% reduction in their gravimetric score and by calculating the average percentage reduction for all patients. For the DLQI score, the average score for all patients at baseline was compared with the average score at the indicated follow-up visit. A further analysis calculated the percentage of patients that achieved at least a 5-point reduction in DLQI, which previously has been reported to be the change in the DLQI that represents a clinically meaningful improvement after therapy.[7] This last calculation was made only for patients who had a DLQI score of at least 5 at baseline. An overall patient satisfaction measure was calculated as the percentage of subjects who rated themselves as very satisfied or somewhat satisfied with the procedure results. An analysis for odor reduction was conducted by calculating the percentage of subjects that had not noticeable underarm odor at the follow-up visits.

Statistical Analysis

Statistical analysis was conducted using SAS (SAS version 9.1; SAS Institute, Inc., Cary, NC). Exact binomial 95% confidence intervals were calculated for percentage values. For analysis of changes in DLQI for which paired values were available, a paired t-test was used to establish whether the average difference was more than 5 points. The McNemar exact test was used to determine statistical significance for the proportion of subjects reporting not noticeable underarm odor at follow-up visits. For any missing data points (e.g., for missed visits), the last observation carried forward method was used to fill in the missing values unless otherwise noted.

Safety Assessments

At each study visit, subjects were asked a general question about their health. Reported procedure effects were categorized as Grade 0 if they were minor expected sequelae from the procedure (such as local swelling or bruising). Other events were categorized as Grade 1 (minor) to Grade 3 (severe). The duration of all events was tracked, and the investigators assigned the degree that the event was related to the procedure or device (none, remote, possible, probable, unknown).

Results

Demographic information and baseline sweat assessment values for the group of enrolled subjects are shown in Table 2. Twenty-six of the 31 enrolled subjects completed study visits through 12 months of follow-up. Twelve subjects had two procedure sessions, and 15 had three procedure sessions within the allowed 6-month window. Four subjects had only one procedure session. (One subject achieved full sweat reduction with the one session, two declined further treatment because of side effects, and one declined because of lack of efficacy.)

Efficacy

The primary and secondary efficacy results for each follow-up visit are shown in Table 3, along with 95% confidence intervals. The primary efficacy HDSS result was 90% or higher as measured at all four follow-up visits. (See Figure 2 for the distribution of HDSS values at each time point.) Additional analyses of HDSS at the final 12-month visit shows that 94% (29/31) of the subjects had at least a 1-point drop in HDSS and 55% (17/31) had a 2-point drop or greater in HDSS.

TABLE 2. Demographic Characteristics and Baseline Sweat Assessments for the 31 Subjects

Characteristic	*Value*
Age, median (range)	33 (18–65)
Sex, *n* (%)	
Male	8 (26)
Female	23 (74)
Race, *n* (%)	
Caucasian	27 (87)
Asian	4 (13)
Body mass index, average, kg/m^2	24.8
Baseline Hyperhidrosis Disease Severity Scale score, *n* (%)	
3	20 (65)
4	11 (35)
Baseline average gravimetric reading, mg/5 minutes	190
Baseline Dermatologic Life Quality Index, average	11.8

The efficacy measured as the percentage of subjects with a 50% or greater reduction in gravimetric assessment (90%, 94%, 90%, and 90% at the 30-day, 3-month, 6-month, and 12-month visits, respectively) further supports this result. The average reduction in sweat for all patients was 83%, 82%, 82%, and 82% at the 30-day, 3-month, 6-month and 12-month visits, respectively. Figure 3 shows the per-patient reduction in sweat from baseline at the 12-month follow-up visit. The percentage of subjects who showed a reduction in DLQI score of at least 5 points was 96%, 89%, 89%, and 85% at the 30-day, 3-month, 6-month, and 12-month visits, respectively, and the average DLQI reduction was statistically significantly greater than 5 points (the average reduction was 10.4, 10.2, 9.6, and 9.9 points for the 30-day, 3-month, 6-month, and 12-month visits, respectively,

TABLE 3. Sweat Efficacy Assessment Results at Study Follow-Up Visits

Efficacy Measure	*30 Days*	*3 Months*	*6 Months*	*12 Months*
HDSS reduction to score of 1 or 2, *n* (%) [95% CI]	28 (90.3) [74.3–98.0]	29 (93.6) [78.6–99.2]	28 (90.3) [74.3–98.0]	28 (90.3) [74.3–98.0]
≥50% reduction in sweat (gravimetric), *n* (%) [95% CI]	28 (90.3) [74.3–98.0]	29 (93.6) [78.6–99.2]	28 (90.3) [74.3–98.0]	28 (90.3) [74.3–98.0]
Average reduction in sweat (gravimetric), % [*n* = 31]	83.1	82.3	82.1	81.7
Average DLQI score [*n* = 31]	2.5	2.7	3.1	3.0
Reduction in DLQI score, average [95% CI]*	10.4 [8.3–12.4]	10.2 [7.9–12.4]	9.6 [7.3–12.0]	9.9 [7.5–12.2]
Reduction of DLQI by ≥5 points, *n* (%) [95% CI]*	26 (96.3) [81.0–99.9]	24 (88.9) [70.8–97.7]	24 (88.9) [70.8–97.7]	23 (85.2) [66.3–95.8]

*Included only patients with a baseline DLQI of ≥5 [*n* = 27].
CI, confidence interval; DLQI, Dermatologic Life Quality Index.
95% confidence intervals are shown in square brackets.

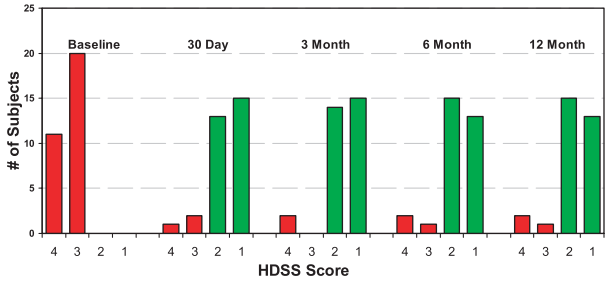


Figure 2. Distribution of Hyperhidrosis Disease Severity Scale (HDSS) scores at the different study visits. Ninety percent or more of subjects had a reduction to scores of 1 or 2 after treatment at all of the follow-up visits.

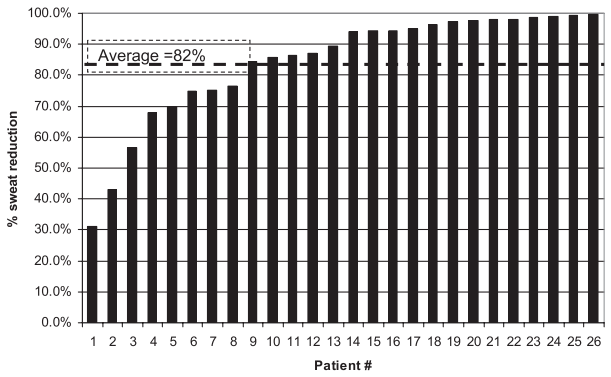


Figure 3. Individual patient percentage reduction in sweat as measured by gravimetric assessment comparing results at 12 months with baseline. Only the subjects who attended the 12-month visit (*n* = 26) are shown.

$p < .001$ for all four values). The elimination of sweat glands can be seen in histologic samples that one subject provided. Figure 4A shows a sample taken at baseline, with the sweat glands clearly evident below the skin. Figure 4B shows a sample taken in the same axilla 105 days after the last treatment, with no sweat glands evident.

Ninety percent of subjects who completed the questionnaire (27/30) reported being very satisfied or somewhat satisfied at the 30-day follow-up visit. This percentage was 96% (27/28) at the 3-month visit, 93% (25/27) at the 6-month visit, and 88.5% (23/26) at the 12-month visit.

The data on subject-reported odor evaluation also showed that a large percentage of subjects who started the study with a self-reported underarm odor as noticeable (to any degree) found that their underarm odor was not noticeable after the treatment. The percentage of subjects who had not noticeable odor at baseline was 12.9% (4/31); at the follow-up visits the proportion was 67.7% (21/31), 71.0% (22/31), 74.2% (23/31), and 61.3% (19/31) at the 30-day, 3-month, 6-month, and 12-month visits, respectively ($p < .001$ at all time points).

Safety

The reported Grade 0 events showed that a large number of subjects experienced mild procedure effects that typically lasted a few days to a week; the most common were edema (90% of subjects), redness and vacuum acquisition marks (87% of

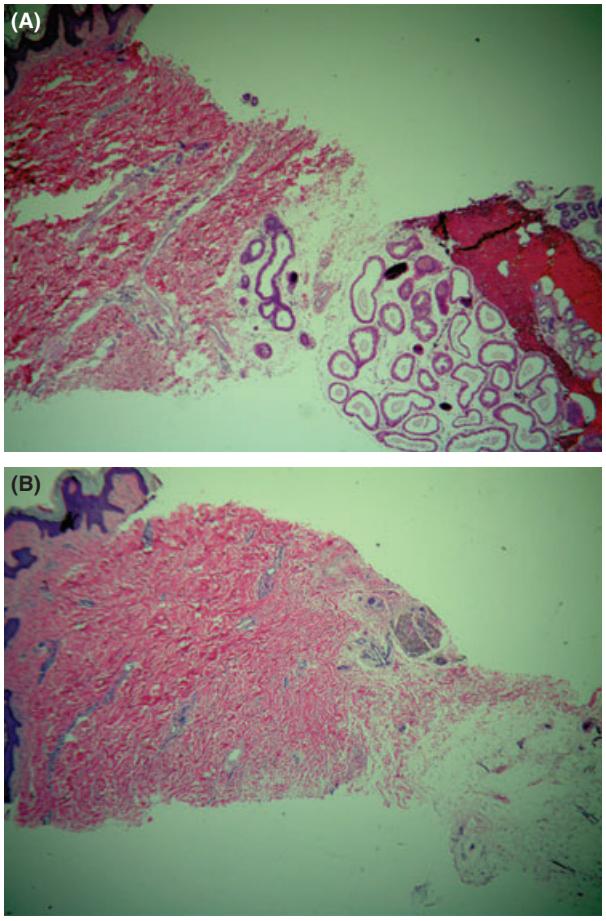


Figure 4. Histology samples show (A) baseline appearance of sweat glands present just under the skin and (B) sample taken from a different location in the same axilla after treatment. The post-treatment sample shows that sweat glands are no longer present under the skin. (Hematoxylin-eosin sample, magnification ×40.)

subjects), and discomfort (84% of subjects). The longer-term effects (all resolved) were altered sensation in the skin of the axillae (65% of subjects, median duration 37 days, range 4 days to 4 months) and palpable bumps under the skin of the axillae (71% of subjects, median duration was 41 days, two subjects had the effect at study exit). The duration for axillary hair loss (self-reported by 26% of subjects) was not calculated because, in the majority of affected subjects, it was ongoing at the time of study exit.

Procedure effects that were rated to have even a remote chance of being procedure related that were evident outside the axillae were seen in 18 (58%) subjects; 88% of the events were rated as mild. The most common effect seen (16 events in 12 subjects) was altered sensation in the skin of the treatment limb (median duration 50 days, range 6 days to 12 months), and all resolved. The second-most-common effect was swelling outside the axilla, in the arm or chest, (median duration 7 days, range 2–23 days). One subject experienced transient neuropathy of the left arm with associated muscle weakness after the procedure; the prognosis from the consulting neurologist was complete resolution. The subject showed improvement 6 months after treatment, after which she was lost to follow-up.

Discussion

Primary axillary hyperhidrosis is a common problem with a significant effect on quality of life. Previous treatment modalities include topical antiperspirants, botulinum toxin injections, surgical interventions, and oral anticholinergic medications.

There has recently been the development of a novel microwave energy device that destroys eccrine glands at the interface of the deep dermis and subcutis, minimizing damage to surrounding tissue. An earlier-generation device was reported to be efficacious and safe in a randomized, blinded, multicenter study.[3] A newer-generation device was tested for safety and efficacy. Optimization of treatment parameters and treatment protocol was also assessed during the study.

After the failure of topical antiperspirants, injection with botulinum toxin is the most common intervention. In one study,[8] the HDSS efficacy was 85% (121/142) 4 weeks after treatment and 90% (115/128) 12 weeks after treatment (where efficacy was calculated as the percentage of subjects reaching an HDSS score of 1 or 2). Longer duration of effect was not measured in the study. A study with longer follow-up[9] reported efficacy of 75% 4 weeks after treatment (where efficacy was calculated as the percentage of subjects with a

≥2-point drop in HDSS) and an estimated Kaplan–Meier efficacy of 22% at 52 weeks. A similar analysis for the study in this report shows efficacy of 18 out of 31 (58%) at 30 days and essentially the same value (17/31, 55%) 12 months after treatment. These data illustrate the primary difference between botulinum toxin and microwave treatment, in that the effect of the botulinum toxin injections is temporary, with an average duration of 6.7 months,[9] and the microwave treatment has shown stable results through the last follow-up visit at 12 months.

At the visits 30 days and 3, 6, and 12 months after the allowed treatment series, 90.3%, 93.6%, 90.3%, and 90.3% of subjects, respectively had achieved the primary end point of an HDSS score of 1 or 2. Gravimetric analysis, a secondary end point, showed a reduction of sweat of 83.1%, 82.3%, 82.1%, and 81.7% from baseline at the same time points. The average reduction in the DLQI at the above-mentioned time points was 10.4, 10.2, 9.6, and 9.9, which is a dramatic change in DLQI. It is also significantly higher than improvements that represent a clinically meaningful change in DLQI after therapy for primary axillary hyperhidrosis.[7] Overall, patient satisfaction was high, with 90% of patients reporting satisfaction at each of the four follow-up time points through 1 year. The treatment also seems to affect subject-reported underarm odor, with a statistically significant increase in the percentage of patients who reported not noticeable underarm odor. The efficacy of the treatment did not seem to vary with the number of procedures.

Short-term adverse events related to the therapy were generally minor. Post-treatment edema, erythema, and discomfort in the treatment area were common and resolved quickly after therapy. Some patients experienced longer-lasting transient effects, such as altered sensation in or around the treatment area, papule and nodule formation in the axilla, and hair loss. Some subjects were still experiencing axillary hair loss when they exited the study. One patient experienced treatment-related neuropathy that was resolving at 6 months, after which she was lost to follow-up.

The miraDry system is a novel microwave energy device that can be used to treat axillary hyperhidrosis through selective heating of the lower layer of skin, where the eccrine and apocrine glands are located. Patient satisfaction with the procedure is high, and adverse events are typically transient and well tolerated. This system provides a durable, noninvasive alternative therapeutic modality for patients with this common and frustrating problem.

Acknowledgments We would like to thank Quiring Statistical Consultations for their assistance in statistical analysis.

References

1. Strutton DR, Kowalski JW, Glaser DA, Stang PE. US prevalence of hyperhidrosis and impact on individuals with axillary hyperhidrosis: results from national survey. J Am Acad Dermatol 2004;51:241–8.
2. Solish N, Bertucci V, Dansereau A, Hong HC-H, et al. A comprehensive approach to the recognition, diagnosis, and severity-based treatment of focal hyperhidrosis: recommendations of the Canadian Hyperhidrosis Advisory Committee. Dermatol Surg 2007;33:908–23.
3. Johnson JE, O'Shaughnessy KF, Kim S. Microwave thermolysis of sweat glands. Lasers Surg Med 2012;44:20–5.
4. Glaser DA, Coleman WP, Fan LK, Kaminer MS, et al. A randomized, blinded clinical evaluation of a novel microwave device for treating axillary hyperhidrosis: the Dermatologic Reduction In Underarm Perspiration Study. Dermatol Surg 2012;38:185–91.
5. Kowalski JW, Eadie N, Dagget S, Lai P-Y. Validity and reliability of the Hyperhidrosis Disease Severity Scale (HDSS). J Am Acad Dermatol 2004;36:P51. Poster presented at the 62nd Annual Meeting of the American Academy of Dermatology; February 6–10, 2004; Washington DC. Poster P198.
6. Basra M, Fenech R, Gatt R, Salek M, et al. The dermatology life quality index 1994–2007: a comprehensive review of validation data and clinical results. Br J Dermatol 2008;159:997–1035.
7. Kowalski JW, Ravelo A, Weng E, Slaton T. Minimal Important Difference (MID) of the Dermatology Life Quality Index (DLQI) in patients with axillary and palmer hyperhidrosis. J Am Acad Dermatol 2007;52:AB52. Poster presented at the 64th Annual Meeting of the American

Academy of Dermatology; March 3–7, 2006. San Francisco, CA. Poster P546.

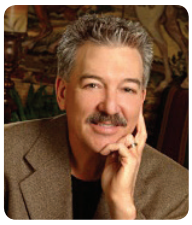
8. Solish N, Benohanian A, Kowalski JW. Prospective open-label study of botulinum toxin type A in patients with axillary hyperhidrosis: effects on functional impairment and quality of life. Dermatol Surg 2005;31:405–13.
9. Lowe NJ, Glaser DA, Eadie N, Daggett S, et al. Botulinum toxin type A in the treatment of primary axillary hyperhidrosis: a 52-week multicenter double-blind, randomized, placebo-controlled study of efficacy and safety. J Am Acad Dermatol 2007;56:604–11.

Address correspondence and reprint requests to:
H. Chih-ho Hong, MD, FRCPC, #22–15300 105th Avenue, Surrey, BC V3R 6A7, Canada, or
e-mail: chihho@interchange.ubc.ca

Building a Successful miraDry Business: A Case Study

Michael Maris, MD and Glenda Andrews, Practice Administrator
Dermatology Consultants, Dallas Texas

Dermatology Consultants was the first practice in Dallas, Texas and one of the first in the country to offer the miraDry procedure. The procedure uses the miraDry System which is the first and only FDA-cleared device for treating excessive underarm sweat that provides a lasting solution. Dr. Michael Maris and Glenda Andrews, his practice administrator, share their experience integrating the system into their busy dermatology practice, and provide tips for building a successful miraDry business.



Dr. Maris

Glenda

Dermatology Consultants purchased their system in January 2012. The miraDry system has proven to be successful, both in providing an effective clinical solution for a common problem and generating a new revenue stream for their practice.

Breakthrough Technology

"Once every 6 or 7 years, there is a new technology that comes along that changes the face of what we're doing in skin care. It was CO_2 lasers in the beginning, then collagen injections at one point. And now, I am firmly convinced, that new technology is miraDry."
– Dr. Maris

When the miraDry system became available in 2012, Dr. Maris was not planning to purchase any new capital equipment. However, he changed his mind because he was impressed with the technology and clinical study results, and felt the procedure would offer his patients a clinically effective and safe solution.

At that time, clinical study data demonstrated an efficacy rate of over 90%, 82% average underarm sweat reduction, and 90% patient satisfaction when patients were measured 6 months post-treatment.[1]

More recent clinical study results continued to show an efficacy rate of over 90% when measured 24 months post-treatment.[2]

"I think the miraDry system offers a breakthrough technology that is going to last and I believe it provides a solution for a problem that we have not been able to address very effectively in the past,"
– Dr. Maris

miraDry Procedure

Big Market Opportunity

1 in 5 adults are bothered by their underarm sweat[3]

Dr. Maris sees a big market opportunity for the miraDry procedure. In a 2009 survey conducted by Ipsos Vantis, a leading market research firm, 1 in 5 adults said that their underarm sweat bothered them.[3] In the beginning, his philosophy was to target people previously diagnosed with axillary hyperhidrosis. *"We've found that patients who have hyperhidrosis are very motivated to have the treatment done. They only need to hear about the procedure once, and they will come. We've had patients come to our practice from throughout Texas, and many fly in from other states to have this treatment."*

Beyond the previously diagnosed hyperhidrosis patient, Dr. Maris sees a bigger market opportunity – patients who find their excessive sweat a nuisance. *"Once the word gets out about how effective the miraDry procedure is, and how noninvasive and safe it is, we're going to be seeing a lot of sweat-bothered patients asking for this treatment."*

Seamless Integration

Dr. Maris and his team found the learning curve to be "almost nil" – the procedure is straightforward and the software interface guides the practitioner throughout the entire treatment. He was so confident about his team's ability to quickly learn and perform the procedure that the local ABC news affiliate in Dallas filmed their first two patients for a TV news story.

90% Patient Satisfaction

Dr. Maris estimates that their patient satisfaction rate is slightly better than the 90% rate he's seen in the clinical data, which makes the miraDry procedure unique among his services.

"Until miraDry was introduced, no piece of equipment, whether a laser, IPL device, radiofrequency application, nor any other physical modality used in our office has given a consistent 90% satisfaction rate. I feel confident in giving patients that expectation with miraDry." - Dr. Maris

For Glenda, the miraDry procedure is exciting because it complements the practice's philosophy to make a difference in people's lives.

"The miraDry procedure is one of the first sweat reduction procedures that patients are excited about, because it really works. They've gone through a lifetime of excessive underarm sweating. This is a solution to their problem." - Glenda

Multi-Faceted Marketing Approach

"miraDry is the most exciting treatment I have ever tried to market because everything I have done has worked." - Glenda

With a background and interest in marketing, Glenda is the driving force for building the practice's miraDry business. She believes in the procedure, and her enthusiasm is reflected in her marketing efforts. Her marketing strategy is multi-faceted, and includes programs targeted to external audiences as well as their existing patients.

This approach has produced positive business results. Glenda reports that almost every program she has tried has more than paid for itself by bringing in patients for treatment.

- **Website Marketing:** Glenda is proactive in utilizing the practice website to build awareness and educate her patients. Their website prominently features the miraDry procedure, and includes videos and news broadcasts for patients to view. She even created a dedicated website – www.miraDryDFW.com – which is unique and memorable for the Dallas area.
- **Local Media Outreach:** Dermatology Consultants secured a news story in Dallas from the very beginning. The story received widespread coverage throughout the state. The story featured a patient testimonial – increasing the impact of the story – and led to numerous phone inquiries.
- **Advertising:** A 30-second TV ad ran during "The Doctors" show. This ad yielded enough patients to more than pay for the cost of the commercial, and is an ongoing initiative.
- **Billboard:** Glenda tested a billboard featuring a bold headline: "Bothered by Sweat?" and a "(214) NoSweat" phone number. The billboard was successful, and resulted in numerous inquiries from patients, some even calling from their cars while stuck in traffic. They are planning to increase their billboard presence.
- **E-Blast:** Glenda sent an e-blast to their current patient database. This created awareness and yielded scheduled treatments.
- **Online Directories:** Practice information was added to several online local directories as well as the International Hyperhidrosis Society (IHHS) website. Being listed on the IHHS website is important because IHHS helps educate the public that excessive sweating is a medical issue and directs patients to their practice.

Exceeded Financial Expectations

"The miraDry system paid for itself within 6 months." – Glenda

In Glenda's experience, she finds that it takes more than a year for a new piece of equipment to pay for itself. The miraDry experience was very different and exceeded her expectations. After taking into account marketing expenses, as well as the cost of the system and consumables, Glenda says the system paid for itself within 6 months. Over the first 12 months, they have performed over 120 procedures, and about 90% of the patients are new to the practice, which offers a great side benefit as a business builder.

5 Tips for Success

Dr. Maris and Glenda summarize the top 5 steps they took to build their miraDry business.

1. **Design a marketing plan with a comprehensive mix** – start by leveraging your existing marketing programs to get the word out, and don't be afraid to experiment with new tactics to build awareness
2. **Get your front desk and office staff enthusiastic about the procedure** – educate them about the procedure and share patient results with them; staff love to talk about a procedure that makes patients happy
3. **Create patient awareness about underarm sweat and miraDry as a new treatment option** – focus efforts to reach patients both in-office and externally; take advantage of all the news stories out there about the miraDry procedure to educate patients
4. **Go digital** – maximize the use of the Internet (online searches and directories) and create an interactive website to educate patients on the miraDry procedure and the practice
5. **Constantly measure your results and refine the marketing plan** - find out where your miraDry patients are coming from to figure out what's working the best

CONCLUSION

Dr. Maris feels that of all the additions to his practice, the miraDry procedure has been one of his most gratifying. The miraDry system has delivered for him. His patients are happy with their results, his staff is enthusiastic and he feels that the future for the miraDry procedure is very bright.

About Dr. Maris and His Practice

Dr. Michael Maris is an American Board Certified Dermatologist. He has been recognized by his peers in the D Magazine as "Best Doctor" and in the Texas Monthly as a "Super Doc". He is known for the quality of his results in the mini lift and received a National Award in 2011. Dr. Maris is a past president for the Dallas Dermatological Society and has been in practice for over 25 years. He is also an Associate Professor at The University of Texas Southwestern Medical School. Dr. Maris is one of the first physicians to bring the new technology of miraDry to the Texas area. Combining innovative techniques with state-of-the-art technology allows Dr. Maris to offer his patients better results with less discomfort and down time.

Glenda Andrews has been in marketing, sales and practice management for 30 years. She is currently the administrator/ marketing director for Dermatology Consultants.

References:
1. An Evaluation of the miraDry System to Treat Subjects with Axillary Hyperhidrosis: Six Month Follow-up; H. Chih-ho Hong, MD and Mark Lupin, MD; 2011 ASDS Annual Meeting (October 2011)
2. Clinical Evaluation of a Microwave Treatment for Axillary Hyperhidrosis: Long-Term Follow-up; Mark Lupin, MD and Chih-ho Hong, MD; 2012 ASDS Annual Meeting (October 2012)
3. November 2009 Ipsos Vantis Market Study with 661 consumers (# of sweat events not related to athletics); clinical segment clinically diagnosed, sweat-bothered score >7 on 10-point scale. Data on file.

Miramar Labs, Inc.
445 Indio Way, Sunnyvale, CA 94085
408-940-8700
www.miraDry.com

MK0207.A 02/13

Print Article

QMP's Plastic Surgery Pulse News

Unwanted Armpit Sweating: Treatment With the miraDry Microwave Device

David J. Goldberg, MD, JD

Axillary hyperhidrosis is thought by many to be an underreported problem with few treatment options. In a 2002 survey,[1] 2.8% of individuals thought they had excessive or abnormal sweating, with 1.4% feeling that the problem was concentrated in their armpits. In a 2008 online survey,[2] 33% of adults felt they had excessive underarm sweating, but only 5% sought any form of help. In another survey conducted in 2009,[3] 4% of adults in the United States were diagnosed by a physician to have hyperhidrosis. Another 17% were bothered by their amount of non-exercise-induced sweating. Of note, the impact that excessive sweating has on quality of life is thought to be similar to that of both psoriasis and acne. The Dermatology Life Quality Index (DLQI) mean baseline score for axillary hyperhidrosis is 10.45, whereas the DLQI score is 10.53 for psoriasis and 7.45 for acne.

There are few treatment options for axillary hyperhidrosis. Antiperspirants can do only so much, and many patients do not want botulinum toxin injections for this purpose. However, a new procedure based on microwave technology, miraDry (Miramar Labs; Sunnyvale, CA), was approved by the FDA in January 2011 to treat primary axillary hyperhidrosis. It has now just become commercially available. The technique uses microwave energy to deliver thermal damage to the sweat glands.

The miraDry technology focuses microwave energy at the dermal-fat interface. The energy becomes concentrated along this interface and creates a focal heat zone that is concentrated at the level of the sweat glands. The overlying epidermis is not affected because continuous surface cooling prevents backward thermal conduction of heat.

Data from a seven-site study were presented at the 2011 American Society for Lasers in Medicine and Surgery meeting.[4] For the study, 80 subjects were treated with a prototype of the current miraDry device, and 40 were treated with a control device. Patients returned for follow-up visits at 6 months and 12 months. Examiners used both the Hyperhidrosis Disease Severity Scale (HDSS) and the actual weight of sweat secreted to determine the effectiveness of the treatment.

In the study, almost 66% of those treated were women, and a little more than 33% were male; 85% were Caucasian. Patients with the miraDry technology experienced a significant decrease in the HDSS, with the greatest results seen at 6 months. The gravimetric weight of sweat also decreased more than 50%, with the greatest results again seen at 6 months. There was still some improvement at 12 months. Adverse events were mild and usually consisted of transient altered armpit sensation. All adverse events resolved over time. No subjects thought that the adverse events affected their daily activities.

Based on the results of this study, miraDry microwave treatment represents an exciting new approach to the treatment of unwanted armpit sweating.

References

1. Strutton DR, Kowalski JW, Glaser DA, et al. US prevalence of hyperhidrosis and impact on individuals with axillary hyperhidrosis: results from a national survey. J Am Acad Dermatol 51:241-248, 2004.
2. International Hyperhidrosis Society survey of 2,897 general population adults. New York: Harris Interactive, 2008.
3. Ipsos Vantis. Independent research conducted for Miramar Labs. Private communication, 2009.
4. Kilmer S, Coleman W III, Fan L, et al. A randomized, blinded clinical study of a microwave device for treatment of axillary hyperhidrosis. Presented at the Annual Meeting of the American Society for Laser Medicine and Surgery, Grapevine, TX, April 2011.

Printed from QMP's Plastic Surgery Pulse News V3 N4. St. Louis: Quality Medical Publishing, 2009

Close Window

FOCUSED ISSUE FEATURE

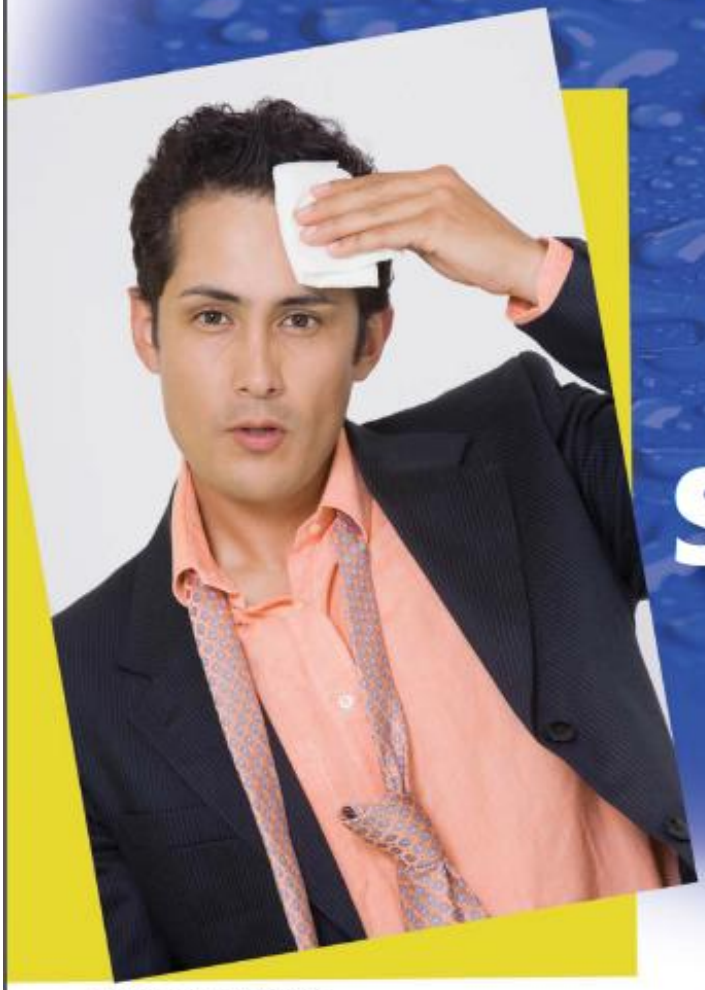


IMAGE LICENSED BY INGRAM PUBLISHING

Don't Sweat It

Jessi E. Johnson and Steve Kim

When considering the medical applications of microwave technology, ablating sweat glands is probably not what initially comes to mind. However, hyperhidrosis (the medical term for excessive sweating) is a condition estimated to affect up to 3% of the population [1]. There is also evidence that an additional 17% of the population have symptoms that are similar to those diagnosed with the condition [2]. Imagine a scenario where someone is inactive, sitting at his or her desk in a cool, dry environment, yet is sweating from the hands, feet, or underarms as if exercising. This is the type of situation a hyperhidrosis sufferer might face on a daily basis. Beyond physical irritation, there is significant evidence that the condition can result in occupational, emotional, psychological, social, and physical impairment leading to increased amounts of depression and other negative effects [1]. The treatment of sweat is also common in the general population in addition to severe sufferers, as evident from the large amounts of money spent on deodorants

Jessi E. Johnson and Steve Kim (skim@miramarlabs.com) are with Miramar Labs, Inc., Santa Clara, California, United States.

Digital Object Identifier 10.1109/MMM.2014.2377584
Date of publication: 6 February 2015

Previous Page | Contents | Zoom in | Zoom out | Front Cover | Search Issue | Next Page

and antiperspirants (e.g., US$2.9 billion in the United States in 2012) [3]. In this article, an overview of the current treatment options for axillary (underarm) hyperhidrosis, potential energy-based approaches, and the microwave technique developed for treating this potentially debilitating condition is presented. The challenges of commercializing such a medical microwave device are also discussed.

Diagnosing Hyperhidrosis

The method to diagnose primary hyperhidrosis has been well established [4]. A diagnosis can be made for a person with localized excessive sweating of at least six months without a secondary cause and for at least two of the following:

- at least one episode per week
- bilateral and relatively symmetric sweating
- impairment of daily activities
- onset before 25 years of age
- family history of hyperhidrosis without a known cause
- cessation of sweating during sleep.

Once a diagnosis has been made, there are various tools to determine the severity of the problem. The hyperhidrosis disease severity scale (HDSS), gravimetric assessment, and starch–iodine test are some of the more common tools used. The HDSS is a rating scale in which patients are asked how dramatically sweat affects their daily activities and a value of one through four is assigned, with those scoring three or four considered to be sufferers of severe hyperhidrosis [5]. Although the test is somewhat subjective, it has been validated [6] and utilized successfully in large-scale clinical trials of hyperhidrosis treatments [5], [7], [8]. The gravimetric assessment simply involves placing a paper of known weight in the axilla for a fixed amount of time and weighing the total amount of sweat secreted. A statistically significant correlation with gravimetric results and normal individuals versus hyperhidrosis patients has been demonstrated [9]. The starch–iodine test consists of applying a thin layer of povidone–iodine solution in the axilla and subsequently sprinkling a thin layer of powdered corn starch over it. As the patient begins to sweat, the regions of the skin where sweat is secreted turn a blackish color due to the sweat reacting with the starch/iodine mixture, while no color is observed in the dry areas [10].

Current Therapies

Some of the common treatments for treating axillary hyperhidrosis include prescription-strength antiperspirants, surgical procedures, and botulinum toxin (Botox) injections. Prescription-strength antiperspirants are more effective at providing a barrier to sweat secretion than over-the-counter solutions and are often the first option for patients. However, this approach is not always efficacious and can cause treatment-limiting irritation [11]. Local surgical procedures where sweat glands are sliced away from the skin/fat interface can also be performed and, while effective, are invasive and can have a significant amount of postoperative complications [11]. Finally, the neurotoxin Botox can be injected into the axilla and has been shown to inhibit sweat secretion by 82–87% posttreatment. This is a temporary solution, however, lasting between four and 12 months [11]. In the approach taken by the authors, the sweat glands are targeted with heat with the intent of ablating the glands such that they cannot secrete sweat. A major objective is to provide a lasting effect (such as that observed in local surgery) but to do it noninvasively and with minimal patient recovery time.

Possible Energy Modalities

For energy-based approaches to treating hyperhidrosis, the objective is ablation of the sweat glands that lie at a depth of approximately 2–3 mm. The glands can typically be found in close proximity to the boundary between the skin and fat layer, as shown in Figure 1. Common energy-based devices that might be considered for this type of dermatological application consist of laser, conducted RF, or ultrasound devices. Each of these energy types has unique properties and its own potential advantages or disadvantages when applied to treating dermatologic conditions.

Laser-based systems are commonly used for hair removal through a process called "photothermolysis." By choosing a specific wavelength, light energy is absorbed preferentially by dark hairs that have a large absorption coefficient in the optical range. The selective absorption of the hair leads to heating and subsequent destruction of the hair follicle. However, laser light energy is typically insufficient for treating patients with light-colored hair since the lack of color (and corresponding smaller absorption coefficient) does not allow the preferential heating of the follicle. In

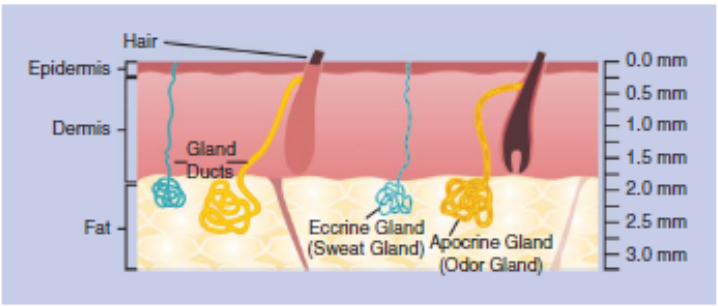


Figure 1. *The anatomy of the skin. The skin layer (epidermis and dermis) is 1.75 mm thick on average. The sweat glands lie near the skin/fat interface.*

terms of targeting the sweat glands for hyperhidrosis therapy, light energy poses a similar difficulty since the sweat glands are colorless. Despite this limitation, laser-based techniques for treating hyperhidrosis have recently been reported [12], [13]. Goldman et al. [12] describe an invasive laser-based approach that uses a fiber-optic probe inserted into an 18-gauge needle. The needle is inserted beneath the skin to bring the laser energy in close proximity to the sweat glands. In [13], the use of lenses and multiple beams is described as techniques to target the sweat glands despite the lack of inherent absorption by these structures.

Another common approach in dermatology is a low-frequency RF solution in which RF current, typically in the high kilohertz to low megahertz range [14], is conducted through tissue between an electrode and a ground plane (monopolar) or between two electrodes (bipolar). The resistance of tissue to the flow of current leads to tissue heating. The current densities from RF electrodes tend to be highest at the tip, in regions of abrupt change in the electrode shape (e.g., at the edges of a wide electrode or at the tip of a narrow electrode) [15]. The local intense heating at the electrode may present a significant challenge if trying to heat efficiently at a depth in the tissue while protecting the skin surface. Higher-frequency RF approaches (in the mid-megahertz range) use similar concepts but utilize capacitively or inductively coupled RF applicators that induce dielectric heating [16]. These types of applicators also tend to create large fringing fields and subsequent heating near the electrode edges that might pose similar difficulty for efficient subsurface targeting. While the challenges with this approach might be significant, systems are currently under development to utilize an RF-based approach for treating hyperhidrosis [17]. The thermographs presented in [17] appear to exemplify the type of intense heating in close proximity to the electrode that might be expected from an RF-based approach.

Recently, ultrasound investigations for treating hyperhidrosis have also been reported [18], [19]. In one ultrasound approach, high-intensity focused ultrasound is utilized—with a curved transducer shaped to target a specific focal zone in the tissue. The focal region may be steered to different depths by adjusting the frequency or mechanical configuration of the transducer [19]. Skin thickness variation would potentially necessitate skin thickness estimates to be determined and on-the-fly adjustment of depths to be performed during treatment sessions. Similar to the aforementioned invasive laser-based approach, Commons et. al. [18] utilized an insertable probe to deliver the energy in close proximity to the sweat glands.

These three energy modalities are detailed schematically in Figure 2. While each may have potential, a microwave approach was chosen by the authors to utilize some of the unique properties of tissue and electromagnetic field configuration possible in the microwave frequency range. The theory and approach is described in the "Advantages of Microwaves" section.

Advantages of Microwaves

Theory

The use of microwave energy provides some inherent advantages when targeting sweat glands. As shown in Figure 1, the sweat glands reside in close proximity to the boundary between the skin and fat. In the microwave frequency range, the skin and fat tissues have significantly different dielectric properties. The skin is a high-water-content tissue and consequently has a fairly large dielectric constant and conductivity ($\varepsilon_r = 38.6$, $\sigma = 4.3$ at 5.8 GHz) [20]. Conversely, fat tissue is a low-water-content tissue, which has a smaller dielectric constant and conductivity ($\varepsilon_r = 5.0$, $\sigma = 0.3$ at 5.8 GHz) than the skin [20]. This contrast results in a significant reflection ($|\Gamma| \approx 0.5$ for a normally incident plane wave) at the skin/fat interface that creates a standing wave pattern in the skin. The E-field (and corresponding power absorption level) is maximum at the interface and will drop to a minimum at one quarter of a wavelength away from the interface. Based on the axillary ultrasound measurements of 70 patients taken during a clinical trial [21], the average skin thickness

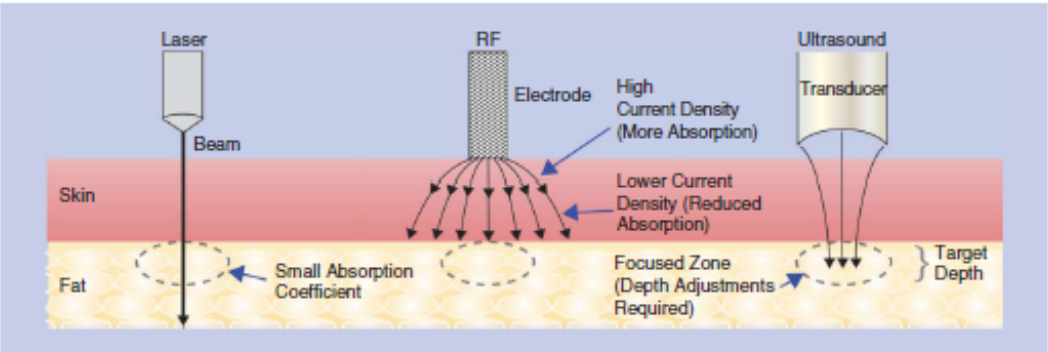


Figure 2. *The characteristics of possible energy modalities for treating hyperhidrosis.*

in the underarm is approximately 1.75 mm. Utilizing the dielectric properties of skin and setting 1.75 mm as one quarter of a wavelength, a theoretical optimal frequency of 6.9 GHz for minimum absorption at the skin surface is obtained. At this frequency, the absorption level is at its maximum at the skin/fat interface and drops to a minimum value at the skin surface. The result is preferential targeting of the subsurface sweat glands while protecting the upper layers of the skin.

Due to the fact that a range of frequencies around the theoretical optimal frequency still give a significantly minimized absorption level at the skin surface, 5.8 GHz (± 75 MHz) is selected as a practical frequency to utilize. The use of 5.8 GHz is convenient due to the fact that it is in the industrial, scientific, and medical band, which ensures minimal interference with commercial communication systems. To demonstrate the effect of frequency on the standing wave pattern, a simple calculation of a plane wave traveling through a 1.75-mm-thick skin layer and striking the skin/fat interface was conducted for frequencies of 2.4, 5.8, and 10.0 GHz. The *E*-fields were computed and utilized to determine the corresponding power absorption pattern, expressed as the specific absorption rate (SAR) ($SAR = \sigma^* |E|^2/2$). The resulting SAR patterns are shown in Figure 3. At 5.8 GHz, the absorption level at the skin surface is only 30% of the maximum absorption at the interface and demonstrates the desired optimal profile. When the frequency becomes too low (e.g., 2.4 GHz), the wavelength in the skin becomes much longer than one-quarter wavelength and the absorption at the skin surface is much closer to the maximum absorption level at the skin/fat interface. Thus, the heating through the skin layer would be much more uniform. If the frequency were too high (e.g., 10 GHz), the wavelength in the skin would become much shorter than one-quarter wavelength. In this case, we would get a dual-peak response in which the minimum absorption level occurs in the midskin layer and there are maxima at both the skin/fat interface as well as the skin surface. It is also notable in Figure 3 that the absorption level in fat tends to be quite low. This is due to the inherently low conductivity of fat that makes it difficult to heat directly. However, active cooling can be added to the skin surface to both protect the skin and allow heat to conduct into the upper fat layer where the sweat glands reside.

Modeling

Figure 4 shows a simplified model of the commercial microwave applicator developed for achieving preferential heating patterns at 5.8 GHz utilizing the concept described in the "Theory" section. The model consists of an array of four coaxially fed open-ended rectangular waveguide antennas. The antennas are dielectric filled to reduce the size and operate in transverse electric (TE10) mode. A cooling system is formed from a 1-mm layer of deionized water and a ceramic cooling plate that allows active cooling of the skin surface. The applicator is placed on a section of lifted tissue consisting of 1.75-mm-thick skin, 9.5-mm-thick fat, and underlying muscle tissue. In practice, a vacuum chamber is utilized to achieve lifting of the tissue, which separates the target skin and fat layers and prevents heating of underlying muscle tissue. Further details regarding the configuration of the device can be found in [22].

The model was implemented in the Computer Simulation Technologies Microwave Studio (Framingham, Massachusetts, United States) and optimized for impedance match, size, and absorption pattern. The absorption pattern for one of the channels in the array is shown in Figure 5 and demonstrates the typical preferential absorption pattern achieved by the system.

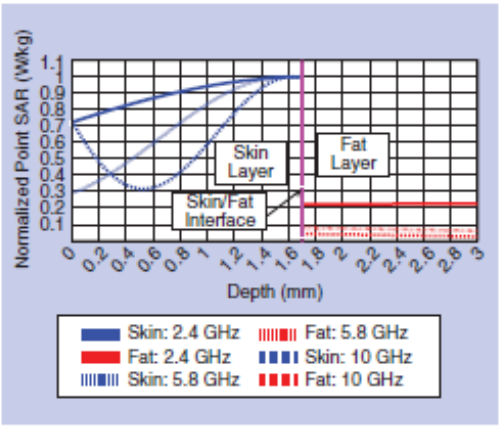


Figure 3. *The normalized absorption profiles (the point SAR versus depth) for a plane wave striking the skin/fat layer at frequencies of 2.4, 5.8, and 10.0 GHz. The skin surface begins at 0 mm.*

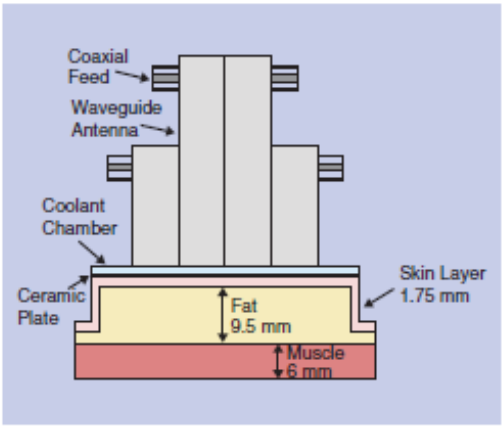


Figure 4. *A simplified model of a commercial applicator for treating axillary hyperhidrosis. The dielectric properties of the tissue are skin: $\varepsilon_r = 38.6$, $\sigma = 4.3$; fat: $\varepsilon_r = 5.0$, $\sigma = 0.3$; and muscle: $\varepsilon_r = 49.5$, $\sigma = 5.4$ [20].*

Previous Page | Contents | Zoom in | Zoom out | Front Cover | Search Issue | Next Page

Another advantageous aspect of utilizing microwaves for targeting sweat glands is a relative insensitivity of the absorption pattern to variations in skin thickness. The peak in the *E*-field always formulates at the skin/fat interface, where the reflection occurs and at 5.8 GHz, the *E*-field tends to be near the minimum value at the skin surface independent of skin thickness. This concept was analyzed by repeating the simulation of Figure 5 for skin thicknesses in the normal range of 1.25–2.25 mm [21]. Figure 6 shows the relative one-dimensional (1-D) point SAR profiles versus the depth for skin thicknesses of 1.25, 1.75, and 2.25 mm from these simulations. Figure 6 demonstrates that unlike the other energy modalities previously mentioned, there is a relative insensitivity to skin thickness with the microwave-based approach.

Preclinical Testing

Extensive preclinical testing is typically required before attempting human clinical trials. For the development and verification of the hardware implementation of the model shown in Figure 4, a porcine (pig) model was utilized for in vivo animal testing. This is a standard model used in dermatology [23] since porcine and human skin are similar in morphology and physiology [24]. The microwave dielectric properties are also comparable between porcine and human skin [25]–[27]. An antenna array with 15 °C coolant and set to 30 W per antenna (with antennas activated sequentially) was utilized to treat the flank of several pigs at a variety of energy levels. (All preclinical work was done at the Association for the Assessment and Accreditation of Laboratory Animal Care accredited facilities.) The animals were kept alive for a period of one to three months and then the tissue was cross-sectioned to allow gross pathological examination of the affected regions. An example of these results is shown in Figure 7 for energy levels of 599, 630, and 756 J. The darkened areas indicate lesion locations, and it is clearly shown that protection of the upper skin layers was achieved even for a very aggressive energy level of 756 J. This result demonstrates the ability of microwaves to efficiently target typical sweat gland depths and has paved the way for human clinical work. Further details on the preclinical testing conducted can be found in [23].

Clinical Trials

A conservative approach was taken to the clinical testing of the microwave device presented here. After obtaining rigorous amounts of bench and preclinical data, initial human trials consisted of treating very small zones in the axilla at lower energy levels [28]. After conclusively demonstrating safety with this approach, slightly larger areas and higher energy levels were gradually introduced. The goals for the clinical trial work were 1) safety and 2) to use the standard metrics described earlier (the HDSS score, starch–iodine test, and gravimetric test) to assess efficacy. Figure 8 shows the pre- and posttreatment starch–iodine results from a large, randomized, sham-controlled study [8]. The lack of dark coloration 12 months after treatment strongly suggested a dramatic reduction in the secretion of sweat in the axilla due to the therapy.

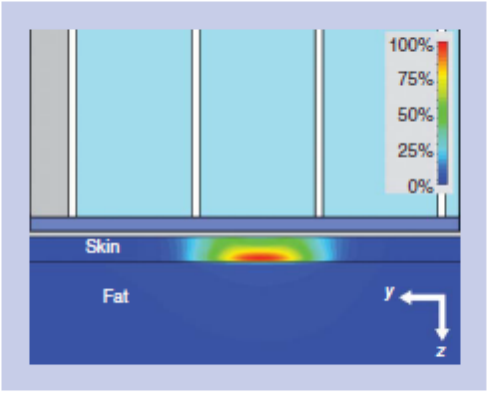


Figure 5. *The absorption profile for a commercial hyperhidrosis device: skin thickness = 1.75 mm and frequency = 5.8 GHz.*

A long-term clinical trial of 31 subjects who were followed up for 24 months was conducted for the commercial version of the microwave treatment system [29], [30]. The patients were prescreened for a minimum HDSS score of three or four as well as a gravimetric value of 50 mg (measured over 5 min) in each axilla. The HDSS and gravimetric scores were tracked over time to assess the efficacy and duration of the approach. The HDSS and gravimetric results are shown in Figure 9. The results demonstrated a significant and lasting HDSS reduction (from three or four to one or two) in more than 90% of

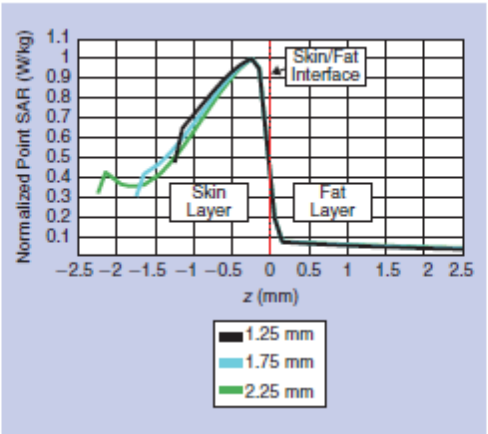


Figure 6. *The 1-D normalized SAR profiles through the center of the waveguide antenna down into the tissue and a comparison of skin thickness models from 1.25 to 2.25 mm. The plot is normalized such that z = 0 mm occurs at the skin/fat interface for each trace.*

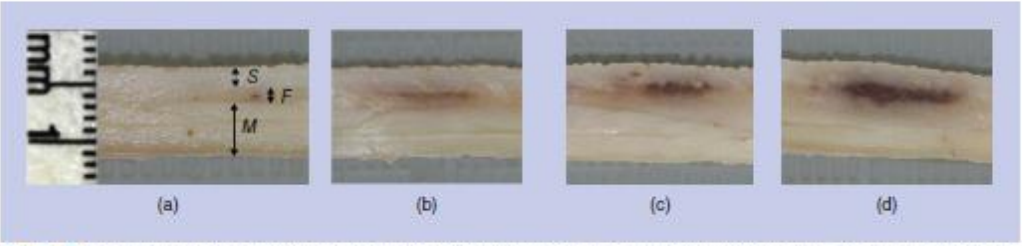


Figure 7. *The gross pathology examination one month after treatment for tissue treated at various energy levels in a porcine model: (a) untreated, (b) 599 J, (c) 630 J, and (d) 756 J. The dark region (localized hematoma) approximates the area affected by the energy. Note that the baseline untreated case shows the location of the skin layer (S), the fat layer (F), and muscle (M).*

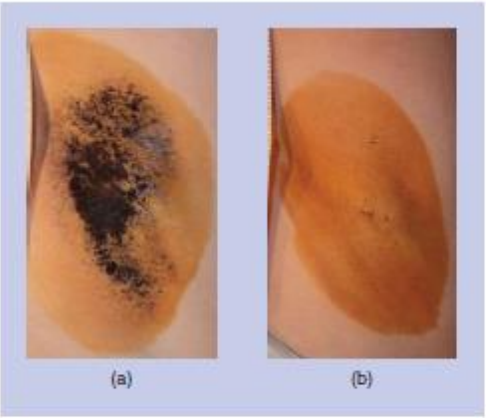


Figure 8. *(a) The pretreatment starch–iodine test results on a study subject and (b) the posttreatment results obtained 12 months after two treatment sessions.*

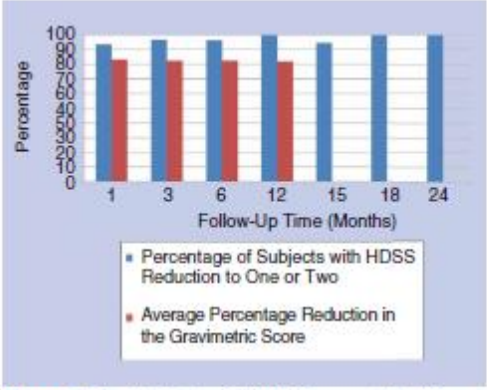


Figure 9. *The distribution of the HDSS scores at the different study visits (blue bars) and corresponding average percentage reduction in the gravimetric score (red bars). After treatment, 90% or more of subjects had HDSS scores of one or two at all of the follow-up visits. The gravimetric remained higher than 80% for all visits.*

the patients over a period of 24 months. The gravimetric data were collected for 12 months and showed an 82% average reduction, giving another positive indication of an effective therapy. The positive clinical results for a large number of patients, combined with a low occurrence of adverse events [8], [29], [30], lend credence to the use of a microwave-based approach to achieve effective preferential heating of the sweat glands and protection of the skin surface.

Commercialization Challenges

Obtaining efficacious clinical outcomes is a major achievement but is far from the final step in commercializing a medical device. Microwave medical device manufacturers face a variety of challenges when trying to develop a saleable product in the United States and abroad. A few of these are detailed in the "Regulatory Requirements," "Safety Requirements," and "User Interface" sections.

Regulatory Requirements

In the United States, companies must comply with a variety of regulations at the state and federal levels. Approval from the U.S. Food and Drug Administration (FDA) to market the device is the major requirement for selling a device in the United States. Devices are typically divided into three classes, with Class I being the least risk and with no FDA clearance required. (The manufacturer must still meet the manufacturing regulations and list their establishment with the FDA.) For Class II devices, most can utilize the pathway called a "510(k) notification," where the manufacturer demonstrates that their device is substantially equivalent to another device on the market, and the time to approval is typically shorter. A lengthier premarket application is generally required for higher-risk Class III devices or more novel Class II devices. For the hyperhidrosis device presented in this article, a 510(k) path was followed that utilized previously approved microwave medical devices (although a clinical study was also conducted to establish the effectiveness of the microwave device for the treatment of hyperhidrosis).

Safety Requirements

Patient and operator safety is paramount in the development of any medical device, and it drives many of the system requirements. For the system presented in

this article, creating a device with low stray radiation, accurate power and temperature measurements, and systemwide redundancy were of the utmost importance in creating safe and efficacious results. Stray radiation limits are dictated by an international standard, International Electrotechnical Commission 60601-2-6, which calls for a maximum 10-mW/cm^2 exposure limit for the operator [31]. This is similar to the limit defined in the IEEE C.95 standard for telecommunications [32], [33] for controlled environments. Compliance is typically demonstrated via *E*-field probe measurements made in various locations in the system. Microwave power accuracy is ensured by implementing robust calibration procedures and utilizing load and temperature insensitive measurements both internal to the system and for external calibration fixtures. Skin surface temperature and vacuum monitoring are utilized to ensure tissue contact and safe temperature levels at the skin surface. Temperature probes must be designed for minimal interaction with the microwave field, which can be challenging. Finally, significant redundancy is required to ensure that failures or inaccuracies in the system are detected before causing a risk to the patient. In general, this is achieved by performing multiple measurements of key system parameters in multiple locations (e.g., sensing power in both the handpiece and console) and having a robust error-checking scheme in place.

User Interface

The ability of a doctor or practitioner to easily follow the correct steps during a procedure, understand the behavior of the system, and address typical errors that might occur are all key aspects of ensuring a safe and efficacious result for patients. The system presented in this article achieves ease of use by utilizing a graphical user interface that guides the user sequentially through a procedure. This includes installation of the protective bioTip barrier (described in the "Commercial Product" section), the application of anesthesia, and a template system that guides the user to specific locations on the axilla and keeps track of the locations treated. The system also has a comprehensive error-analyzing/reporting scheme to classify errors and guide the user's response. For example, if tissue is not being acquired (i.e., lifted into the vacuum chamber) by the handpiece, a message indicating that the user should adjust the alignment of the handpiece might be displayed. For more serious error conditions that might result in a user or patient hazard, the system will disable itself so that the user cannot apply energy. Such features that allow the user to confidently perform procedures and easily understand what is going on are a very significant aspect of the design of the system.

Commercial Product

The commercial system described in this article is shown in Figure 10. Figure 10(a) shows the console portion of the system, which includes a 100-W, 5.8-GHz solid-state generator, a coolant pumping/chilling system, a vacuum system, control hardware/software, and a touchscreen user interface. The handpiece is connected to the console via an integrated umbilical containing microwave and control cables and lines for flowing of coolant and drawing vacuum. Figure 10(b) shows the handpiece in place over the axilla of a patient. The handpiece includes the antenna array described in the "Preclinical Testing" section, a cooling system, temperature and

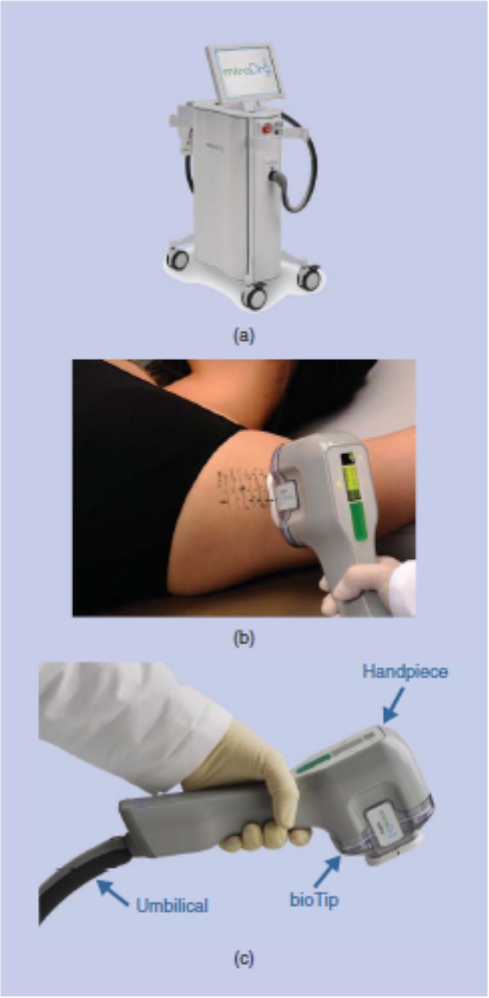


Figure 10. *The commercial system presented in this article. (a) The console that includes a solid-state 5.8-GHz high-power generator, cooler/chiller, vacuum system, controls, and user interface. (b) The handpiece that includes an antenna array, cooling system, temperature/power monitoring system, and controls/indicators. (c) The handpiece with the sterile, disposable bioTip attached that allows tissue acquisition with a vacuum and forms a patient/handpiece barrier.*

Previous Page | Contents | Zoom in | Zoom out | Front Cover | Search Issue | Next Page

power monitors, and control hardware and software. A hand switch for initiating treatments as well as temperature and placement indicators displayed to the user can be observed in the figure. Figure 10(c) shows a side view of the handpiece with the bioTip attached. The bioTip is a sterile disposable attachment that serves as a protective barrier between the handpiece and the patient. The bioTip also has a chamber to allow lifting of the tissue as described in the "Modeling" section. The system has been on the market since late 2011.

Conclusions

Axillary hyperhidrosis, while not a life-threatening condition, can be very debilitating and have dramatic effects on severe sufferers. Shortcomings in the current standard approaches for treating hyperhidrosis have led to the exploration of energy-based approaches for noninvasive lasting treatment of this condition. The dielectric contrast and standing wave effects in the skin layer in the microwave frequency range give the microwave approach some inherent advantages that have been utilized to create a viable commercial product for treating this condition.

References

[1] D. R. Strutton, J. W. Kowalski, D. A. Glaser, and P. E. Stang, "US prevalence of hyperhidrosis and impact on individuals with axillary hyperhidrosis: Results from a national survey," *J. Amer. Acad. Dermatol.*, vol. 51, no. 2, pp. 241–248, 2004.

[2] *Online Market Study of 3000 Individuals Across the U.S.*, Survey commissioned by Miramar Labs, Ipsos Vantis Healthcare, Sunnyvale, CA, 2010.

[3] *Deodorants and Antiperspirants–US–February 2012*, Market Study, Mintel Group Limited, London, England, 2012.

[4] J. Hornberger, K. Grimes, M. Naumann, D. A. Glaser, N. J. Lowe, H. Naver, S. Ahn, and L. P. Stolman, "Recognition, diagnosis, and treatment of primary focal hyperhidrosis," *J. Amer. Acad. Dermatol.*, vol. 51, no. 2, pp. 274–286, 2004.

[5] N. Solish, A. Benohanian, and W. K. Jonathan, "Prospective open-label study of botulinum toxin type A in patients with axillary hyperhidrosis: Effects on functional impairment and quality of life," *Dermatol. Surg.*, vol. 31, no. 4, pp. 405–413, 2005.

[6] J. W. Kowalski, N. Eadie, S. Daggett, and P. Y. Lai, "Validity and reliability of the hyperhidrosis disease severity scale (HDSS)," presented at the Annu. Meeting American Academy Dermatology, Washington, D.C., 2004, Paper P198.

[7] N. J. Lowe, D. A. Glaser, N. Eadie, S. Daggett, J. W. Kowalski, and P.-Y. Lai, "Botulinum toxin type A in the treatment of primary axillary hyperhidrosis: A 52-week multicenter double-blind, randomized, placebo-controlled study of efficacy and safety," *J. Amer. Acad. Dermatol.*, vol. 56, no. 4, pp. 604–611, 2007.

[8] D. A. Glaser, W. P. Coleman, L. K. Fan, M. S. Kaminer, S. L. Kilmer, R. Nossa, S. R. Smith, and K. F. O'Shaughnessy, "A randomized, blinded clinical evaluation of a novel microwave device for treating axillary hyperhidrosis: The dermatologic reduction in underarm perspiration study," *Dermatol. Surg.*, vol. 38, no. 2, pp. 185–191, 2012.

[9] T. J. Stefaniak and M. Proczko, "Gravimetry in sweating assessment in primary hyperhidrosis and healthy individuals," *Clin. Auton. Res.*, vol. 23, no. 4, pp. 197–200, 2013.

[10] J. M. Swinehart, "Treatment of axillary hyperhidrosis," *Dermatol. Surg.*, vol. 26, no. 4, pp. 392–396, 2000.

[11] H. W. Walling and B. L. Swick, "Treatment options for hyperhidrosis," *Amer. J. Clin. Dermatol.*, vol. 12, no. 5, pp. 285–295, 2011.

[12] A. Goldman and U. Wollina, "Subdermal Nd:YAG laser for axillary hyperhidrosis," *Dermatol. Surg.*, vol. 34, no. 6, pp. 756–762, 2008.

[13] N. S. Uebelhoer, P. Shumaker, and Y. Domankevitz, "Treatment of sweat glands," U.S. Patent Application 12 960 191, Aug. 2011.

[14] A. Rosen and H. Rosen, *New Frontiers in Medical Device Technology* (Wiley Series in Microwave and Optical Engineering), 1st ed. New York: Wiley, June 1995.

[15] I. D. McRury, D. Panescu, M. A. Mitchell, and D. E. Haines, "Non-uniform heating during radiofrequency catheter ablation with long electrodes: Monitoring the edge effect," *Circulation*, vol. 96, no. 11, pp. 4057–4064, 1997.

[16] A. W. Guy, "Biophysics of high-frequency currents and electromagnetic radiation," in *Therapeutic Heat and Cold*, 4th ed. Baltimore, MD: Williams and Wilkins, 1990, pp. 179–236.

[17] I. Pinson, O. Olisova, and I. Verkhogliad, "Non-invasive short-wave guided radiofrequency device for long-term sweat reduction in patients with primary axillary hyperhidrosis: A preliminary study," Alma Lasers, Caesarea, Isreal, Tech. Rep. PBAC23091301, 2013.

[18] G. W. Commons and A. F. Lim, "Treatment of axillary hyperhidrosis/bromidrosis using VASER ultrasound," *Aesthetic Plast. Surg.*, vol. 33, no. 3, pp. 312–323, 2009.

[19] R. Makin, P. G. Barthe, and M. H. Slayton, "Methods for treatment of sweat glands," U.S. Patent 8 282 554 B2, Oct. 9, 2012.

[20] S. Gabriel, R. Lau, and C. Gabriel, "The dielectric properties of biological tissues: III. Parametric models for the dielectric spectrum of tissues," *Phys. Med. Biol.*, vol. 41, no. 11, p. 2271, 1996.

[21] D. A. Glaser, "Efficacy and safety of the DTS-G2 system in patients with axillary hyperhidrosis (DRI-UP)," in IDE Approved Clinical Study, Sponsored by Miramar Labs, Sunnyvale, CA, Tech. Rep. NCT00931359, 2009.

[22] J. E. Johnson, M. E. Deem, S. Kim, A. Salamini, T. Su, P. Smith, D. Hallock, Y. Ben-Haim, and S. Saraf, "Systems, apparatus, methods and procedures for the noninvasive treatment of tissue using microwave energy," U.S. Patent 8 406 894 B2, Mar. 26, 2013.

[23] J. E. Johnson, K. F. O'Shaughnessy, and S. Kim, "Microwave thermolysis of sweat glands," *Lasers Surg. Med.*, vol. 44, no. 1, pp. 20–25, 2012.

[24] N. Vardaxis, T. Brans, M. Boon, R. Kreis and L. Marres, "Confocal laser scanning microscopy of porcine skin: Implications for human wound healing studies," *J. Anatomy*, vol. 190, no. 4, pp. 601–611, 1997.

[25] C. Gabriel, S. Gabriel, and E. Corthout, "The dielectric properties of biological tissues: I. Literature survey," *Phys. Med. Biol.*, vol. 41, no. 11, pp. 2231–2249, 1996.

[26] S. Gabriel, R. Lau, and C. Gabriel, "The dielectric properties of biological tissues: II. Measurements in the frequency range 10 Hz to 20 GHz," *Phys. Med. Biol.*, vol. 41, no. 11, p. 2251, 1996.

[27] A. Peyman and C. Gabriel, "Cole–Cole parameters for the dielectric properties of porcine tissues as a function of age at microwave frequencies," *Phys. Med. Biol.*, vol. 55, no. 15, pp. N413–N419, 2010.

[28] M. S. Kaminer, W. P. Coleman III, L. K. Fan, S. L. Kilmer, S. Kim, R. N. Nossa, K. F. O'Shaughnessy, and P. Solomon, "First clinical use of a novel microwave device for treatment of axillary hyperhidrosis," presented at the Annu. Meeting American Academy Dermatology, Chicago, IL, 2010.

[29] H. C.-H. Hong, M. Lupin, and K. F. O'Shaughnessy, "Clinical evaluation of a microwave device for treating axillary hyperhidrosis," *Dermatol. Surg.*, vol. 38, no. 5, pp. 728–735, 2012.

[30] M. Lupin, H. C.-H. Hong, and K. F. O'Shaughnessy, "Long-term efficacy and quality of life assessment for treatment of axillary hyperhidrosis with a microwave device," *Dermatol. Surg.*, vol. 40, no. 7, pp. 805–807, 2014.

[31] *Medical Electrical Equipment—Part 2-6: Particular Requirements for the Basic Safety and Essential Performance of Microwave Therapy Equipment*, IEC Standard 60601-2-6, Edition 2.0, Apr. 2012.

[32] *IEEE Standard for Safety Levels with Respect to Human Exposure to Radio Frequency Electromagnetic Fields, 3 kHz to 300 GHz*, IEEE Standard C95.1–2005.

[33] *IEEE Standard for Safety Levels with Respect to Human Exposure to Radio Frequency Electromagnetic Fields, 3 kHz to 300 GHz. Amendment 1: Specifies Ceiling Limits for Induced and Contact Current, Clarifies Distinctions Between Localized Exposure and Spatial Peak Power Density*, IEEE Standard C95.1a–2010.

MiraDry:

A Notable Advance in Treating Primary Axillary Hyperhidrosis

Harnessing the power of microwaves, a new device offers a patient-friendly option for the treatment of hyperhidrosis.

BY WILLIAM P. COLEMAN, III, MD, W. PATRICK COLEMAN IV, MD, AND KYLE M. COLEMAN, MD

In a technological tour de force, microwave energy has been harnessed to provide the latest breakthrough for the treatment of primary axillary hyperhidrosis. The miraDry (MiraMar Labs) system represents the first use of this 5800 MHz wavelength energy in dermatology.

The proprietary system focuses microwave energy delivery directly to the dermal-fat interface for targeted thermal destruction of sweat glands. Microwaves create heat by causing physical vibration of dipole molecules. Microwave energy has good absorption in tissues with significant water content, such as the dermis and sweat glands, because of their high dipole moments; however, there is poor absorption in the subcutaneous layer because of its low dipole moment.

TAKE HOME TIPS

The miraDry system represents the first use of 5800 MHz wavelength energy in dermatology. The proprietary system focuses microwave energy delivery directly to the dermal-fat interface for targeted thermal destruction of sweat glands.

THE CHALLENGE OF HYPERHIDROSIS

Axillary hyperhidrosis is a difficult quality of life problem for many individuals. A mail survey in 2002 found 2.8 percent of respondents felt they had excessive or abnormal/unusual sweating (approximately 1.4 percent complained of axillary hyperhidrosis).[1] An online survey in 2008 found that 33 percent of adults felt that they have too much underarm sweat but only five percent sought help.[2] The impact of axillary hyperhidrosis on the Dermatology Life Quality Index (DLQI) has been calculated to be similar to the effects of psoriasis and acne.[3] Sufferers complain of social embarrassment, ruined clothes, and an increased tendency to develop skin irritation and infections.

TREATMENT OPTIONS

Previous medical and surgical approaches used for this

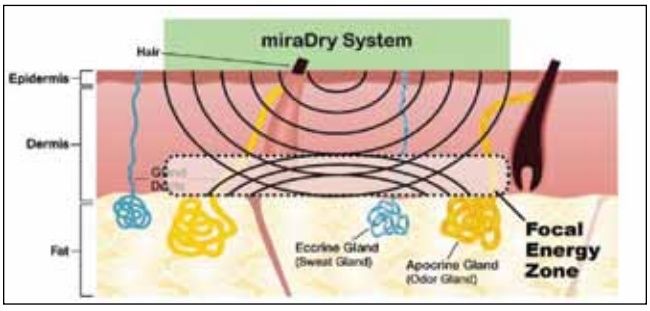


Fig. 1. MiraDry concentrates microwave energy at the dermal-fat border. Energy becomes concentrated along this interface and creates a Focal Energy Zone.

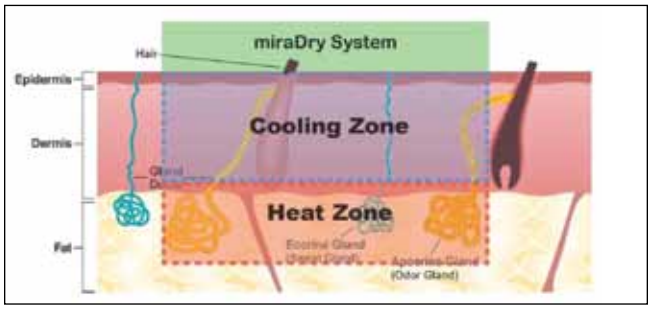


Fig. 2. Continuous hydroceramic cooling prevents thermal conduction of heat superficially and creates a heat zone at the level of sweat glands, resulting in thermolysis.

common problem have all had drawbacks. Prescription topical antiperspirants, like aluminum chloride hexahydrate 25%, can stain clothes, irritate skin, and have no lasting benefit; yet, these topical therapies often fail to suppress sweating sufficiently. Oral anticholenergic medications may cause xerostomia, cylcloplegia, mydriasis, as well as bowel and bladder dysfunction. Botulinum toxins, while highly successful, require significant doses every six to eight months, which can be prohibitively expensive.[4] Surgical excision of the axilla and dermal curettage leave unsightly scars and may restrict range of motion. Liposuction of sweat glands has been shown to work well but is invasive. Endoscopic thoracic sympathectomy is also invasive and may lead to Horner's syndrome, pneumothorax, hemothorax, gustatory sweating, and compensatory hyperhidrosis. An effective non-invasive technique is attractive to patients and is a welcome addition to dermatologists.

Fig. 3. The miraDry console contains a chiller, vacuum pump, and custom software that controls energy delivery.

Fig. 4. The miraDry handpiece delivers a 1cm x 3cm zone of therapy and contains four antennas and active cooling to protect the dermis. Fig. 5. (Inset): A sterile and disposable BioTip lifts skin from the underlying structures and stabilizes tissue during the cycle.

MiraDry (microwave thermolysis) is a non-invasive office procedure that received US Food and Drug Administration (FDA) 510(k) clearance in January 2011 for treatment of excessive underarm sweat. This novel device delivers microwave energy to the dermal-fat interface to destroy sweat glands (Figure 1). Continuous hydroceramic cooling prevents thermal conduction of heat superficially and creates a heat zone at the level of sweat glands, resulting in targeted thermolysis (Figure 2). The device consists of three components: 1) a console (Figure 3), composed of a chiller, vacuum pump, and custom software that controls energy delivery; 2) a handpiece (Figure 4), which delivers a 1cm x 3cm zone of therapy and contains four antennas as well as active cooling to protect the dermis; and 3) a sterile and disposable BioTip (Figure 5) that lifts skin from the underlying structures and stabilizes tissue during the therapy cycle.

THE MIRADRY PROCEDURE

The miraDry procedure is straightforward. The dermatologist identifies the areas of excessive sweating (usually the entire hair bearing area) and then a proper-sized template is used to mark out a treatment grid (Figure 6). After administering local anesthesia, the operator moves the handpiece from zone to zone in a specified pattern until the entire hyperhidrotic area is treated. Software on the console guides the user through the treatment session so that each zone is treated, but only once (Figure 7).

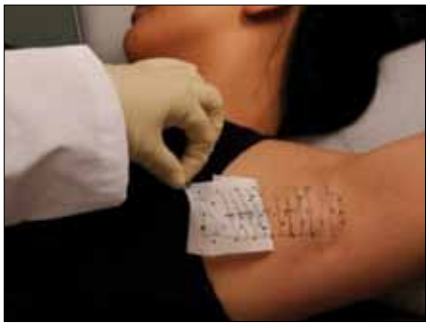


Fig. 6. Proper-sized templates help mark out a treatment grid.

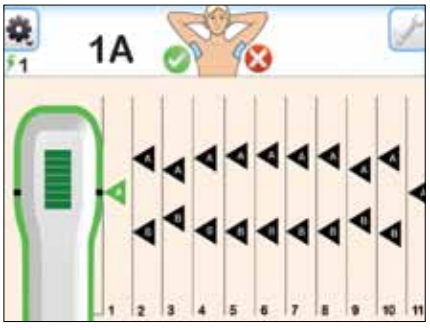


Fig. 7. Software guides the user so that zones are treated correctly.

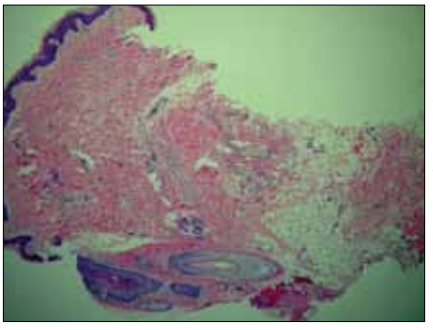


Fig. 8. Six months after miraDry treatment, no viable sweat glands are visible.

(Photograph courtesy of Dr. Nobuharu Kushikata.)

TABLE 1: THE HYPERHIDROSIS DISEASE SEVERITY SCALE (HDSS)	
☐ 1.	My sweating is never noticeable and never interferes with my daily activities
☐ 2.	My sweating is tolerable but sometimes interferes with my daily activities
☐ 3.	My sweating is barely tolerable and frequently interferes with my daily activities
☐ 4.	My sweating is intolerable and always interferes with my daily activities

Swelling and bruising are common immediately after treatment and may persist for several days. The procedure typically lasts 60-75 minutes, depending on the size of treatment area. Two procedures (spaced three months apart) are required for optimal results.

The miraDry device is highly effective in destroying sweat glands. Axillary biopsies as early as 11 days post-treatment demonstrate eccrine and apocrine gland cells devoid of nuclei as well as complete cellular necrosis. At six months, histology confirms a complete absence of sweat glands in the treated area (Figure 8).

Studies of the effectiveness and safety of miraDry have been encouraging. A randomized, blinded, sham-controlled, investigational device exemption (IDE) study utilizing an investigational device on 120 patients at seven sites resulted in 89 percent of severely hyperhidrotic subjects reaching a level of 1 or 2 on the Hyperhidrosis Disease Severity Scale (HDSS; Table 1) at one month. Sixty-nine percent maintained this effect at one year.[5] Treatment side effects were mild and transitory. The most common complaint was temporary altered sensation in the skin. One subject exited the study with complaint of altered sweating on the face. The commercial version of miraDry was studied in an open label trial of 31 hyperhidrotic subjects followed for 12 months.[6] Efficacy of sweat reduction was measured using HDSS, gravimetric assessment, and DLQI, as well as gravimetric changes. Over 90 percent of subjects demonstrated a reduction of HDSS to level 1 or 2 at 12 months. The average gravimetric reduction in sweat was 81.7 percent at one year post treatment, and 85.2 percent reported a greater than five-point reduction in the DLQI. There was also a statistically significant reduction in underarm odor based on patient surveys. Interestingly, many patients reported hair loss in the axilla, which the female subjects actually appreciated. The side effect profile was similar to that seen in the IDE study, although one patient reported a treatment-related triceps neuropathy, which was resolving at six months when she was lost to follow up. Clinical experience gathered since commercial release of miraDry confirms the results of these two published studies.

Most patients are quite satisfied with the treatment. It is clear that two treatments three months apart are required to obtain a lasting result. A small number of patients may benefit from a third procedure targeting resistant areas of persistent sweating. Although transient, altered sensation in the skin seen in some patients is the most significant potential side effect of treatment and appears to be related to the amount of energy delivered as well as to the thickness of the patient's skin. Very slender patients have a smaller tissue buffer between the treated dermal-fat interface and the underlying sensory nerves and may have a higher chance of experiencing altered sensation. Experienced users recommend decreasing the energy dose on the most peripheral portions of the axilla (especially on the arm side) in individuals with low body fat.

MiraDry is a fascinating new technology that promises to radically change dermatologists' approach to treating hyperhidrosis. ■

William P. Coleman III, MD, is clinical professor of dermatology, and adjunct professor of surgery (plastic surgery) at Tulane University Health Sciences Center. He is on staff at Coleman Center For Cosmetic Dermatologic Surgery, Metairie, LA.

W. Patrick Coleman IV, MD, is on staff at Coleman Center For Cosmetic Dermatologic Surgery, Metairie, LA.

Kyle M. Coleman, MD, is on staff at Westlake Dermatology and Cosmetic Surgery in Austin, TX.

1. Strutton DR, Kowalski JW, Glaser DA, et al. US prevalence of hyperhidrosis and impact on individuals with axillary hyperhidrosis: results from a national survey. J Am Acad Dermatol. 2004; 51:241-8.

2. Harris Interactive survey conducted for The International Hyperhidrosis Society.

3. Basra MKA, Fenech R, Gatt RM, et al. The Dermatology Life Quality Index 1994-2007: a comprehensive review of validation data and clinical results. Br J Dermatol. 2008; 159:997-1035.

4. Lowe NJ, Glaser DA, Eadie N, et al. North American Botox in Primary Axillary Hyperhidrosis Clinical Study Group. Botulinum toxin type A in the treatment of primary axillary hyperhidrosis: a 52-week multicenter double-blind, randomized, placebo-controlled study of efficacy and safety. J Am Acad Dermatol. 2007; 56:604-11.

5. Glaser DA, Coleman WP III, Fan LK, et al. A randomized, blinded clinical evaluation of a novel microwave device for treating axillary hyperhidrosis: the dermatologic reduction in underarm perspiration study. Dermatol Surg. 2012; 38:185-91.

6. Hong HC, Lupin M, O'Shaughnessy KF. Clinical evaluation of a microwave device for treating axillary hyperhidrosis. Dermatol Surg. 2012; doi: 10.1111/j.1524-4725.2012.02375.x.

New microwave device for hyperhidrosis proves promising

August 01, 2012
By Joely Kaufman, M.D.

Joely Kaufman, M.D.

Hyperhidrosis, or excessive sweating, can be a physically and emotionally distressing condition. In 2004, the United States prevalence rates were estimated to be 1.4 percent (more than 4 million people; Strutton DR, Kowalski JW, Glasser DA, et al. *J Am Acad Dermatol*. 2004;51(2):241-248).

Though there are many forms of hyperhidrosis, primary hyperhidrosis is the type not associated with any underlying disease. Axillary hyperhidrosis accounts for the majority of the cases of primary hyperhidrosis. The effects on quality of life can be devastating, with currently no ideal permanent treatment (Basra MK, Fenech R, Gatt RM, et al. *Br J Dermatol*. 2008;159(5):997-1214).

Sweat is produced primarily from eccrine glands, with a small contribution from apocrine glands. The glands are composed of coiled ducts that are deeply seated in the dermis, with a portion of the duct traveling through the epidermis to secrete its contents to the skin surface. They have muscarinic receptors that are activated by acetylcholine (hence the efficacy of botulinum toxin). There is some evidence to the presence of adrenergic receptors in addition to the muscarinic receptors. This may be one reason why botulinum toxin does not offer 100 percent reduction in sweating in all patients.

Glandular tissue can be present at 1.25 mm through depths of 3.5 mm, which is generally at the interface between deep dermis and subcutaneous fat (Lawrence CM, Lonsdale Eccles AA. *Br J Dermatol*. 2006;155(1):115-118). Obviously, there are variations in skin thickness between individuals and within the same individual at different body sites, altering these depths. Depth is important when considering the approach to treatment with laser and light devices.

Microwave option

Microwave energy was first introduced to the medical literature at least 60 years ago (Herrick JF, Krusen FH, et al. *Fed Proc*. 1947;6(1 Pt 2):129). It is not until recently, however, that microwave technologies are being used more commonly in medicine. Currently, microwave energy is being used for the treatment of prostate enlargement and some tumors, both malignant and benign. Microwave energy has also been shown to kill malaria and other parasites, making it an interesting option for future treatment of infectious disease (*New York Times*. August 2011).

Microwaves are part of the electromagnetic spectrum at wavelengths between 1 mm and 1 meter and frequencies typically between 300 MHz and 300 GHz. Microwave ovens emit waves of 2.45 GHz (12.23 cm, www.iop.org).

The term "micro" is actually a misnomer, since the wavelengths are not in the micron size but in the range of millimeters to meters in length. In medical devices, an antenna or antennae are used to transfer the electromagnetic energy to the tissue.

miraDry miracle

A new device was recently cleared (Food and Drug Administration 510(k)) in January 2011 for reduction in excessive underarm sweating (miraDry, Miramar Labs). The device emits microwaves of 5,800 MHz (5.8 GHz) that deposit thermal energy deep into the skin. This thermal energy is able to penetrate deeply enough to reach the eccrine glands and result in permanent damage to them without significant damage to the deeper or more superficial structures.

The device consists of a chamber that contains both a microwave and a cooling device. The skin is sucked into the chamber via a vacuum and microwave energy is delivered to the dermal, subcutaneous junction while the superficial dermis and epidermis are cooled. Microwave energy induces thermal changes in the eccrine gland, inducing necrosis of the sweat gland and subsequent periglandular fibrosis. Histologic examination post-treatment in one subject demonstrated the absence of normal eccrine glands for 180 days. Though the microwaves can be "aimed" at a certain depth level in the skin, thermal conduction will affect other objects in that same depth, as it is not specific for eccrine glands.

Microwave energy will selectively heat water-containing objects more readily than other tissue. As the dermis contains more water than the subcutaneous tissue, microwave heat will build up in this tissue first, but not exclusively (Johnson JE, O'Shaughnessy KF, Kim S. *Lasers Surg Med*. 2012;44(1):20-25). Other structures present at this same depth level will also be affected, including nerves, vessels and hair follicles.

Some conduction of heat will occur in surrounding tissues, so cooling is important with this technology in order to protect the epidermis and superficial dermis from damage. Studies in a porcine model using the miraDry devices show that the peak specific absorption rate is located at the dermal/hypodermal interface with less than 2 percent of the peak heat reaching the muscle layer. Obviously, thermal energy intense enough to damage the gland will be painful, and local infiltrative anesthesia is needed prior to treatment.

The handpiece is 10 mm x 30 mm and the entire axilla is treated with serial placements of this handpiece on the affected area. In each individual area, the microwave energy is delivered for 30 seconds, followed by a 20-second post-cooling period. The entire treatment takes an average of 60 to 75 minutes. Currently, two sessions approximately three months apart are recommended.

Clinical trials with the system indicate its effectiveness for reduction in sweating. Hong et al conducted an open-label trial enrolling 31 patients with hyperhidrosis severity scales of 3 or 4 (Hong H, Lupin M, O'Shaughnessy KF. *Dermatol Surg*. 2012;38(5):728-735). Patients were treated with the miraDry system and followed for 12 months. Subjects received one to three sessions over a six-month period. Average sweat reduction was 83 percent, which persisted over 12 months. At the 12-month follow-up, 94 percent of patients had at least a one-point drop in HDSS.

Side effects

Post-procedure edema, redness and bruising were common (90 percent). These side effects typically resolved within seven days. Other side effects, including skin sensory alterations and nodules under the skin, were more lasting. In the Hong et al study, there were two patients who had nodules under the skin at 12 months after treatment.

Some hair loss in the area of treatment was also noted as a side effect. This would be expected, as the anatomic location of the hair follicle is near the eccrine glands and hence near the thermal zone of treatment. Though this may be a desirable side effect for some, others may find this to be a complication.

The miraDry system is opening the doors to a new form of electromagnetic energy application on skin. The results from the published studies are encouraging when analyzing the HDSS reduction scores and patient feedback.

Future studies indicating the best parameters and operator techniques to avoid these side effects will be useful, as the incidence rate in the earlier studies is significant. Long-term follow-up (greater than one year) is still needed to determine the permanency of this treatment, since clinical studies to date end at 12 months. Additionally, adjustments will need to be made to make this technology useful in locations other than the axilla.

Joely Kaufman, M.D., is in private practice at Dr. Brandt Dermatology Associates and a voluntary assistant professor, University of Miami Department of Dermatology & Cutaneous Surgery.

www.medscape.com

Microwave Treatment Effective for Axillary Hyperhidrosis

An Expert Interview With Mark Lupin, MD

Fran Lowry | |April 30, 2012

April 30, 2012 (Kissimmee, Florida) — *Editor's note: In 2011, the US Food and Drug Administration approved a new technique for the treatment of axillary hyperhidrosis, or excessive underarm sweat, that uses microwaves to destroy sweat cells.*

The miraDry System, manufactured by Miramar Labs, noninvasively delivers energy to the underarm area where the sweat glands are located, creating localized heat to eliminate the glands.

The effects are long-lasting because the sweat glands, once destroyed, do not regenerate, according to Mark Lupin, MD, a dermatologist from the University of British Columbia in Vancouver, Canada.

Dr. Lupin presented the 18-month follow-up data from a study that assessed the efficacy and safety of the miraDry System here at the American Society for Laser Medicine and Surgery (ASLMS) 2012 Annual Conference. He spoke with Medscape Medical News *about the treatment.*

Medscape: How common is axillary hyperhidrosis?

Dr. Lupin: It is estimated that 1 in 5 adults are affected by severe sweating, based on 2 different surveys in the United States. About 4% of the American population is diagnosed with axillary, or underarm, sweating and another 17% report that their sweat is excessive to the point that it bothers them but they have not discussed the problem to their doctors.

People think that it is not a medical condition and that it may be normal or they're not aware that there are treatment options other than antiperspirants.

Medscape: What causes axillary hyperhidrosis?

Dr. Lupin: This is excess sweating beyond what is considered normal to maintain consistent body temperature. There can be a familial tendency. With generalized sweating, we make sure there are no medical reasons, like thyroid disease or diabetes. But for underarm sweating, it's a variation of normal. The amount of sweating is sometimes 4 to 5 times what is normal; we don't measure it by just the amount of sweat, but how it impacts people's daily lives.

Medscape: What were the treatments for this condition in the past?

Dr. Lupin: Treatment options are antiperspirants, including over-the-counter and prescription antiperspirants. Then there is onabotulinumtoxinA (Botox). In Canada, Health Canada approved onabotulinumtoxinA for sweating in 2001, so it has been used for more than a decade. It is quite effective, but not long-lasting.

Surgery is the third most common modality, but it is invasive. It involves making an incision, then an instrument is applied under the surface of the skin that attempts to destroy the sweat glands from underneath.

Medscape: Can you explain how the miraDry System works?

Dr. Lupin: The miraDry System uses microwaves locally applied to the underarm area. It destroys the sweat glands by heating the interface where they are located, the hyperdermal interface. So it works by heating. It actually cools at the same time as it heats, so it protects the surface of the skin. Therefore, it's a completely noninvasive device.

Medscape: Could you tell us about the study and what you found after 18 months of follow-up?

Dr. Lupin: There was a study in the United States looking at an earlier generation of this microwave device. The point of our study was 2-fold — one was safety and the second was efficacy. The previous study was 12 month; our study so far is at 18 months, but we plan to go to 2 years.

We had 31 patients from 3 different centers in Canada. The median age was 33 years; the age range was 18 to 65 years. There were 23 women and 8 men. We looked at the amount of sweating by weighing the sweat with grammametrics testing. Patients had to have at least 50 mg over 5 minutes. The baseline average for the 31 patients was 187 mg over 5 minutes.

We looked at subjective and objective criteria. Objectively, we measured the sweat, and patients had to self-report the severity of their sweating according to an established scale, called the Hyperhidrosis Disease Severity Scale (HDSS).

We used injectable lidocaine for local anesthesia to both underarm areas and then we treated them with several pulses of the microwave energy on each underarm. Every 30 days we would evaluate the effectiveness and safety.

Patients ended up having 2 or 3 treatments in total; we would wait at least 2 to 3 months before we would do subsequent treatment. The average number of treatments was 2 to get the best result.

The approved device now in the United States is a generation-4 device. We have a generation-3 device; they've actually made it even safer. Two treatments 3 months apart is now the recommendation.

We found that the gravimetric reduction, that is the total amount of sweat that they have at 12 months, was 84% less. We also looked at well-established index called the Dermatology Life Quality Index (DLQI), a 10-point questionnaire rated from 0 to 30, where 30 is severe and affects people's quality of life, and 0 is no impact.

The baseline DLQI score was 11.8; after 12 months, it was 1.9, so it had a significant impact on the patients' quality of life.

We also did a general patient satisfaction with the procedure; on average, it was about 90%.

The fourth and final thing was the HDSS — a scale from 1 to 4 (4 is severe, 1 is mild). It is really a scale that shows how much this problem bothers people on a daily basis.

All patients had to be 3 or 4 to begin with; at the end of 12 months, 100% of patients were 1 or 2, which was our goal.

The interesting thing about the 18 months is that the results at 1 month persisted to 18 months. We saw that results in all measures — patient satisfaction, the amount of sweating, HDSS score, DLQI score — at 1 month were almost the same as they were at 18 months.

So it works quickly and it persists at least 18 months.

Medscape: Were there any adverse effects from the treatment?

Dr. Lupin: As with any medical procedure, there are always some side effects. There is no medical procedure that doesn't have something, so some patients had transient redness — that was expected. There was some soreness and tenderness in the area that could last for 2 to 3 weeks, and some patients had swelling in the underarm area...which ranged from 1 week to 8 weeks.

Unexpectedly, about one third of patients found that they had less hair in the underarms, and two thirds found that they had less odor, because the other glands in the underarms that produce odor were affected by treatment, so we had a "hat trick" — reduced sweating, reduction of hair, and some reduction of odor.

Medscape: What can doctors tell their patients now about this treatment?

Dr. Lupin: Now we can say that there are 4 approved treatments for axillary hyperhidrosis. There are prescription antiperspirants, there is onabotulinumtoxinA, there is surgery, and now there is miraDry. We can tell patients that it is long-lasting and it is most likely permanent, because it doesn't just put the sweat glands to sleep, it actually removes the sweat glands, and we know that sweat glands can't regenerate. There is no reason the sweat should ever come back, so we can tell them it's a long-lasting noninvasive option — in fact, the longest-lasting noninvasive option.

Medscape: Can ablating the sweat glands under the arm be harmful?

Dr. Lupin: We have the same question when we use onabotulinumtoxinA. The simple answer is it's no more harmful than using an antiperspirant. It's not removing enough sweat that it will affect temperature regulation or cause heavy sweating somewhere else. The nice thing about it is that it is just a local effect. Think of it as doing what an antiperspirant would do but doing it most likely permanently and more effectively.

The study was funded by Miramar Labs. Dr. Lupin reports a financial relationship with Miramar Labs.

American Society for Laser Medicine & Surgery (ASLMS) 2012 Annual Meeting. Presented April 18, 2012.

Send comments and news tips to news@medscape.net.

Cite this article: Microwave Treatment Effective for Axillary Hyperhidrosis. *Medscape*. Apr 30, 2012.

Microwave Technology Offers a New Approach to Excessive Sweating

A new device offers a long-term solution to excessive sweating.

BY SUZANNE BRUCE, MD

Although hyperhidrosis is estimated to affect three percent of the population, the International Hyperhidrosis Society maintains that roughly half of those affected are not formally diagnosed. Whether or not they have received a diagnosis of hyperhidrosis, patients affected by excessive sweating have had few treatment options that offer lasting efficacy. This has been disappointing for both the patients and providers, as the effects of excessive sweating can be seen in social, professional, and other areas of life.

A novel treatment for hyperhidrosis, the miraDry System (Miramar Labs) delivers precisely controlled microwave energy non-invasively to sweat glands where accumulated energy results in thermolysis of the glands. The handpiece includes a continuous hydro-ceramic cooling system that protects the superficial dermis and keeps heat at the level of the sweat glands. Treatment results in permanent damage to sweat glands and long-term reduction in sweating.

When I heard about the miraDry technology at the American Society for Dermatologic Surgery Annual Meeting in November 2011, I thought it was a great option for people who suffer from hyperhidrosis. It offers a convenient and effective treatment for a relatively common patient concern. In studies reported by the company, patients reported an 82 percent reduction in sweat after a round of two treatments. Data show that damaged sweat glands do not regenerate, making microwave therapy a long-term solution to hyperhidrosis. We introduced the procedure into the practice in early 2012 and have seen good results and steadily increasing demand since then.

> The population of patients dealing with excessive sweating may be large and underserved. Cosmetic practices are used to using technology like lasers and other energy-using devices, so this procedure fits well in an aesthetic practice.

A WELCOMED OPTION

Previously existing options for the treatment of hyperhidrosis include iontophoresis and botulinum toxin injections. Iontophoresis generally cannot be applied to the underarms, and results are typically short-term, requiring ongoing treatment for the patient. Botulinum toxin injections can be provided to the underarms as well as to the hands and feet, and they provide a reduction in sweating for up to several

Patient response to treatment has been positive to date, with patients expressing satisfaction with the results of treatment. In fact, some patients have described treatment as "life-changing."

months. Effects are not permanent, however, and patients will inevitably require retreatment. Continuous treatments can become costly and potentially inconvenient. Before offering miraDry, botulinum toxin was the only treatment for axillary hyperhidrosis we offered in our practice.

Over the past year, we have been pleased with the consistency in treatment outcomes. Results achieved with the miraDry system for axillary hyperhidrosis have been what we expected. We inform patients that they will need two to three treatments to achieve optimal results. The majority of our patients have had marked sweat reduction after two treatments; only two or three patients have required a third treatment.

Patient response to treatment has been positive to date, with patients expressing satisfaction with the results of treatment. In fact, some patients have described treatment as "life-changing."

MARKETING CONSIDERATIONS

There tends to be a stigma associated with hyperhidrosis. Patients may be reluctant to discuss the problem, especially if they don't know that treatment options exist. Therefore, marketing and patient education are important.

A PEARL FOR SUCCESSFUL INTEGRATION

Any time we introduce a new procedure we meet monthly for the first six months and then quarterly thereafter with our entire process team, including MDs/PA, representatives from the front and back office, our lead patient care coordinator, marketing director, and our miraDry representative. At these meetings, we track our progress and address any issues that have arisen in any aspect of our service delivery system.

At the same time, however, we have found that many patients with hyperhidrosis are researching the condition online and are aware of new treatment options; it's important to market so that such patients are aware that you offer treatment.

We have promoted miraDry on our website, in our e- and print newsletters, at our annual open house, and at seminars. For seminars, we typically incorporate discussion of hyperhidrosis and miraDry within presentations on other topics. Promoting a seminar solely for excessive sweating did not or will not attract people with this condition, due to the stigma associated with it. We are currently trying our first billboard advertisement.

With our current strategies in place, the volume of procedures has steadily increased since introduction. We are doing on average one procedure per day.

PRACTICAL CONSIDERATIONS

Beyond potential patient interest/demand and the evidence associated with miraDry, another attractive feature of the system is its compact size and portability. The machine can roll from room to room so we keep it in a storage room when we are not using it. The lone consumable is the sterile, disposable BioTip.

We have had very few logistical challenges in incorporating miraDry into our practice. The time it takes to do the procedure is very consistent from patient to patient so scheduling is easy.

From a practical standpoint, we have found it beneficial to have patients pay up-front for the two procedures. This way, the patient becomes mentally committed to undergoing treatment twice and therefore achieving optimal response. They don't have unrealistic expectations, expecting resolution of sweating from a single treatment.

A NOVEL APPROACH TO A WIDESPREAD NEED

The population of patients dealing with excessive sweating may be large and underserved. While hyperhidrosis is a medical condition, it's important to note that excessive sweating can negatively influence an individual's quality of life with social, professional, and aesthetic ramifications. Certainly miraDry fits well into a general dermatology practice because we frequently see hyperhidrosis patients. At the same time, cosmetic practices are used to using technology like lasers and other energy-using devices, so this procedure also fits well in an aesthetic practice. ■

Suzanne Bruce, MD founded her practice in Houston in 1997. She is a former Vice President of the Texas Dermatological Society and a former President of the Houston Dermatological Society.

www.medscape.com

Microwave-Based Therapy for Treating Axillary Hyperhidrosis

An Expert Interview With Suzanne L. Kilmer, MD

Steven Fox | |April 21, 2011

April 21, 2011 (Grapevine, Texas) — *Editor's note: Since neurotoxins were approved in 2004 for treating hyperhidrosis, they have been the primary treatments used to manage this common — but infrequently discussed — medical problem.*

Dr. Suzanne L. Kilmer

However, at a presentation here at the American Society for Laser Medicine and Surgery (ASLMS) 31st Annual Meeting, attendees heard about another promising approach: the use of a microwave-assisted device to permanently destroy axillary sweat glands, and thus eliminate underarm hyperhidrosis.

Suzanne L. Kilmer, MD, director of the Laser and Skin Surgery Center, Sacramento, California, as well as associate clinical professor at the University of California–Davis, delivered the presentation. Afterward, she responded via email to questions from Medscape Medical News *about this novel use of microwave technology.*

Medscape: You have been investigating the use of a microwave-based approach to treat a problem that does not usually get a lot of attention at medical meetings: axillary hyperhidrosis. Would you first of all tell us a bit about how common a problem axillary hyperhidrosis is?

Dr. Kilmer: Axillary hyperhidrosis [excessive underarm sweating] is a condition that can be a substantial burden, affecting people in their workplace [and] in their relationships, and it can even significantly affect their self-esteem.

Some studies have estimated that about 1.4% of the US population meet the criteria for axillary hyperhidrosis, and as many as a third of people surveyed say they perspire too much in their underarms. This is a condition that affects a lot of people, but many don't know that there are options to treat it.

Medscape: Please give us some background on the technique you have been using, and how it works.

Dr. Kilmer: Well, of course as dermatologists we use a lot of energy-based devices, such as lasers, to heat the skin to cause beneficial effects. As you know, microwave devices are widely used in other areas of medicine, so it's natural to apply the technology here.

The sweat glands in your underarms that create the excessive wetness are located just under the skin. What this new microwave device allows us to do is to create very focused heat right at that layer, and eliminate the sweat glands.

Medscape: Please tell us about what you did in your study, and what you found out.

Dr. Kilmer: Our clinic worked with 6 other clinics in the United States to test the microwave technology. We enrolled 120 subjects into 2 groups. One group received the treatment with the device, and the other group received a sham treatment.

Each procedure involved 3 steps: (1) placing a grid on the underarm using a temporary tattoo, (2) injecting local anesthetic in the treatment area, and (3) positioning the handpiece of the device (*miraDry*, Mirmar Labs) at precise locations on the grid, so that we'd treat one small area at a time. Most subjects (90%) in the study had 2 treatment sessions a couple of weeks apart.

After the treatment sessions, the groups were followed for either 6 months (the sham group) or 12 months (the treatment group). At various follow-up points (30 days, 3 months, 6 months) we compared the amount of sweating reported in each group.

We determined that there was a statistically significant difference in the quality-of-life measure between the treatment and sham groups. For the treatment group that was followed out a full year after their treatments, we found that the efficacy of the treatment was very stable.

Medscape: Is this a permanent fix for hyperhidrosis? If not, how long do the effects usually last?

Dr. Kilmer: [P]atients in the study were followed for 12 months, and the efficacy of the procedure was fairly stable from 3 months out to 12 months, showing sustained results. The developers of the device [have] histology data out to 6 months on several patients that have been treated with miraDry, and this histology data shows that the sweat glands have disappeared. The miraDry procedure thermally destroys the sweat glands in the axilla, and sweat glands do not regenerate.

Medscape: Are there any significant adverse effects associated with using this technique?

Dr. Kilmer: Well, it involves a bit more discomfort than treatment with botulinum toxin injections. Almost all of the patients that were treated experienced some mild swelling and tenderness in their underarms after the procedure, which is to be expected based on how the treatment works. About 71% of the side effects reported in the clinical trial were mild and consisted of issues such as temporary swelling, or some transient altered sensation in the skin. A few patients reported pain that required short-term use of prescription medications.

Medscape: How long do most treatments take? And are there data available on its cost?

Dr. Kilmer: The procedure typically takes about an hour for most patients. This includes all prep time. The procedure is not yet commercially available, so I can't comment on what it will cost.

Medscape: How can clinicians who use the procedure determine if it has been effective in an individual patient? Is there a reliable way to assess that, other than feedback from the patient?

Dr. Kilmer: In our experience it's been very easy for patients to see the effect of the treatment and communicate that to us. If we want independent verification, there are methods that visually show us where a person is still sweating (one is called a starch-iodine test), or we can weigh the amount of sweat that is being produced in a standardized way.

What really matters to the patient, though, is how the procedure reduces embarrassing sweat outbreaks and the constant wetness under their arms. So quality-of-life measures are important.

Medscape: Neurotoxins have been the most common treatment for this problem up until now, correct? How do the results with the microwave-based treatment compare with results using neurotoxins?

Dr. Kilmer: The neurotoxin mechanism of action is very different, in that it more or less just "paralyzes" the nerves that activate sweat.

A key issue with the botulinum toxin injections is that the effect wears off over time, so that approach provides relief for only about 7 months on average. In that limited time, however, the efficacy is quite good. In some randomized studies, the efficacy in treated groups was about 75%, and the efficacy in the placebo group was about 25% — a difference of 50 percentage points.

In our study, if we do the analysis the same way, the efficacy results were 67% for the treatment group [and] 13% for the sham group — a difference of 54 percentage points. So I feel that the results compare very favorably. Considering that our data showed that this microwave-based treatment provides lasting results, I think it's a viable option for

patients.

Dr. Kilmer is a consultant to Miramar Labs, and the company has provided grants to support Dr. Kilmer's research.

American Society for Laser Medicine and Surgery (ASLMS) 31st Annual Conference. Presented April 3, 2011.

Send comments and news tips to news@medscape.net.

Cite this article: Microwave-Based Therapy for Treating Axillary Hyperhidrosis. *Medscape*. Apr 21, 2011.

2-Year Study Results Point to Permanence

miraDry Long-term Results Point to Permanent Sweat Reduction

SANTA CLARA, Calif., Dec. 11, 2014 /PRNewswire/ — Miramar Labs®, Inc., a leading medical device manufacturer and maker of the miraDry® System, today announced the results of recently published 2-year data showing that miraDry efficacy observed at 30 days remains stable through 2 years.

The miraDry System delivers energy non-invasively to the area under the arm where sweat glands reside, creating localized heat to destroy and eliminate those glands. Since sweat glands do not regenerate, these results are expected to be permanent.

The study published in the journal Dermatologic Surgery reported[1]:

- Greater than 90% efficacy
- 70% reduction in the number of patients reporting problematic odor
- Greater than 90% of patients had a dramatic improvement in quality of life based on DLQI score reduction
- High patient satisfaction

Since its launch, the miraDry system has been used in over 30,000 treatments worldwide and currently boasts a 90% patient satisfaction rating in commercial use, among the highest of all aesthetic procedures.

“Since sweat and odor glands do not regenerate, these results are expected to be permanent,” commented Michael Kleine, Miramar Labs President and CEO. “This is a tremendous breakthrough, not only for excessive sweaters, but for anyone who manages nuisance sweat and odor. Everyone sweats, but now, with miraDry, patients can choose not to.”

For more information, visit the miraDry website at www.miraDry.com, or follow miraDry on Facebook/miraDry and Twitter @miraDry.

About Miramar Labs:
Founded in 2006, Miramar Labs is a privately owned medical device company dedicated to bringing the next generation energy modality to the field of dermatology. Miramar Labs is the tenth company created by The Foundry, a leading medical device incubator based in Menlo Park, California. Supported by rigorous clinical research, Miramar Labs is focused on addressing medical conditions for which there are significant unmet clinical needs. The company’s first priority is the treatment of excessive underarm sweat, a medical condition that significantly affects the quality of life of millions of people. Physicians and patients are encouraged to visit www.miradry.com for additional information about Miramar Labs.

Contact
Donna Levy
Miramar Labs
408-579-8718

miraDry® Procedure is Clinically Proven

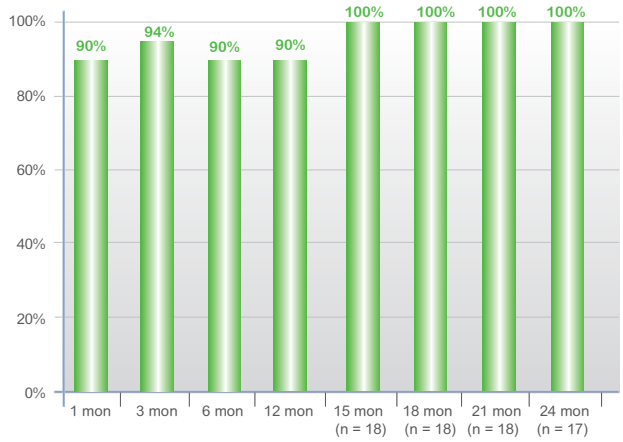
miraDry Commercial Device Study[1,2]

- Dramatic, lasting and stable efficacy at final study visit at 24 months

31 adult subjects
2 sites

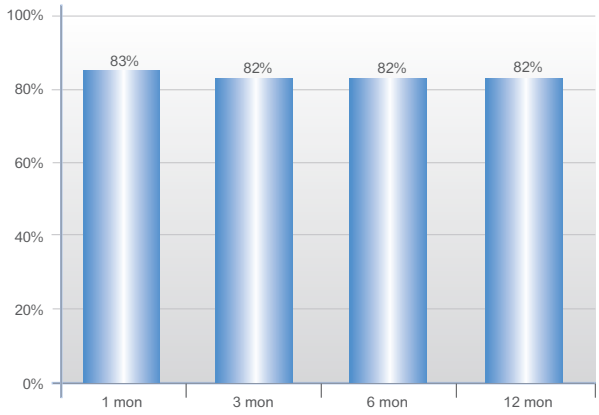
>90% Clinical Efficacy and Stability

(% Subjects with HDSS Reduction to 1 or 2)

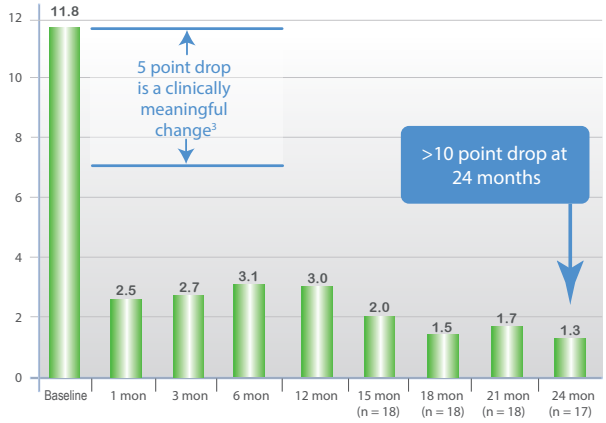


82% Average Sweat Reduction

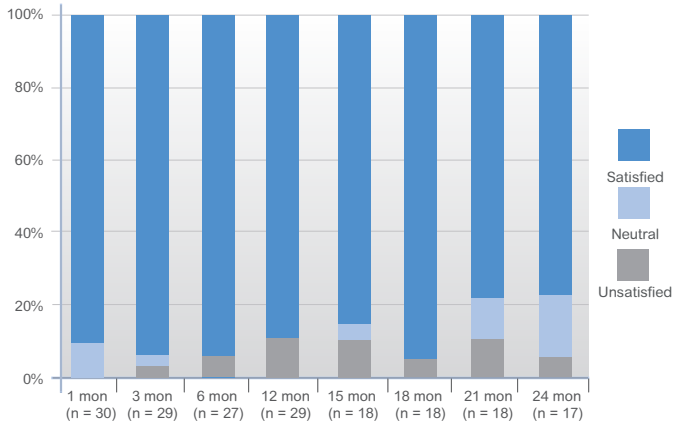
(Gravimetric)



Dramatic Reduction in DLQI



High Patient Satisfaction



miraDry Randomized, Blinded Study demonstrates stable efficacy[4]

- Stable efficacy through final study visit 12 months after treatment
- Statistically significant difference between treated and sham groups
- Randomized, blinded, sham controlled study with investigational system
- Data used for FDA clearance
- Published in peer-reviewed journal

120 adult subjects
7 sites

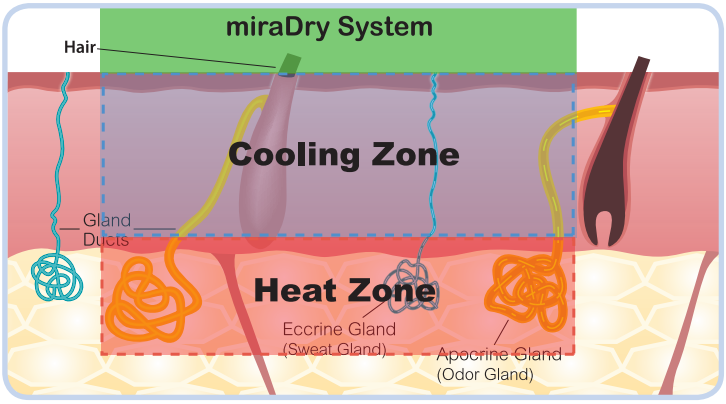
Underarm **sweat.**
Under **control.**

miraDry®

Scientifically Proven

miraDry® Microwave Technology is Ideal for Treating Underarm Sweat

1 Maximum destruction of sweat gland network	• **Targets dermal-fat interface** where the sweat glands reside, independent of skin thickness • Sweat glands **preferentially absorb energy** due to their high-water content versus surrounding fat tissue • Broad and uniform heat zone **destroys dense network of sweat glands**
2 Minimal impact to surrounding tissues	• Hydro-ceramic **cooling protects dermis** • Proprietary design **limits energy dispersion to a shallow region to protect deeper tissue**
3 Non-invasive	• Energy delivered from **outside the skin** • **Lasting results** with a non-invasive, **patient-preferred solution**



The miraDry system creates a shallow heat zone and cooling layer. The result is **controlled thermolysis** of the sweat glands and **protection of surrounding structures.**

Lasting results since sweat glands do not regenerate[5]

www.miraDry.com
miramarlabs
445 Indio Way • Sunnyvale, CA 94085 • 408-940-8700

1 Lupin MS and Hong C-H. Presented at American Society for Dermatologic Surgery Annual Meeting; October 11-14, 2012; Atlanta, GA.
2 Chih-Ho Hong, MD, Mark Lupin, MD et al; Dermatol Surg 2012; 38:728-735.
3 Kowalski JW et al. J Am Acad Dermatol 2007; 52: AB52.
4 Glaser DA, Coleman WP, Fan LK, et al. Dermatol Surg 2012; 38:185-191.
5 "The ontogenesis of sweat glands is only at the embryonic period, so no new sweat glands are regenerated after birth." Li H, Gang Z, et al. Antigen Expression of Human Eccrine Sweat Glands. J Cutan Pathol 2009: 36: 318-324.

miraDry®

Common problem. Lasting solution.

A clinically proven procedure for axillary hyperhidrosis.

Benefits of the miraDry Procedure

- Lasting efficacy
- Non-invasive
- Strong safety profile
- High patient satisfaction
- Minimal to no patient downtime
- Straightforward, in-office procedure with immediate results
- Two procedures required (spaced 3 months apart)
- Can be performed by Physician Assistant or Nurse Practitioner (state law dependant)

System Specifications

Microwave output frequency	5.8 GHz
Microwave energy output	5 manufacturer defined set points (25% range)
Coolant	Integrated cooling system uses deionized water at 15°C
Vacuum	-508 to -559 mm of Hg (-20 to -22 inches of Hg)
Dimensions	1.19m H x 0.52m W x 0.81m D (46.75” H x 20.25” W x 31.75” D)
Weight	50.8 kg (112 lbs)
Conforms to	5 International Standards

miramarlabs®

Miramar Labs • 445 Indio Way • Sunnyvale, CA 94085 • P: 408-940-8700 • F: 408-940-8795

MK0038 Rev. A 09/11

MIT MIRADRY®

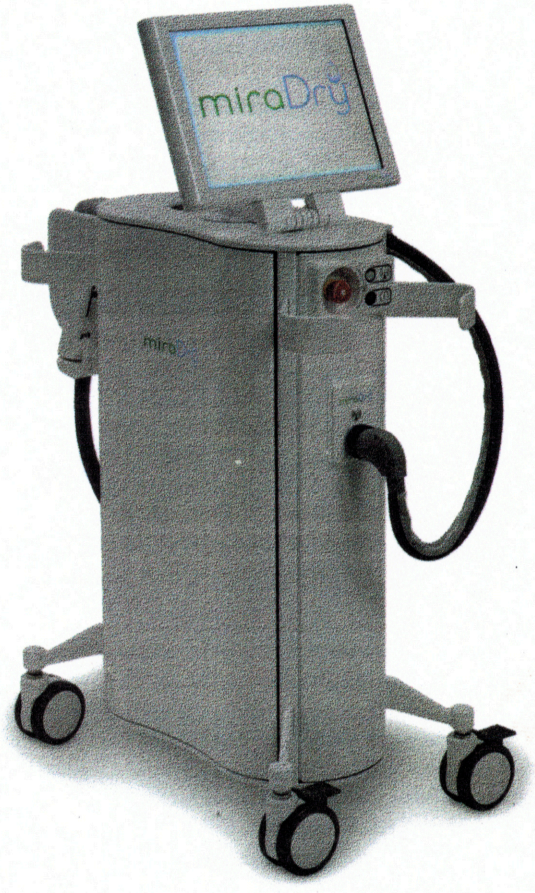
SAGEN SIE STOP DEM ACHSELSCHWEISS!

EXZESSIVER ACHSELSCHWEISS? SCHWEISSRÄNDER, DIE IHREN ALLTAG BEEINTRÄCHTIGEN? WENN SIE DIESE UNANNEHMLICHKEITEN NICHT MEHR HINNEHMEN WOLLEN, BIETEN IHNEN DIE SPEZIALISTEN VON DELC BIEL EINE DEFINITIVE UND NICHTINVASIVE LÖSUNG AN: DIE MIRADRY® BEHANDLUNG!

Achselschweiss, ob exzessiv oder nicht, kann einem das Leben vermiesen! Verlust an Selbstvertrauen, unschöne Schweissränder, unkontrollierbarer Schweissgeruch. miraDry® ist für diese immer wiederkehrenden Probleme eine einfache, definitive und nichtinvasive Lösung mit Sofortwirkung. Um Sie darüber zu informieren, haben wir Herrn Dr. Adrian Krähenbühl zum Interview getroffen. Er ist der Gründer des Centers DELC (Dermatologie, Laser, Chirurgie) in Biel, in welchem diese Behandlung seit mehr als einem Jahr mit überzeugenden Resultaten durchgeführt wird.

HERR DR. KRÄHENBÜHL, ERKLÄREN SIE UNS BITTE DIE MIRADRY® BEHANDLUNG

miraDry® wurde von der US-Unternehmung Miramar Labs entwickelt. Es ist das einzige von der sehr strengen FDA (Food and Drugs Administration) zugelassene Verfahren, das eine dauerhafte Schweissreduzierung auf nichtinvasive Weise bei Personen ermöglicht, die unter einer Hyperhidrose (übermässige Schweissabsonderung) leiden, oder die sich ganz einfach durch den Achselschweiss gehemmt fühlen. Die Behandlung wird mithilfe eines Gerätes durchgeführt, das mit präzise kontrollierter elektromagnetischer Energie in Form von Mikrowellen die Schweissdrüsen unter Hitzeeinwirkung beseitigt. Das Resultat ist definitiv, denn diese Drüsen regenerieren sich nicht. Die Entfernung der axillären Schweissdrüsen beeinträchtigt übrigens das Gleichgewicht des Organismus in keinster Weise, da diese lediglich 2% der rund vier Millionen Schweissdrüsen im Körper ausmachen.



WIE LÄUFT DIE MIRADRY® BEHANDLUNG AB?

Zuerst definieren wir die Lage der Schweissdrüsen bei jeder Achsel. Anschliessend wird das miraDry® Handstück an die genau bezeichneten Zonen gehalten, die Haut leicht angesaugt und die präzise kontrollierte elektromagnetische Energie in die Schweissdrüsen geleitet. Gleichzeitig schützt ein Kühlsystem die Oberfläche der Haut vor Verbrennung. Dank Lokalanästhesie ist die rund zwei Stunden dauernde Behandlung schmerzlos. Das Resultat überzeugt durch Sofortwirkung und ist dauerhaft. Mit Ausnahme von sportlichen Aktivitäten, die erst nach acht bis zehn Tagen wieder aufgenommen werden sollten, kann die Person direkt nach der Behandlung wieder ihrem normalen Alltag nachgehen.

WIE VIELE SITZUNGEN EMPFEHLEN SIE?

Eine einzige Sitzung genügt, um 50% bis 70% des Achselschweisses zu reduzieren, was meistens zufriedenstellend ist. Leidet die Person unter einer übermässigen Schweissabsonderung, kann eine zweite Behandlung nach zwei bis drei Monaten durchgeführt werden.

WIE VIEL KOSTET DIE BEHANDLUNG?

Der Preis der ersten Behandlung beträgt CHF 2900.-, die zweite Behandlung (sofern nötig) kostet CHF 1500.-.

miraDry®, die weltweit wirkungsvollste und nichtinvasive Lösung für die Reduzierung des Achselschweisses erwartet Sie in Ihrem Center DELC in Biel!

DELC
Dermatologie Laser Chirurgie

DELC – Dermatologie Laser Chirurgie – Marktgasse 17 – 2502 Biel-Bienne – Tel. 032 325 44 33 – www.delc.ch

Long-term follow-up demonstrating reduction of axillary hair utilizing microwave technology

Brian Zelickson MD[a], Jeremy A. Brauer MD[b], David B. Vasily MD[c], Lori A. Brightman MD[b], Leonard J. Bernstein MD[b], Elliot T. Weiss MD[b], Robert Anolik MD[b], Roy G. Geronemus MD[b]

[a] Zel Skin & Laser Associates – Edina, MN
[b] Laser & Skin Surgery Center of New York – New York, NY
[c] Lehigh Valley Dermatology Associates – Bethlehem, PA

Background and Objectives:

Microwave energy has been used commercially in treatment of axillary hyperhidrosis with anecdotal reports of hair reduction. We present long term observations as well as additional analyses of our multi-center study examining axillary hair reduction after treatment with a microwave energy device.

Study Design and Methods:

Prospective multi-center study of subjects with unwanted axillary hair. Individuals meeting all exclusion and inclusion criteria were enrolled and treated using a non-invasive microwave energy. One to two treatment sessions using standard conservative parameters were employed. Quantitative hair counts were calculated from standardized images by a panel of three blinded investigators. Overall hair reduction (average of the two axillae) at the follow-up visits (at 3, 6, 9 and 12 months post-treatment) compared to baseline was calculated. An additional blinded, independent evaluation of side-by-side views of each full axilla was also conducted, and a qualitative evaluation of the hair reduction was completed.

Results and Conclusions:

Fifty-six patients (80% female, average age 32.5, 62% darker hair color) were enrolled in the study. The average hair reduction from a quantitative, blinded assessment was 65.8%, 71.8%, 74.6% and 74.9% at the 3, 6, 9 and 12 month follow-up visits. The range of hair reduction for light-colored hair was 66%-72%, and for dark-colored hair was 66% - 76% (no statistically significant difference). However there is evidence for an energy-level dependent response ($p<0.0001$). The blinded side-by-side analysis found a similar success rate, with approximately 70% of the axilla being rated as having at least a 50% reduction in hair.

We report long-term findings using a non-invasive microwave device to reduce underarm hair. Reduction of approximately 70% in both light and dark axillary hair was seen, and is stable through 12 months of follow-up.

ASLMS 2015 #60

Background and Objectives

Background:

A microwave device has been used commercially for over 3 years to reduce underarm sweat and there have been anecdotal reports of hair reduction. It was hypothesized that the heat generated at the dermis/fat interface (see Figure 1) may also affect the hair bulbs, resulting in a reduction of underarm hair. As the mechanism of action does not rely on the chromophore in the hair, it is possible that the effect may be independent of hair color.

Prior reported results showed hair reduction of approximately 70% after 3 months of follow-up. This study reports on a full year of follow-up in an attempt to demonstrate stability of the previously observed effects.

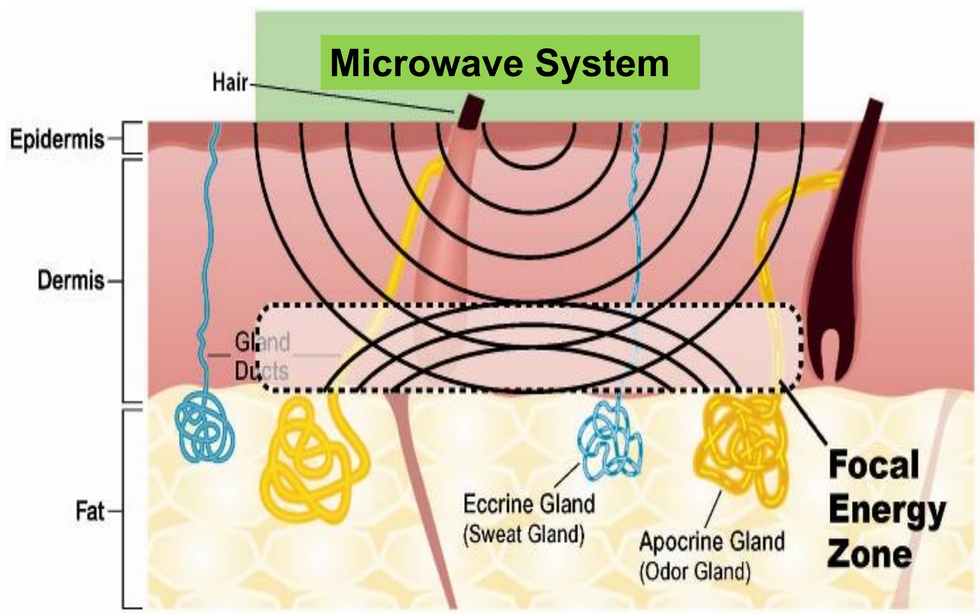


Figure 1. Mechanism of action of the study device

Table 1. Subject Demographics (n=56)

	Median (years)	32.5
	Age Range (years)	18 - 61
Gender	Male, n (%)	11 (20%)
	Female, n (%)	45 (80%)
Axillary hair color	Light, n (%)	21 (38%)
	Dark, n (%)	35 (62%)
Race	Caucasian, n (%)	49 (88%)
	Black, n (%)	1 (2%)
	American Indian, n (%)	2 ($%)
	Native Hawaiian n (%)	1 (2%)
	Other, n (%)	3 (%%)
Skin Type	Fitzpatrick Type I	13 (23%)
	Fitzpatrick Type II	18 (32%)
	Fitzpatrick Type III	15 (27%)
	Fitzpatrick Type IV	8 (14%)
	Fitzpatrick Type V	2 (4%)
	Fitzpatrick Type VI	0
BMI (average)		25.8

Objectives:

Utilizing the same settings and treatment regimen used for the underarm sweat reduction, measure the amount of hair reduction. Determine if the reduction is dependent upon:

- hair color
- treatment parameters
- length of follow-up

Study Design and Methods

This multicenter study enrolled and treated 56 adult subjects who had not had prior axillary laser hair removal. Two-dimensional photographs were obtained of each axilla. One photo was taken that identified a 2cm x 2cm box in the center of the axilla (see Figure 2) and was used for a quantitative hair reduction measurement. Another photo was taken of the axilla with no markings, which was used for side-by-side qualitative assessment.

All subjects received treatment with the commercial device; 43 subjects had two treatment sessions and 13 subjects had one session. The energy level used for treatment was based on the current practice at each clinic. The device allows 5 different energy settings, corresponding to 2.4sec of delivered power (Level 1) to 3.0sec of power (Level 5). Settings chosen for the second session were based on patient response from the first session. Follow-up visits were conducted every 3 months after all treatments were complete for a full year. Photos were taken at each visit.

Fig 2. Quantitative Hair Reduction Assessment

A panel of three independent, blinded assessors reviewed each de-identified box photo. Standard computer viewing tools, were used to count the number of hairs in the box. The hair count from each photo was calculated from the average of the three independent readings.

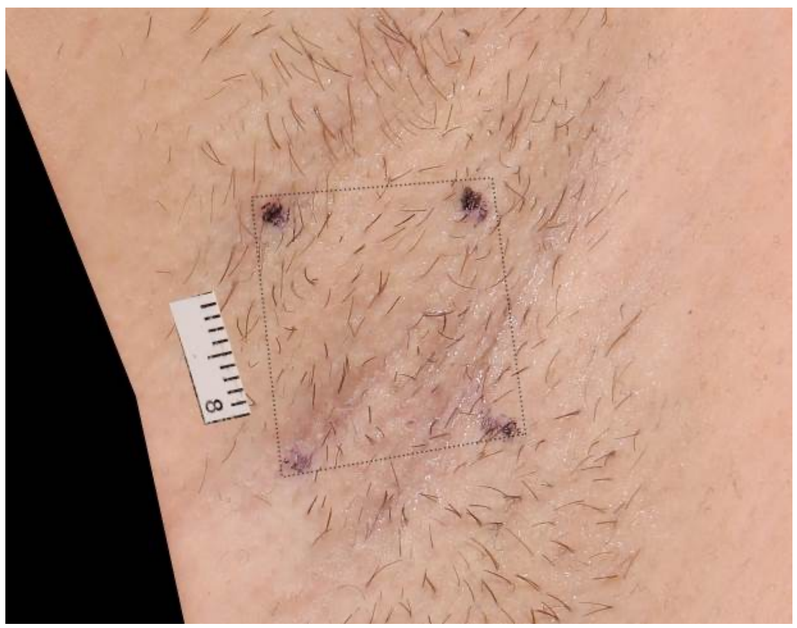
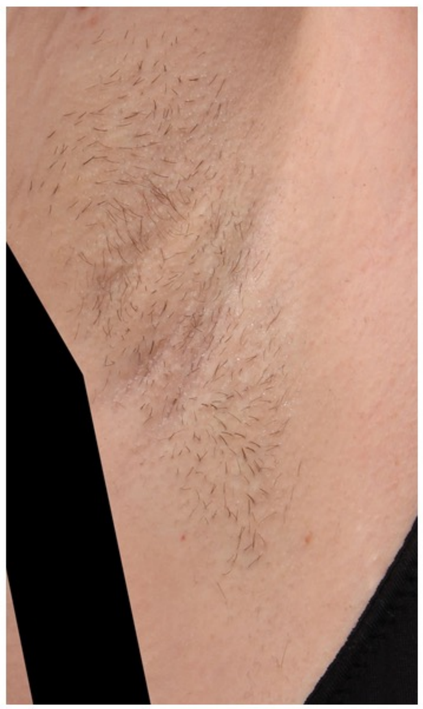


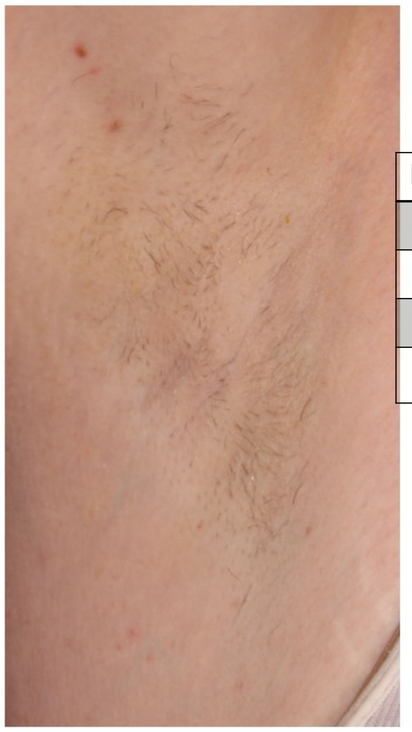
Fig 3. Qualitative Hair Reduction Assessment

A single blinded assessor examined pairs of randomly-ordered photos of individual axillae, where one photo was baseline and one from follow-up. The reviewer chose which photo had the most hair and then gave a qualitative score to the hair reduction (see the rating table).

A



B



Rating	% red
1	0-25%
2	26-50%
3	51-75%
4	76-100%

Results and Conclusion

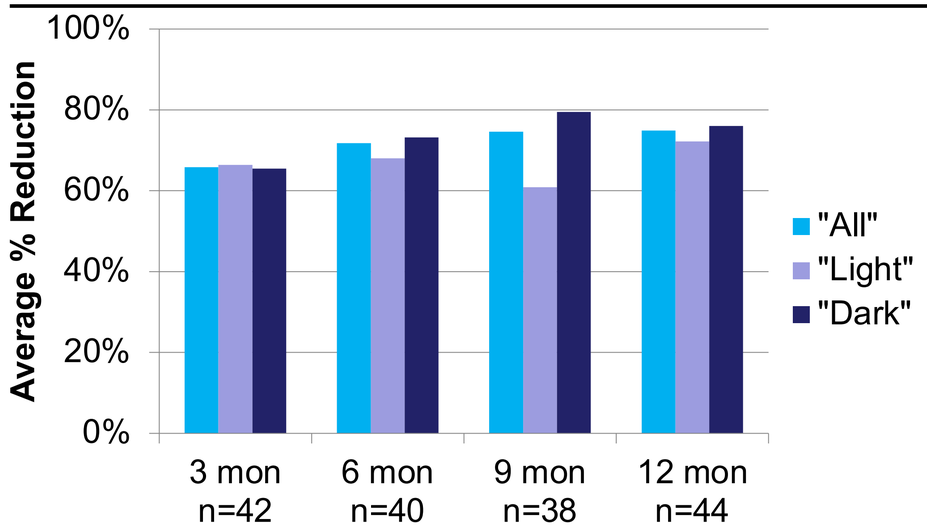


Figure 4. Average Hair Reduction from Quantitative Assessment for each follow-up visit. Results for light and dark hair are broken out separately for the initial 3m and final 12m visits.

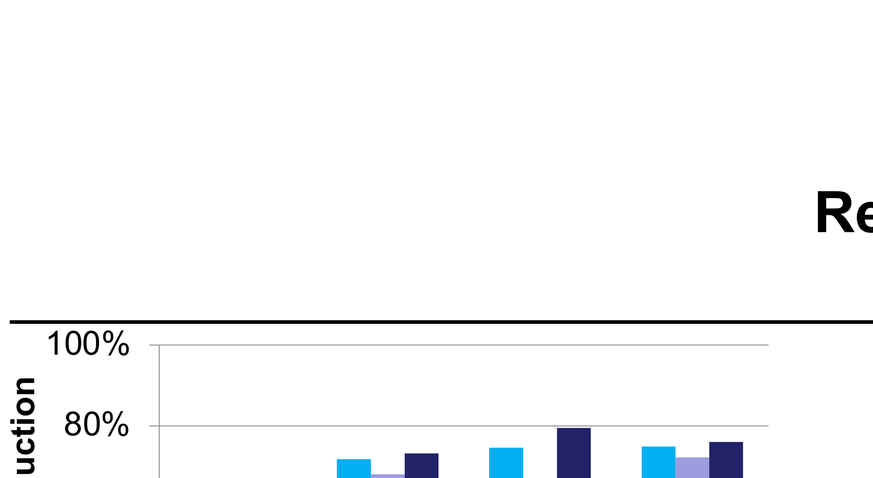


Figure 5. Average Hair Reduction from Quantitative Assessment for the 12m visit vs Energy Level chosen for first treatment. Difference was statistically significant for treating at Energy Level 1, $p<0.0001$.

Conclusions:

We report long-term findings of reduction in underarm hair in patients treated with a non-invasive microwave device. Reduction of approximately 70% in both light and dark axillary hair was seen, and is stable through 12 months of follow-up. There is a statistically significant dependence on treatment settings which should be further explored.

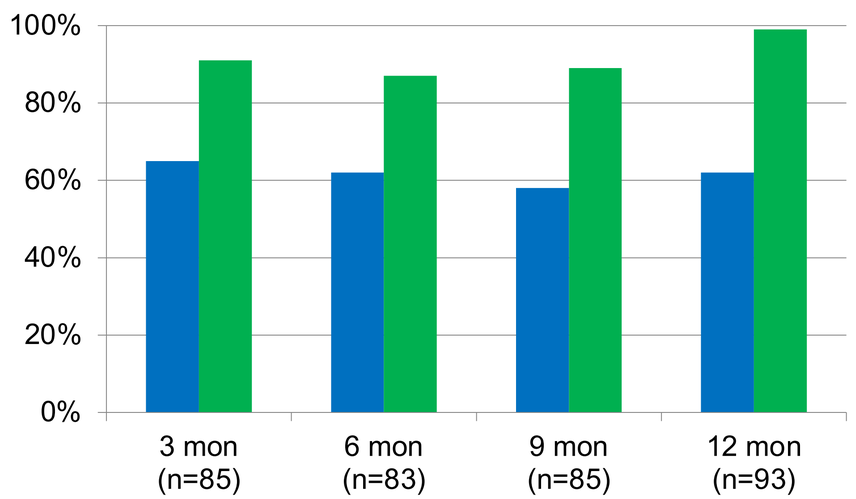


Figure 6. Results of side-by-side qualitative analysis per axilla. Percentage of axilla where the blinded reviewer correctly chose the baseline photo (green bars); % where assessor rated the reduction as being at least 50% (blue bars).

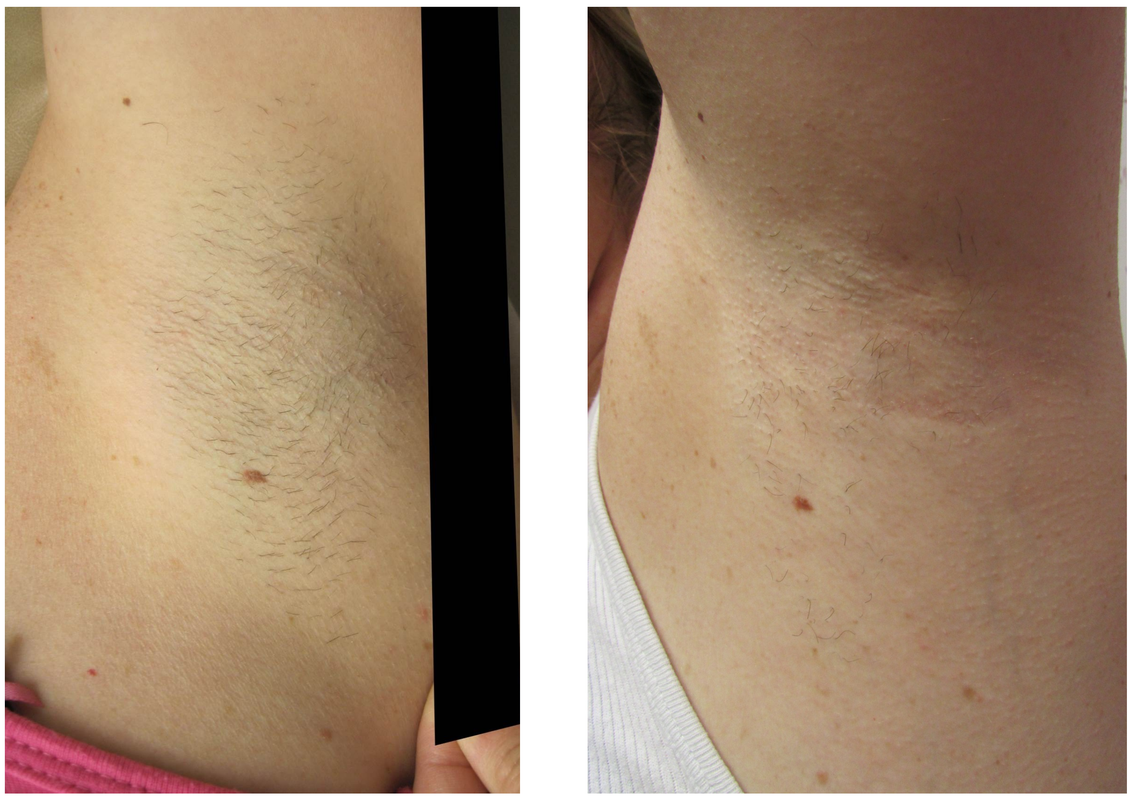


Figure 7. Patient with light brown hair. Assessor correctly chose image on left as baseline. Assessed as 51%-76% reduction.

AXILLARY ODOR REDUCTION FOLLOWING MICROWAVE TREATMENT – A RANDOMIZED, SPLIT-PATIENT STUDY

E. Victor Ross MD [A], John Murray MD [B], Jorge Lujan-Zilbermann MD [B]

ASLMS 2016
April 3, 2016

[A] Scripps Clinic, San Diego, CA
[B] Hill Top Research, St Petersburg, FL

BACKGROUND

- Axillary osmidrosis (excessive underarm odor) can cause social and emotional distress and can have a substantial impact on patients[1]
- Literature on osmidrosis treatments relies on patient-reported odor assessments
- This study used objective underarm odor assessment Judges to quantify odor reduction in subjects treated with a microwave device (miraDry System, Miramar Labs, Santa Clara, CA) proven to reduce underarm wetness

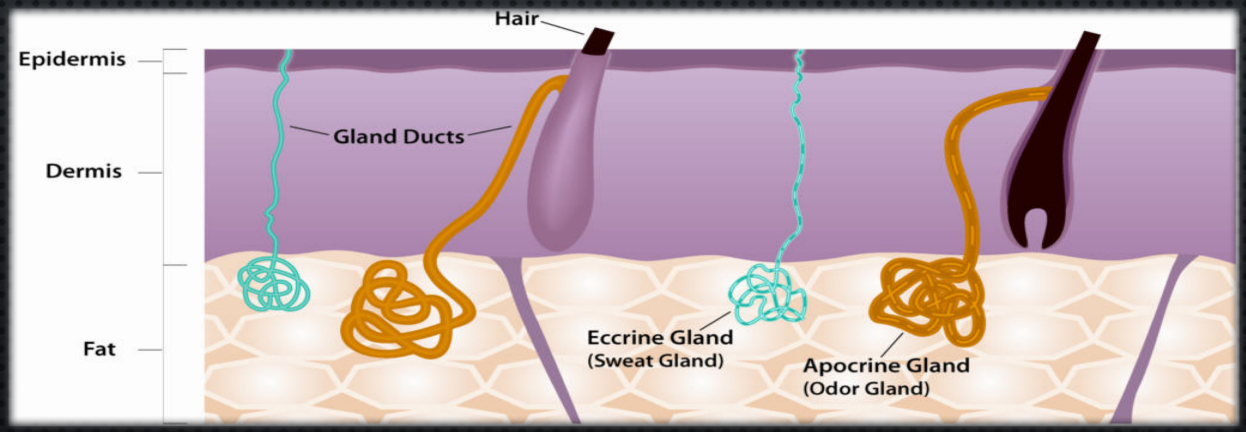
1.Huang, Yu-Hei et al. Reduction in Osmidrosis Using a Suction Assisted Cartilage Shaver Improves QOL. Dermatol Surg. 2010;36:1573-77

BACKGROUND

FDA-cleared non-invasive device utilizing microwave energy

- Focused heat at the dermal/hypodermal interface
- Demonstrated to thermally impact Eccrine (wetness) glands
- Over 90% efficacy for reducing sweat

Hypothesis that heat at the interface may also thermally impact the Apocrine (odor) glands and result in reduction of odor



OBJECTIVE

To quantify the amount of axillary odor reduction when treated with a non-invasive microwave system

- Quantitative odor assessment scores conducted by four (4) blinded, trained Odor Assessors
- Subjects completed follow-up questionnaires and self-reported their odor severity score for each underarm and rated their satisfaction with the procedure

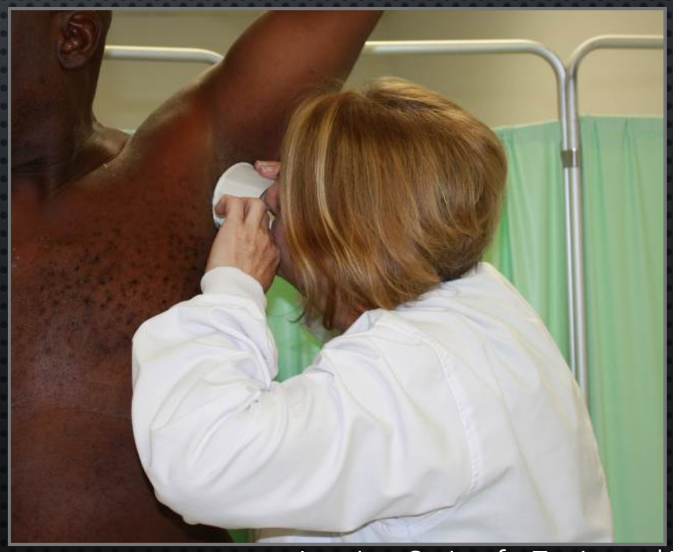
STUDY DESIGN

- Prospective, split-patient, randomized, single center study
- Adult subjects with high underarm odor
- 1 underarm treated (randomized), other underarm untreated and served as control
- 2 treatment sessions with microwave device, 3 months apart: SAME PARAMETERS AS WHAT IS USED TO TREAT WETNESS
- Follow- up visits at 1, 3 and 6 months post final treatment
  - Objective, blinded, quantitative odor assessments
  - Subject questionnaires on self-reported odor severity and satisfaction
- Optional punch biopsies of both underarms to assess histologic changes

STUDY METHODS – ODOR ASSESSMENT

- Quantitative odor assessment methodology adapted from standard for assessing deodorant efficacy[2]
- Subjects underwent 10 day washout period, had controlled underarm wash at 24 hours before assessment, and then wore fragrance free T-shirt until study visit
- 4 trained and blinded Odor Judges used standardized methods and provided malodor scores which were averaged for each underarm

0	**None, no Malodor**
1	Threshold Malodor
2	Very slight Malodor
3	Slight Malodor
4	Slight to Moderate Malodor
5	Moderate Malodor
6	Slightly strong Malodor
7	Moderately strong Malodor
8	Strong Malodor
9	Very strong Malodor
10	Extremely strong Malodor



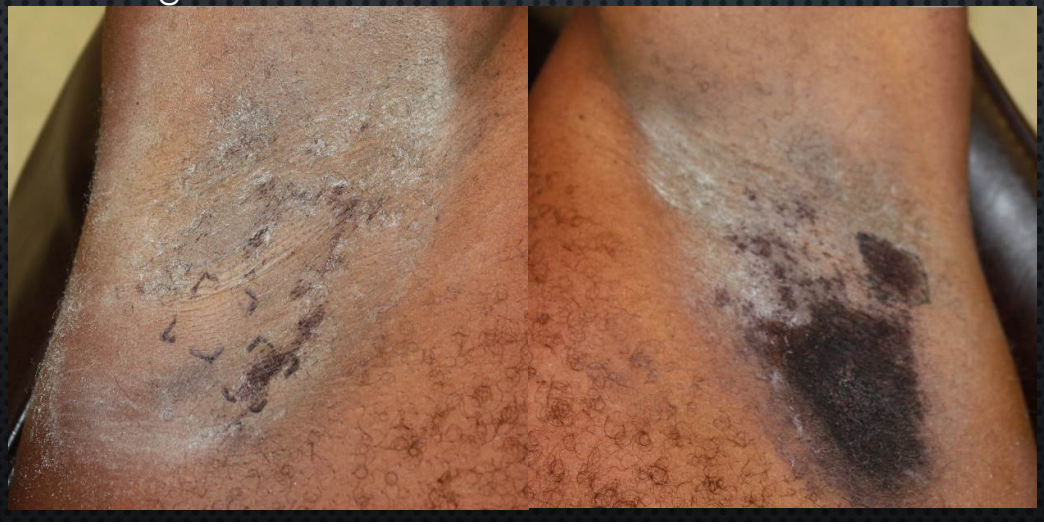
2. American Society for Testing and Materials (ASTM) E1207-14

STUDY METHODS – OPTIONAL BIOPSIES

- Optional 4 mm punch biopsies of both treated and control axilla performed at 6 month follow up
- Consenting subjects had starch iodine (SI) test performed in temperature controlled "hot room"
- Results of SI served as guides for punch biopsy locations
- Blinded histopathology review conducted on tissue specimens

Right Treated Axilla

Left Control Axilla



STUDY DEMOGRAPHICS & SIDE EFFECTS

Demographics – 40 total subjects

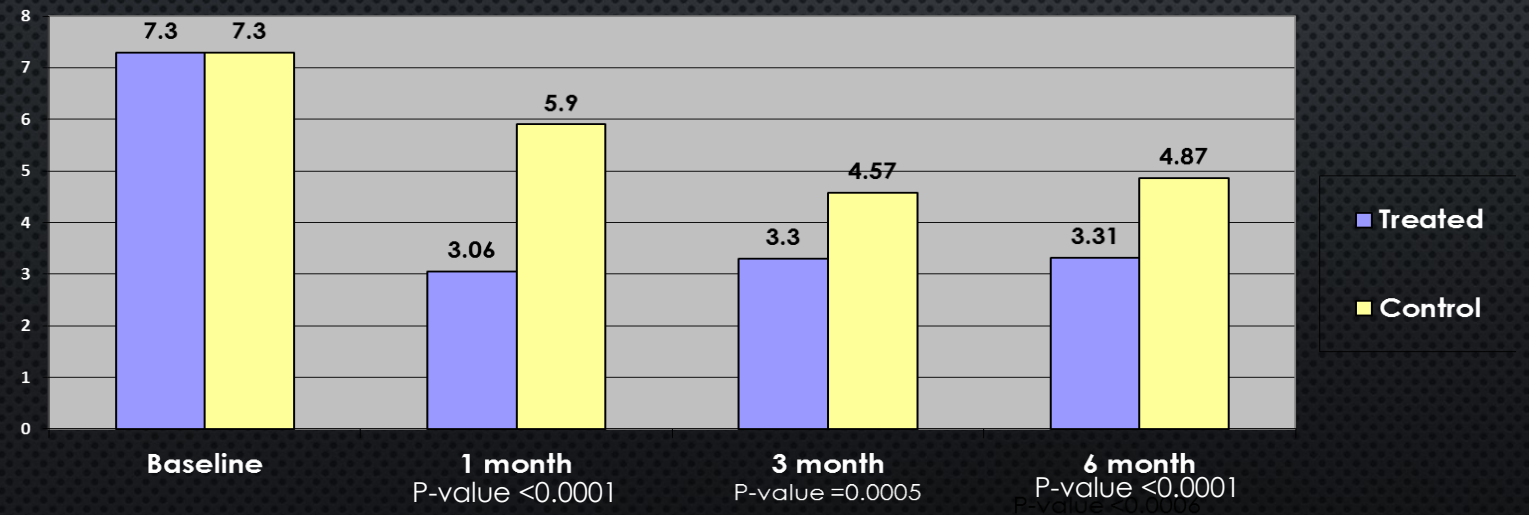
AGE	Median (years) Range (years)	52.2 25 - 75
GENDER	Male, n (%) Female, n (%)	15 (37.5%) 25 (62.5%)
RACE	Caucasian, n (%) Black/African American, n (%)	17 (42.5%) 23 (57.5%)

Adverse Events – related to the study

CATEGORY	AE GRADE	TOTAL # of AEs	TOTAL # of SUBJECTS	% of SUBJECTS
Edema in TX area	Grade 0	3	3	7.5%
Pain in TX area	Grade 0	21	14	53%
Infection or Abscess	Grade 1	1	1	2.5%
Pain Requiring Rx Meds (infection from biopsy)	Grade 2	1	1	2.5%

ODOR REDUCTION RESULTS

- Mean Malodor Scores (Odor Judges) between Treated and Control axilla
- Baseline and follow-up study visits
- Lower score indicates less malodor
- Statistically significant difference favoring Treated axilla for all follow-ups
- Drop in Control axilla scores due to "study effect"



0	None, no Malodor
1	Threshold Malodor
2	Very slight Malodor
3	Slight Malodor
4	Slight to Moderate Malodor
5	Moderate Malodor
6	Slightly strong Malodor
7	Moderately strong Malodor
8	Strong Malodor
9	Very strong Malodor
10	Extremely strong Malodor

PATIENT SATISFACTION RESULTS

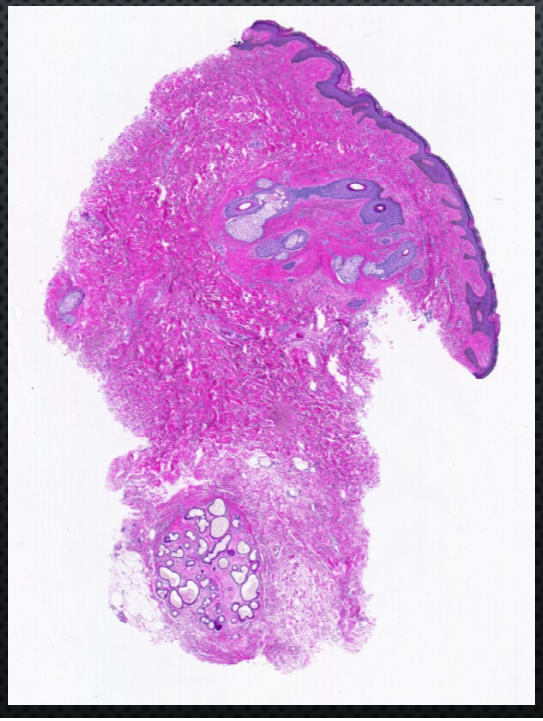
- Subject questionnaires on self-reported satisfaction
- Demonstrated significant satisfaction with treatment at all follow up visits
- 86% at 6 months post treatment

	1 month visit	3 month visit	6 month visit
Satisfied	29 **(83%)**	27 **(75%)**	31 **(86%)**
Not Satisfied	6 (17%)	9 (25%)	5 (15%)
p-value	$p = 0.0001$	$p = 0.0039$	$p < 0.0001$

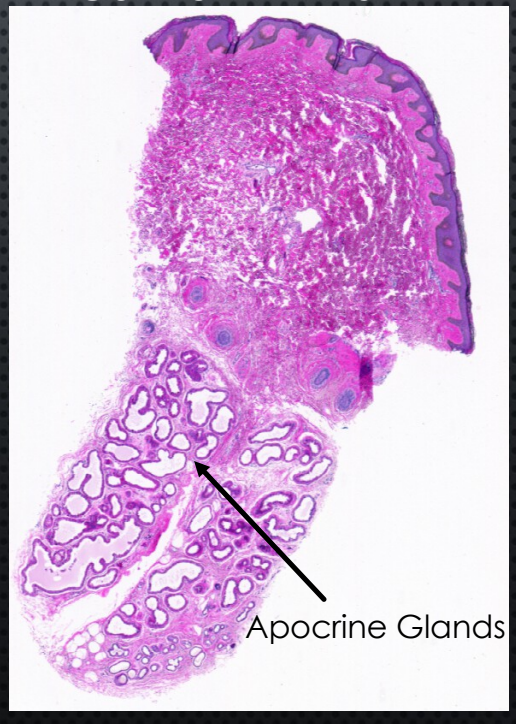
BLINDED HISTOPATHOLOGY RESULTS

- Blinded, paired histologic review demonstrated significantly more periglandular fibroplasia in the Treated specimens
- Control specimens had more Apocrine glands present compared to corresponding Treated specimens
- Pathologist correctly identified 80% of the Treated specimens

Treated Rt Axilla



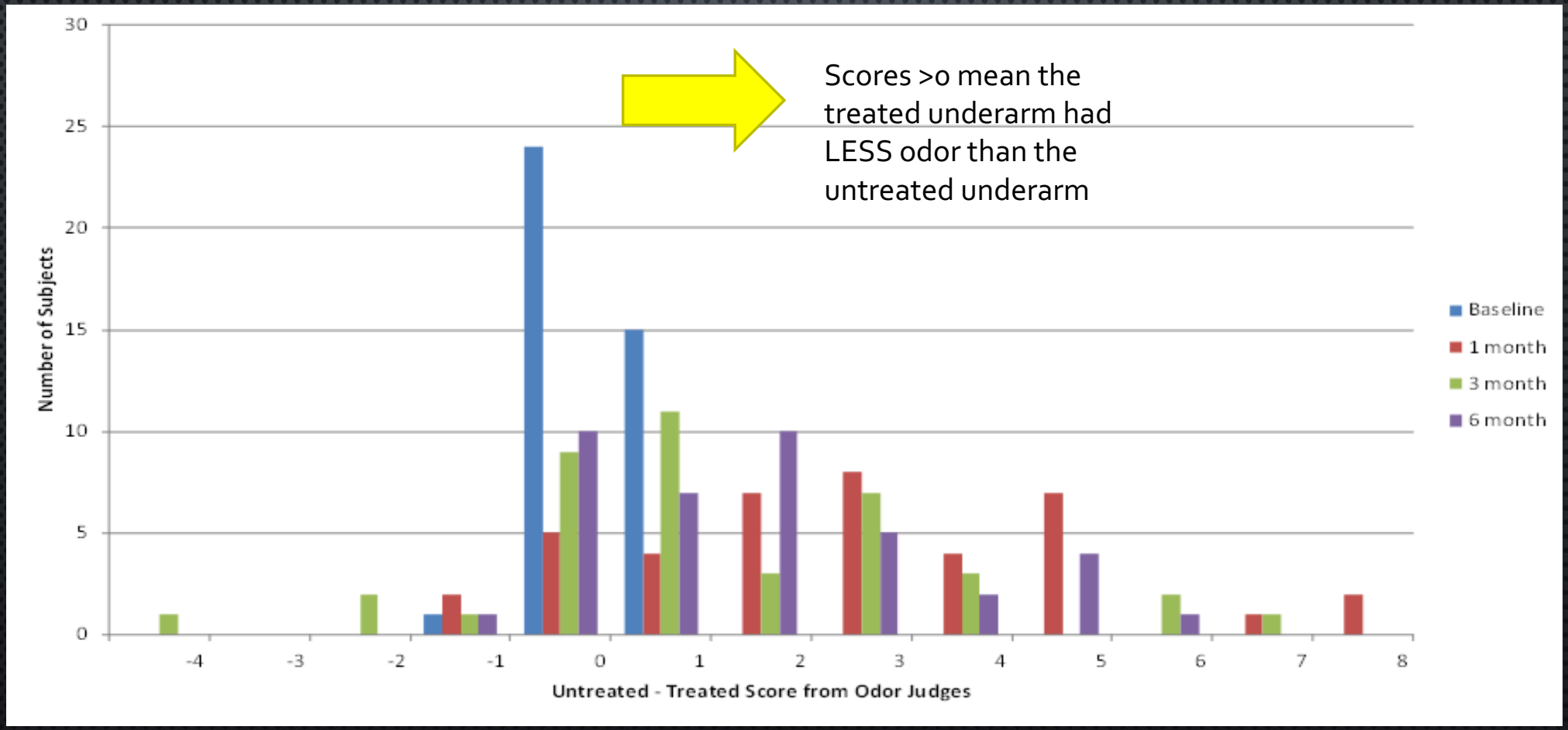
Control Lt Axilla



CONCLUSIONS

- Treatment with a non-invasive microwave energy device demonstrated ability to reduce underarm odor
- Statistically significant average malodor score difference between Treated and Control underarms at 1, 3 and 6 months post treatment
- High level of patient satisfaction (≥75%) with procedure
- Histologic analysis of axilla biopsy pairs showed treatment effect in majority of specimens
- Side effects were mild and consistent with prior reports

SCORE FROM ODOR JUDGES



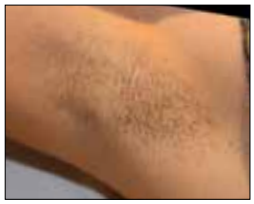
THE AESTHETIC GUIDE®
The Leading Aesthetic Practice Resource™
SEPTEMBER/OCTOBER 2015

miraSmooth Provides Hair Removal

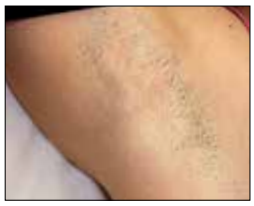
and Sweat Reduction in One Treatment

Whitney P. Bowe, M.D.
Dermatologist
Clinical Assistant Professor of Dermatology
Icahn School of Medicine
Mount Sinai Medical Center
New York, NY

Michelle Place, M.D.
Plastic Surgeon
Danville, CA



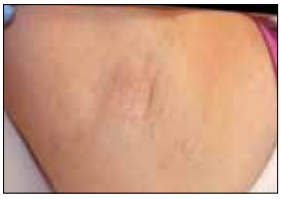
Before Tx



12 months after last miraDry Tx

Photos courtesy of Miramar Labs, Inc.

Before Tx



12 months after last miraDry Tx

Photos courtesy of Miramar Labs, Inc.

By Anthony J. Varro, Contributing Editor

Capitalizing on the non-invasive, permanent benefits of miraWave™ microwave technology, the new miraSmooth™ procedure by Miramar Labs (Santa Clara, Calif.) is the only procedure cleared by the U.S. Food and Drug Administration for permanent reduction of both underarm sweat and underarm hair of all colors.

miraSmooth – a combination of miraDry treatment plus a short course of laser hair removal (LHR) – is one of the most significant innovations in hair reduction in over a decade. This procedure offers patients a solution to permanent hair reduction, in less time than LHR, with the benefit of sweat elimination in the axilla.

Whitney P. Bowe, M.D., a New York-based dermatologist and clinical assistant professor of dermatology at the Icahn School of Medicine, Mount Sinai Medical Center, and Michelle Place, M.D., a Danville, Calif.-based plastic surgeon, are part of the initial miraSmooth roll-out in the U.S.

"What's unique about the technology is that it is color blind," said Dr. Bowe. "One of the limitations we've had with LHR is that it targets the chromophore or pigment molecule, thus you have to have a contrast between the hair color and skin color for it to be effective." Rather than targeting chromophores, "miraWave uses heat to target the junction between the dermis and subcutaneous fat, where the hair follicles live so it doesn't matter what color it is. You're simply using the microwave technology to heat the area to the point that the hair follicle dies."

The miraDry treatment portion of the miraSmooth procedure takes about an hour, said Dr. Bowe. "With local tumescent anesthesia, patients are very comfortable throughout the treatment and downtime is minimal," Dr. Place reported, "and we have not observed any adverse effects."

Patients may experience slight post-procedural swelling and bruising, which respond to ice and non-prescription anti-inflammatory medications, Dr. Bowe noted. "They can usually resume regular activities the same day of treatment; however, they must avoid strenuous workouts for a few days."

Patients typically notice a dramatic reduction in sweating immediately from the miraDry treatment, Dr. Place said. "They're very ecstatic and relieved." By following the company's new Optimized Treatment Protocol (OTP), patients often are happy with their sweat results after one treatment she said.

According to Dr. Place, regarding permanent hair removal, it takes two to three months to accurately judge the reduced hair density. "It's also very convenient for patients to treat their sweating along with their hair in one treatment."

"Traditional LHR usually requires at least 6 to 12 treatments, and maybe even more depending on the patient's ethnicity, hair color and hair density," Dr. Place added. "Conversely, pivotal Miramar research shows that the miraDry procedure can reduce 70% of underarm hair in one to two treatments, regardless of hair color or density. By offering patients a miraSmooth procedure we're confident we will obtain the hair clearance they desire."

#MK0456.A

The latest innovation in permanent underarm hair removal.

- Treats light and white color hair
- Eliminates underarm sweat
- Significant reduction after only 1-2 treatments

miraSmooth™

SMOOTH, DRY UNDERARMS

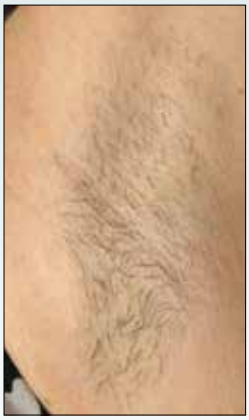
THE AESTHETIC GUIDE®
The Leading Aesthetic Practice Resource™
MAY/JUNE 2016

miraSmooth Adds Revenue

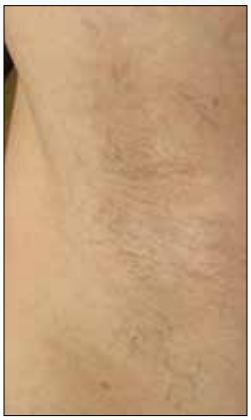
with Existing Equipment

Scott Gerrish, M.D.
Dermatologist
Vienna, VA

"With one treatment, we're seeing 80% to 90% hair reduction. Patients love it."



Axillary region before Tx



Axillary region one year after miraSmooth hair removal Tx

Photos courtesy of Miramar Labs

By Anthony J. Varro, Contributing Editor

The new miraSmooth™ procedure from Miramar Labs (Santa Clara, Calif.) extends the benefits of microwave technology to deliver permanent axillary hair reduction for hair of all colors, using the company's miraDry device.

"Originally, we chose the miraDry device for sweat reduction," said Scott Gerrish, M.D., a dermatologist in Vienna, Va. "Hair removal was a total bonus. By marketing miraDry for sweat and miraSmooth for hair, we're able to target a larger patient population."

"Having another indication for the device is great from a business standpoint," Dr. Gerrish continued. "With one or possibly two treatments, we can achieve a huge reduction and we can treat hair that's blonde, white or gray, and any skin type. It enables us to provide underarm hair reduction in patients we normally could never treat."

Whereas hair removal lasers limited the type of patients Dr. Gerrish could treat, "Any patient is a candidate for miraSmooth because the device uses miraWave™ technology – microwave energy – so it can heat the entire treatment area from 2 to 5 mm deep. It's independent of color, as opposed to laser hair removal (LHR), which seeks out dark colors because lasers need a chromophore – usually pigment – to target." Additionally, LHR often creates post-inflammatory hyperpigmentation in darker-skinned patients.

The process begins with cleaning the treatment area using an antibacterial agent. To numb the armpit, "We use tumescent infiltration. Then, depending on the size of the target area, we'll pick the grid that fits that hair pattern and treat one arm, then the other," Dr. Gerrish explained.

The device is very easy to use. "You basically follow the grid, and hold the handpiece there while the machine delivers the energy. Then you move to the next spot. Generally from start to finish, treatment will take 60 to 75 minutes."

In Dr. Gerrish's experience, one day after treatment patients' underarms are sore – but it's nothing ibuprofen can't handle. "We have them ice the area for a day or two. But generally by the second day, they're dramatically better and can return to work. There's really no downtime – just taking it easy for a day or so. We tell people no exercising for three to four days."

For Dr. Gerrish, who typically performs approximately ten miraSmooth procedures monthly, results are, "Phenomenal. With one treatment, we're seeing 80% to 90% hair reduction," he reported. Most patients are so satisfied that they do not undergo a second application. "Patients love it. Nobody wants high maintenance, or any maintenance. If you can be 'one and done,' that's a great option. It's miraculous. miraSmooth patients are some of the happiest patients I treat." In fact, patients who have undergone treatment represent one of Dr. Gerrish's top referral sources.

Dr. Gerrish has this advice for other aesthetic physicians: "It's a great addition to a practice that does not compete with anything else you're doing. If there are patients you cannot treat because of skin color or hair color, miraSmooth offers an effective solution."

MK0521.A

The latest innovation in permanent underarm hair removal.

- Removes light and white color hair
- Eliminates underarm sweat
- Significant reduction after only 1-2 treatments

miraSmooth™

SMOOTH, DRY UNDERARMS

www.miramarlabs.com

Hyperhidrosis + hair removal: Meet miraSmooth

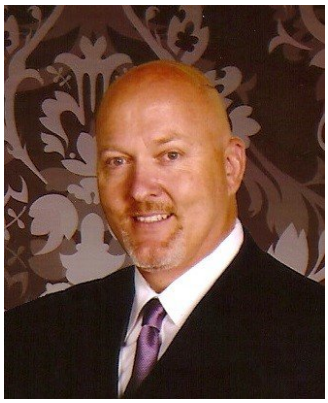
November 24, 2015
By Bill Gillette

The Food and Drug Administration has cleared miraDry — a microwave-based device already approved for eliminating underarm sweat glands — for the permanent reduction of underarm hair of all colors.

Following the FDA clearance, miraDry maker Miramar Labs, Santa Clara, Calif., announced the roll out of the miraSmooth brand, which targets patients looking to eliminate underarm hair. The miraDry/Smooth system is based on Miramar's proprietary miraWave technology, which uses precisely controlled microwave energy. It is this technology that enables the elimination of underarm hair regardless of its color. Thus, Miramar is marketing miraDry/Smooth as the only FDA-cleared device for treating unwanted underarm hair of all colors as well as the permanent reduction of underarm sweat.

"MiraSmooth is the use of the miraDry system, in conjunction with laser hair treatment when appropriate, for axillary hair removal," says Miramar Vice President of Marketing Rob Ellis. "It's a versatile hair-removal option that can be used alone, or in combination with a series of laser hair-removal treatments, and also provides the unique benefit of simultaneously eliminating sweat. The treatment is quick and simple, takes about one hour and is only available in a physician's office."

Mr. Ellis



The FDA clearance of miraDry for hair removal was based on a study performed at three private dermatology clinics. Study co-author Jeremy Brauer, M.D., a dermatologist at the Laser & Skin Surgery Center in New York, tells *Cosmetic Surgery Times* that the study recruited adult subjects seeking underarm-hair reduction.

Dr. Brauer

"They were screened, and those eligible received up to two sessions, three months apart," he says. "Fifty-six subjects were enrolled, with an average age of 33 years; 80% of the subjects were female and 88% were Caucasian."

For the purpose of hair count and blinded physician assessment, photos were taken before each treatment and at each follow-up visit. Subjects gave feedback on their overall satisfaction with the treatment experience, as well as odor rating and sweat ratings, during follow-ups.

NEXT: Hair Reduction Results

Hair Reduction Results

According to Dr. Brauer, the study provides evidence for safe and effective axillary hair reduction.

"Based on the study, patients can expect at least 70% reduction in one to two treatments," he says. "However, our study parameters and technique were optimized for sweat reduction, so while the results are promising, I think that they can and will be better once a protocol is defined for hair reduction. We only treated once or twice and evaluated at follow-up visits that were determined at the start of the study — the latter point being that it's possible hair reduction is observed earlier than

we noted."

As for pain level and after effects, Dr. Brauer says that since local anesthesia is administered prior to treatment, most patients experience little or no discomfort.

"There is a strong safety record with the miraDry procedure," he says. "After treatments patients may experience temporary swelling, soreness, tingling or numbness. These all resolve in a matter of a few days to weeks."

Dr. Brauer says the study's most significant finding was that there were no differences in the reduction of light or dark hair.

"For the first time, there was a device for hair removal that did not depend upon the pigment or color of the hair — essentially making it a 'color-blind' procedure," he tells *Cosmetic Surgery Times*. "The implications for this are far-reaching: treatment of gray hair or blonde hair, and treatment of individuals of all skin types without the concerns associated with standard hair-removal devices."

Helen M. Torok, a Medina, Ohio, dermatologist not involved in the study, says she has not used miraDry but knows about it.

"It was exclusively used for hyperhidrosis," she says, "but during the procedures it was discovered that there was a decrease in hair — and it didn't matter what hair, which translates to the fact that the energy delivered is deep. It would be nice to see if we can use this technology on the face for hirsutism, but the current device is probably too deep and would cause scarring."

According to a Mirmar spokesperon, miraSmooth is currently only offered in the United States. The list price of miraDry is $84,450. For physicians who own a miraDry system, there is no additional cost or device required to offer the miraSmooth procedure.

Disclosure: Dr. Brauer served as a consultant to Miramar.

THE European
AESTHETIC
The Leading Aesthetic Practice Resource™
AUTUMN 2016
GUIDE™

Barcelona Sweat Clinic Builds

Foundation on miraDry Microwave Technology

Marta Alegre, M.D.
Dermatologist
Medical Director
Clinica Liberty
Barcelona, Spain

Oren Gan
Co-Founder and General Manager
Clinica Liberty
Barcelona, Spain

"Much of our success is due to miraDry because in it we have a medical device that is safe, powerful and reliable, which gives us very high patient satisfaction."

miraDry offers permanent reduction of underarm sweat and odor, often requiring only one treatment.

Photo courtesy of Clinica Liberty

By Kevin A. Wilson, Contributing Editor

miraDry® from Miramar Labs, Inc. (Santa Clara, California, U.S.) delivers opportunity for savvy physicians and spa owners who want to tap into a potentially explosive market – the treatment of axillary sweat. Utilizing microwave energy to selectively destroy both apocrine and epocrine sweat glands in the axilla, miraDry offers permanent reduction of underarm sweat and odor, often requiring only one treatment.

Clinica Liberty in Barcelona, Spain has harnessed miraDry as the foundation of its specialty clinic for the treatment of unwanted sweating. According to Marta Alegre, M.D., a dermatologist and medical director of Clinica Liberty, "miraDry is an ideal therapy for this purpose because it is very safe, effective, permanent and easy to perform. The microwave energy is focused at the perfect depth to destroy sweat glands. The high degree of patient satisfaction is amazing."

Microwave energy agitates water molecules to create the heat that causes controlled tissue damage. This unique application of energy is selective for sweat glands because of their high water content. miraDry's microwave emitters direct energy to the junction of adipose and dermal tissue, where sweat glands reside. This energy is naturally reflected for an automatic focusing effect at that point regardless of variations in skin thickness among individuals. The temperature of target cells is elevated to greater than 60° C, which causes instant cell death, while surface skin is protected by hydroceramic contact cooling. This technology also spares nearby tissue structures, such as nerve endings, from undue damage. Treatment takes place under high volume (tumescent) anesthesia, which is easy to administer effectively and maximizes patient comfort. Side effects include the incidence of swollen areas of the axilla, which resolve in a few weeks as part of the recovery process.

Many people desire treatment of underarm sweating and odor for numerous reasons, with various methods used over the years. This is the driving force behind the rise in global popularity of miraDry, and in large part the reason for Clinica Liberty's unique focus. With the emergence of a permanent solution for sweat and odor reduction in miraDry, demand is rising, especially among those seeking treatment of hyperhidrosis. In fact, the name 'Clinica Liberty' represents a newfound freedom from excessive sweating, which for many patients is life-changing, according to general manager and co-founder Oren Gan. "Officially I believe 3% of the world's population suffers from hyperhidrosis," he said, "but I feel the number of potential patients is much higher, especially when you take into account those who may not consider themselves hyperhidrotic, but still feel they sweat too much. The miraDry technology is very easy and convenient to use. We offer a full range of non-surgical treatments for sweating all over the body as well."

About one year ago many believed this type of specialized clinic would not survive, even in a warm climate such as Spain. "We recognized the lack of awareness of treatments and spent a great deal of money on education and marketing, and today we are thriving," Mr. Gan added. "Much of our success is due to miraDry because in it we have a medical device that is safe, powerful and reliable, which gives us very high patient satisfaction."

MK0549.A

Stop underarm sweat.

Half the patients in your practice are interested in eliminating their underarm sweat and odor.[1]*

miraDry® is the first and ONLY non-invasive treatment proven in more than 55,000 procedures worldwide to permanently destroy underarm sweat and odor glands. Fast, safe, and comfortable, miraDry delivers patient satisfaction, among the highest of any non-surgical aesthetic procedure.

Find out more at www.miradry.com

*Not for pediatric use.

[1] www.RealSelf.com,world's largest community for information about cosmetic surgery, dermatology, dentistry, and other elective treatment, poll of 2200 females age 18-64.

MK0332-D 07/16

Strong Demand

High Patient Satisfaction

Clinically Proven

miraDry®

The sweat stops here.™

THE European
AESTHETIC
The Leading Aesthetic Practice Resource™
SPRING 2014
GUIDE™

Physicians Report Complete

Elimination of Hyperhidrosis Using miraDry

Michael Kleine
CEO
Miramar Labs
Sunnyvale, CA, USA

Wim Venema, M.D.
Dermatologist
Assen, The Netherlands

Tapan Patel, M.D.
Aesthetic Physician
London, England

Charles Randquist, M.D.
Plastic Surgeon
Salsjöbaden, Sweden

"miraDry has great potential to improve patients' lives. I see hyperhidrosis as a large, under-appreciated social disability. Since miraDry entered the U.S. market two years ago the number of people seeking treatment has grown with increased awareness."

By Jeffrey Frentzen, Executive Editor

Hyperhidrosis is a condition characterized by excessive sweating in the underarms, on the palms of hands, soles of feet, and other body areas, accompanied by anxiety and stress. People suffering from hyperhidrosis experience negative consequences in both social relationships and professional activity.

Although surgical and injectable procedures have been used with success, more recently a third-generation, non-invasive handheld energy-based device has received a CE Mark for the treatment of axillary hyperhidrosis. With miraDry® from Miramar Labs, Inc. (Sunnyvale, California, U.S.), practitioners can deliver precisely controlled electromagnetic energy (at a 5,800 MHz wavelength) into the dermal-fat interface at a depth of about 2 mm to 5 mm, where it literally destroys the sweat glands for good. Since sweat glands do not regenerate, results are lasting. Published studies have shown the treatment to be highly effective (>80% reduction in underarm sweat), while delivering over 90% patient satisfaction.

The miraDry device consists of a handpiece that distributes a 1 cm by 3 cm zone of therapy and contains four antennas plus proprietary hydro-ceramic cooling to minimize absorption in the dermis and deeper tissue, maintaining patient comfort. Effects of treatment can be seen almost immediately. The company recommends two treatments spaced three months apart for lasting results, based upon clinical studies.

According to Michael Kleine, CEO of Miramar Labs, "there is clearly a significant number of people who are aware they have excessive underarm sweat, and that's a real problem. When you talk to these patients, their sense of embarrassment is at the level of those suffering with psoriasis and acne. They have used the aluminum chlorohydrates and antiperspirants and they were ineffective, or in some cases people didn't want to use them. They've tried temporary remedies, such as Allergan, Inc.'s BOTOX injections every three to six months. Finally, though, there is a non-invasive procedure with excellent efficacy. From the patient's standpoint, when they learn there is a procedure with a high safety profile that actually eliminates the sweat glands, they are extremely pleased."

"miraDry has great potential to improve patients' lives," expressed Wim Venema, M.D., a dermatologist in Assen, The Netherlands. "I see hyperhidrosis as a large, under-appreciated social disability. Since miraDry entered the U.S. market two years ago the number of people seeking treatment has grown with increased awareness. Once the problem is solved, the embarrassment goes away and people begin to feel comfortable speaking about how underarm sweat used to impact their lives. We're unaware of exactly how many people in Europe are afflicted with excessive sweating, but we expect to see the same strong response here as in the U.S."

"We know there is a much larger group of patients that are dealing with this same nuisance of daily underarm sweat," said Tapan Patel, M.D., an aesthetic physician located in London, England. "For this group, the sweating may not be as severe, but it is a bother nonetheless and something they are subconsciously aware of. These individuals also take compensatory measures like their use of antiperspirants or carefully chosen wardrobes."

People with hyperhidrosis are stigmatized by society, noted Dr. Venema. "In that way, sweating is a real restriction of freedom," he stated. "These people try to stay away from circumstances where

"We are seeing a broad spectrum of patients from those who experience severe and consistent sweat outbreaks to those who just find underarm sweat uncomfortable."

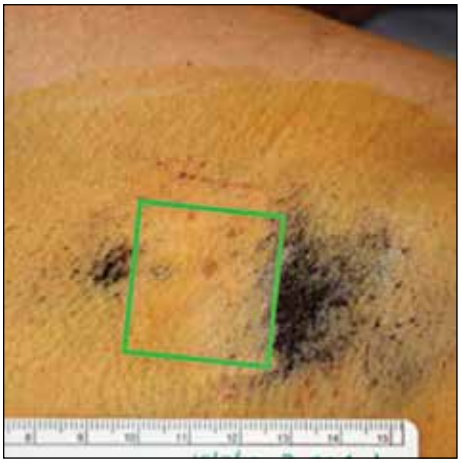


Image shows three year starch iodine test in axillary region. The inky areas show where the patient is still sweating, while the green box shows the treated area without sweat. This was taken three years after the patient received the miraDry treatment.

Photos courtesy of Miramar Labs

they can count on sweating, so they avoid parties and other social gatherings. I have heard from patients that they were refused a promotion because they were sweating too much. After you have treated these patients, they experience a kind of liberation. They can socialize at will and not worry about their sweating."

Charles Randquist, M.D., a plastic surgeon in Saltsjöbaden, Sweden concurred. "A lot of people really suffer with hyperhidrosis, and it is like a handicap for them." miraDry was the first energy-based device Dr. Randquist had ever purchased. "I had not bought a machine in 17 years, and my practice had always been based on surgery and injectables, so basically I left the lasers and other devices behind for a long time. However, when I got acquainted with miraDry as a device and read the science behind it, I saw it as a solution for patients with hyperhidrosis and I have not regretted buying it at all," he shared.

Prior to switching to miraDry, Dr. Randquist used BOTOX, which has been approved in the U.S. and other regions for this indication. "However, miraDry offers a lasting non-surgical, non-invasive treatment for hyperhidrosis with no downtime, which should also attract patients that are reluctant to undergo surgery or injections in these sensitive areas," he continued.

In the past, Dr. Venema had also used other solutions to treat hyperhidrosis, "including surgical methods to eliminate the sweat glands," he said. "When I treated hyperhidrosis with curettage and suction, patients had to stay home for a week and my success rate was around 50%. With miraDry, there is no surgery and the downtime is practically nothing, and the people I treated could go back to work the next day. I think it is more effective."

For both physicians, adding the miraDry to their aesthetic armamentarium has been quite efficacious. "Out of the ten people that I have treated using miraDry, eight patients who are really heavy 'sweaters' have been completely cured," Dr. Venema highlighted. "The other two patients will need a second treatment, but overall it's been a very big success."

Dr. Patel added, "We are seeing a broad spectrum of patients from those who experience severe and consistent sweat outbreaks to those who just find underarm sweat uncomfortable. Regardless of where they fall along this continuum, all of the patients I've treated to date have been very pleased with the miraDry treatment."

In Dr. Randquist's opinion, the miraDry system is the state-of-the-art in treatment of hyperhidrosis. "It's been amazing," he said. "It's a fairly new machine, but so far results have been excellent. In a questionnaire that I distribute to all my patients, miraDry patients have given the treatment excellent ratings. I tried it on staff, my friends and some patients and the results have been remarkable, and no one has complained. The procedure is comfortable and the downtime is very low. I'm happy about that. I want to not only treat my patients with miraDry, I also want to train other physicians and practitioners in its use. It would be beneficial for them financially and patients respond well to the treatment. I'm very pleased."

Supporting Dr. Randquist's statements, Mr. Kleine pointed out that the potential market for this breakthrough product is large because only a small percentage of people who feel they perspire in excess have seen a physician about their condition. "To date, more than 20,000 procedures have been performed worldwide," he expressed. "The system offers physicians a way to bring in new patients, including young patients, and provides a new avenue for expanding their practice."

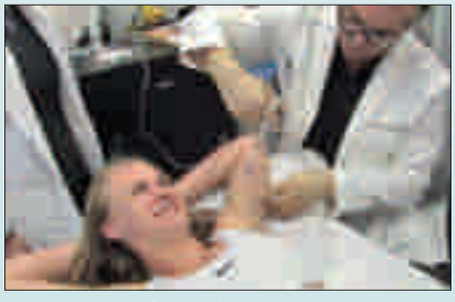
Part# MK0286.A

Expert Touts miraDry Sweat

Treatment a No-Brainer

W. Grant Stevens, M.D., F.A.C.S.
Plastic Surgeon
Marina Del Rey, CA

"Every single one of my miraDry patients has been happy with the results and has thrown away their antiperspirants."



Grant Stevens, M.D. of Marina Plastic Surgery preparing a patient for miraDry Tx

By Jeffrey Frentzen, Executive Editor

Intended for people that want to permanently eliminate underarm sweating and the related odor, miraDry® from Miramar Labs, Inc. (Santa Clara, Calif.), offers a unique, FDA cleared non-invasive procedure. miraDry targets and permanently destroys a patient's underarm sweat and odor glands.

"All of us would prefer not to have wetness under our arms," said W. Grant Stevens, M.D., F.A.C.S., a plastic surgeon in Marina Del Rey, Calif. "miraDry is the only permanent, non-invasive solution that can easily eliminate both perspiration and odor. That's the key – it eliminates both."

The miraDry system's unique miraWave® technology uses hydroceramic contact cooling in combination with 5.8 GHz of microwave energy. This combination creates a focal heat zone, regardless of skin thickness, precisely at the dermal-fat interface that houses sweat and odor glands, while protecting the epidermis, upper dermis and sensitive underlying structures. Most patients see results in as little as one treatment.

"In addition, my patients experience no downtime or pain," said Dr. Stevens. "Occasionally, you will encounter a patient that could benefit from two treatments, but 95% of my patients successfully eliminate their odor and sweat with one treatment that takes one hour."

Recent advances to miraDry include the new optimized treatment protocol (OTP) that uses high volume anesthesia permitting the use of higher, more efficient energy levels during treatment.

"The anesthesia delivery system has been revolutionized," noted Dr. Stevens. "We put ice under the arms to numb the area. Then we give a small, single injection to anesthetize the area. After the area is numb, we mark the grid and direct microwave energy right at the skin. There is no scatter. In less than an hour, you're done and go to work the next day."

"When activated, the miraDry handpiece delivers microwave energy that penetrates to the dermal-fat interface and stays concentrated there," Dr. Stevens added. "It selectively eliminates the sweat and odor producing glands and is safe to use on all skin types. As a side benefit, it also has an effect on hair follicles and we see a reduction in the amount of hair under the armpits of around 70%."

Dr. Stevens' patients have responded well to treatments. "Every single one of my miraDry patients has been happy with the results and has thrown away their antiperspirants," he said.

Selling the procedure to patients is, according to Dr. Stevens, "the biggest no-brainer in the history of mankind. I don't have to convince them. I just ask a simple question: Did you put on antiperspirant today? Everyone says yes. I say, do you want to put it on for the rest of your life? Would you like to eliminate that? Have you ever stained a blouse? I would like to know if there is anyone in Western culture that has not answered yes to these questions."

For the physician, the ROI is great, Dr. Stevens shared. "miraDry pays for itself after only a few months. The consumable is inexpensive, and the device is relatively inexpensive when you compare it to the revenue stream."

THE European
AESTHETIC
The Leading Aesthetic Practice Resource™
SPRING 2016
GUIDE™

miraDry Treatment for Sweat

Provides Rapid ROI

Afschin Fatemi, M.D.
Facial Plastic Surgeon
Medical Director
S-thetic Group
Düsseldorf, Germany

Rainer Jokisch, M.D.
Dermatologist
Frankfurt, Germany

"Upon learning that miraDry is backed by science and clearly works, it only took me a matter of seconds to decide that I wanted it."

By Anthony J. Varro, Contributing Editor

Unlike some energy-based devices that end up gathering dust, the miraDry microwave treatment for sweat by Miramar Labs (Santa Clara, California, U.S.) delivers reliable results, often paying for itself in as little as a few months.

"When I heard that miraDry was the first non-surgical option providing permanent results for sweat, I was extremely intrigued," said Afschin Fatemi, M.D., a facial plastic surgeon and medical director of The S-thetic Group, based in Düsseldorf, Germany, who has used the device for nine months. "In my experience, neurotoxins offer only temporary results and radiofrequency-based devices do not penetrate deeply enough to permanently destroy the sweat glands. Upon learning that miraDry is backed by science and clearly works, it only took me a matter of seconds to decide that I wanted it."

According to Rainer Jokisch, M.D., a dermatologist in Frankfurt, Germany, "miraDry is a promising new non-invasive treatment for permanent reduction of axillary sweat."

miraDry offers permanent results because it penetrates 4 mm to 5 mm deep, Dr. Fatemi explained. His own research (unpublished), showed average sweat reductions of 81% six months after a single treatment. Similarly, Dr. Jokisch estimates that his patients can achieve up to 70% reduction three months after treatment.

Female patient, age 39 four weeks after miraDry Tx of left underarm. Photo was taken immediately after a 30 minute stationary bike workout in heated room.

Dr. Fatemi uses the device at least once daily. "With results like these our system was paid off in three or four months," he stated.

In Germany, 2 million people suffer from axillary hyperhidrosis, Dr. Fatemi reported. Notably, this excludes "sweat-bothered" patients that simply dislike sweating – who are also appropriate treatment candidates.

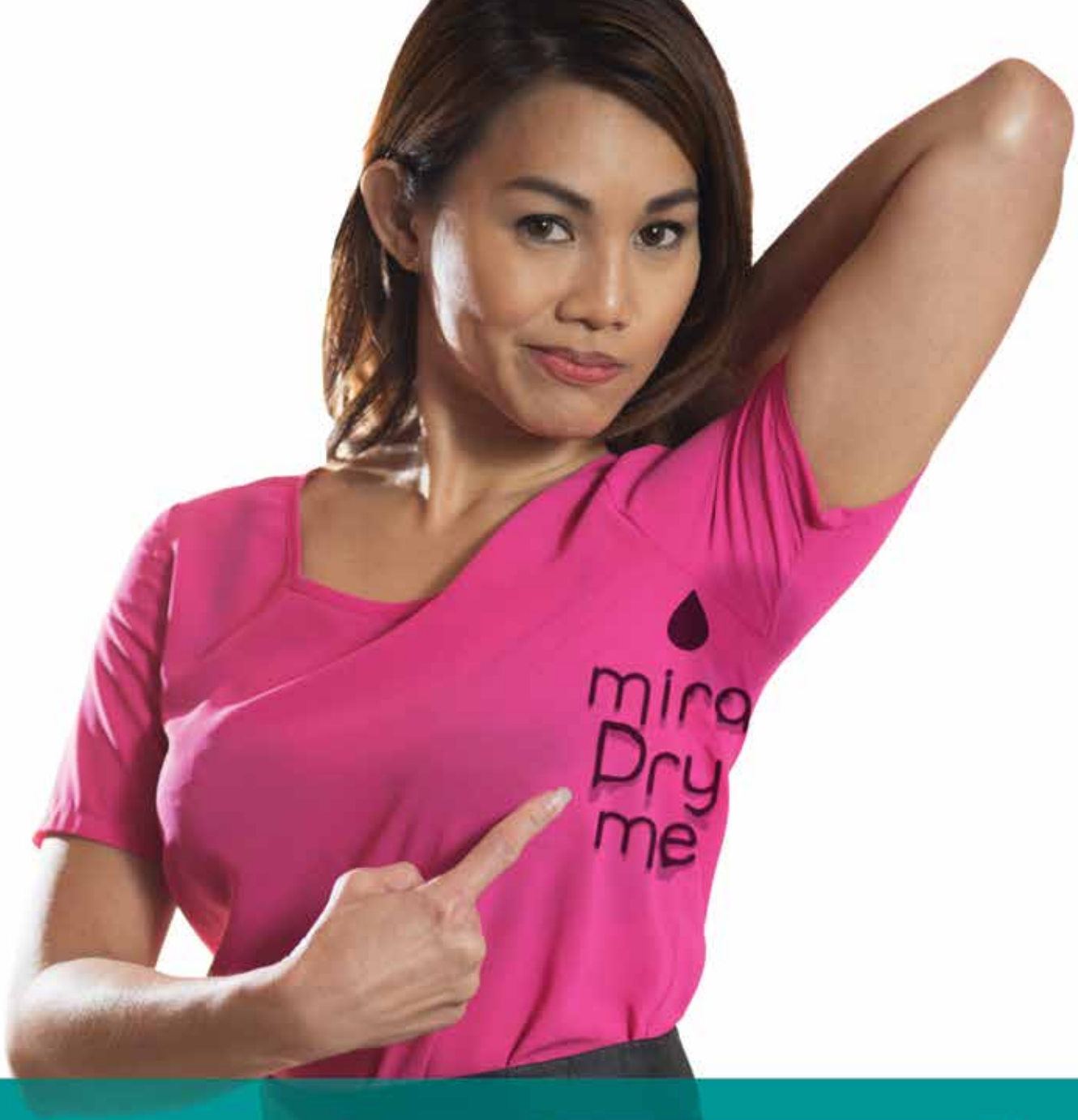
Dr. Jokisch has had the miraDry device since November 2014, and performs 130 treatments annually; exclusively patients with hyperhidrosis. For him, the device paid for itself in six to nine months. Furthermore, "Most of my patients are satisfied. Only 20% request a second application. Side effects are bearable, and we have seen no severe repercussions," he added.

For both physicians, per-procedure costs total approximately €700, including all materials, medications and an assistant. To perform the treatment, Dr. Fatemi simply selects the miraDry setting and injects local anesthesia, which takes five to ten minutes. "Everything else can be done by a nurse or assistant," including marking the patient's underarms before anesthesia injection and running the device, which takes 45 to 60 minutes.

Both Dr. Fatemi and Dr. Jokisch note that patients' underarms are dry immediately after treatment. "If any sweat glands survived patients will know within two to four weeks," Dr. Fatemi advised. "With the original miraDry protocol, patients had to undergo at least two sessions, but now, only about 10% need a second application."

The high patient satisfaction seen in both practices mimics the satisfaction reported on sites such as realself.com. With the patient volume and delegatable nature of the procedure, miraDry has proven to be a sound investment.

MK0495.A



Stop underarm sweat.

Half the patients in your practice are interested in eliminating their underarm sweat and odor.[1*]

miraDry® is the first and ONLY non-invasive treatment proven in more than 55,000 procedures worldwide to permanently destroy underarm sweat and odor glands. Fast, safe, and comfortable, miraDry delivers patient satisfaction, among the highest of any non-surgical aesthetic procedure.

Find out more at www.miradry.com

*Not for pediatric use.
[1] www.RealSelf.com,world's largest community for information about cosmetic surgery, dermatology, dentistry, and other elective treatment, poll of 2200 females age 18-64.
MK0332-D 02/16

Strong Demand

High Patient Satisfaction

Clinically Proven

miraDry®

The sweat stops here.™

THE AESTHETIC GUIDE®
The Leading Aesthetic Practice Resource™
JANUARY/FEBRUARY 2016

miraDry Optimized Treatment

Protocol Enhances Patient Satisfaction

Cynthia Diehl, M.D.
Plastic Surgeon
Raleigh, NC

Rosalyn George, M.D.
Dermatologist
Wilmington, NC

Sheila Nazarian, M.D.
Plastic Surgeon
Beverly Hills, CA

"For many people this is a life-changer. My patients are incredibly happy."

By Anthony J. Varro, Contributing Editor

The Optimized Treatment Protocol (OTP) for the miraDry procedure by Miramar Labs (Santa Clara, Calif.) provides a solution to undesired perspiration that is so comfortable and efficient that patients not only give it rave reviews, but often refer friends and family. The OTP utilizes a high volume of anesthesia (e.g. tumescent) coupled with high energy delivery.

As Cynthia Diehl, M.D., a plastic surgeon based in Raleigh, N.C., said, "miraDry is my favorite machine. I'm so glad I bought it. Initially I hesitated because I'd heard that the numbing injections were very painful, but this has since been resolved with the OTP."

According to Rosalyn George, M.D., a dermatologist in Wilmington, N.C., the response after implementing OTP in her practice has been completely different. "The procedure is more comfortable, and there's much less postoperative discomfort, numbness and tingling."

"For safety, the tumescent anesthesia pushes critical structures farther away from where you're delivering the heat energy," Dr. Diehl explained. This provides the dual benefit of additional safety and patient comfort.

Sheila Nazarian, M.D., a plastic surgeon in Beverly Hills, Calif. added, "The tumescent fluid is much less painful than lidocaine," which reportedly burns when injected.

In Dr. Diehl's experience, when using tumescent anesthesia, "patients are completely comfortable, allowing us to treat at the highest energy level throughout the entire axillary region," rather than dialing down for sensitive areas. "Being able to treat at the highest energy level top-to-bottom provides a more dramatic result," she added.

Dr. Nazarian described post treatment as, "feeling like a sunburn for a day. Patients typically experience swelling for a day or two," she added, as well as painless lumps, bumps and numbness that may last around three weeks.

Dr. George, who personally underwent both the old and new protocols, said the former caused bruising that lasted four weeks, versus one week with the OTP.

The original miraDry protocol usually required two treatments for optimum results. However, with the OTP, Dr. Diehl pointed out that no patient has requested a second treatment. Similarly, Dr. Nazarian reported that 90% to 95% of her patients require only one treatment, which they find more cost-effective. In Dr. George's experience, only patients with true hyperhidrosis require two treatments.

As stated by all three physicians, the vast majority of patients achieve at least 90% sweat reduction. "I haven't had to use deodorant since my treatment in August 2015," said Dr. George.

"All of our patients are very satisfied with the procedure," Dr. Nazarian emphasized. "Its reliability and effectiveness help people gain trust in the practice," which results in interest in other procedures and word-of-mouth referrals.

"This is a procedure that everybody's happy with," Dr. George noted. Changing the protocol and marketing to all patients – those who may simply dislike odor, sweat and aluminum-based deodorants – has greatly increased the number of patients choosing miraDry, she observed.

"For many people this is a life-changer," said Dr. Diehl. "My patients are incredibly happy. What more can I want than for people to leave my office with a home run?"

Female patient, age 39 four weeks after miraDry Tx of left underarm. Photo was taken immediately after a 30 minute stationary bike workout in heated room.

MK0493.A

Stop underarm sweat.

Half the patients in your practice are interested in eliminating their underarm sweat and odor.[1*]

miraDry® is the first and ONLY non-invasive treatment proven in more than 55,000 procedures worldwide to permanently destroy underarm sweat and odor glands. Fast, safe, and comfortable, miraDry delivers patient satisfaction, among the highest of any non-surgical aesthetic procedure.

Find out more at www.miradry.com

*Not for pediatric use.

[1] www.RealSelf.com,world's largest community for information about cosmetic surgery, dermatology, dentistry, and other elective treatment, poll of 2200 females age 18-64.

MK0332-D 01/16

Strong Demand

High Patient Satisfaction

Clinically Proven

miraDry®

The sweat stops here.™

THE AESTHETIC GUIDE®
The Leading Aesthetic Practice Resource™
NOVEMBER/DECEMBER 2014

miraDry Sweat Treatment

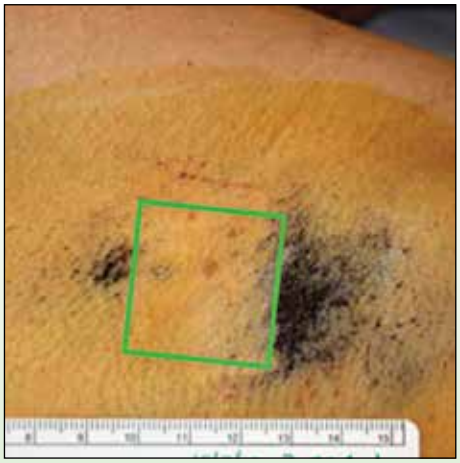
Appeals to Broad Patient Population

Byron Poindexter, M.D.
Plastic Surgeon
Reston, VA

Jason Pozner, M.D.
Plastic Surgeon
Boca Raton, FL

Sue Ellen Cox, M.D.
Dermatologist
Chapel Hill, NC

Susan Van Dyke, M.D.
Dermatologist
Scottsdale, AZ



Starch iodine test in axillary region three years after miraDry Tx. Dark areas show where patient is still sweating. Patient is not sweating in treated area.
Photo courtesy of Larry Fan, M.D.

By Jeffrey Frentzen, Executive Editor

Aesthetic patients that do not want to worry about embarrassing underarm sweat, odor or messy, chalky deodorant stains now have a treatment that offers a permanent solution. miraDry® from Miramar Labs, Inc. (Santa Clara, Calif.), uses precisely targeted microwave energy to destroy a patient's underarm sweat and odor glands. Since these glands do not regenerate, the effects of treatment are permanent.

miraDry is the only FDA cleared, non-invasive procedure that offers long lasting reduction of underarm sweat. Treatment benefits a full range of patients, including those suffering from axillary hyperhidrosis, those who want to stop using deodorants, as well as the much larger population of patients that want to eliminate "nuisance" sweating and odor. "If those bothered by sweat are altering their clothing because of sweating, they want the miraDry treatment," expressed Byron Poindexter, M.D., a plastic surgeon in Reston, Va.

"I liked the concept of permanent sweat removal, as well as removing the smell," said Jason Pozner, M.D., a plastic surgeon in Boca Raton, Fla. "Additionally, lots of health conscious people don't want to use antiperspirants containing aluminum."

Offering dramatic and permanent reduction of both sweat and odor, the procedure has also become popular with image-conscious aesthetic patients of all skin types. As Sue Ellen Cox, M.D., a dermatologist in Chapel Hill, N.C., pointed out, "Among my aesthetic patients the procedure is more for lifestyle reasons and to treat nuisance sweating. These are mostly professional people who do not want to worry about being embarrassed when they're in meetings, for instance."

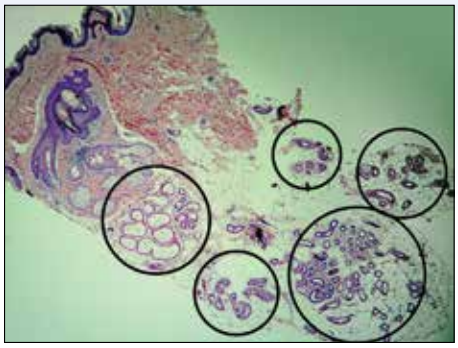
"We position the miraDry procedure as 'everyone sweats, but you don't need to,'" commented Susan Van Dyke, M.D., a dermatologist in Scottsdale, Ariz. Of the patients we've treated, about half are new and half are established. Of the new patients, a little more than half are male. This is very different from our normal demographic that is 85% female. miraDry is bringing new patients to our practice, which gives us the opportunity to expose them to all of the treatments we offer."

Although Dr. Poindexter has used the miraDry device to treat hyperhidrosis patients, he feels that it is a small number given that his surgical practice has a bit of a different focus on cosmetic procedures. "That said, we have seen a larger number of people who fall more in the category of bothered sweaters that benefit from the miraDry procedure."

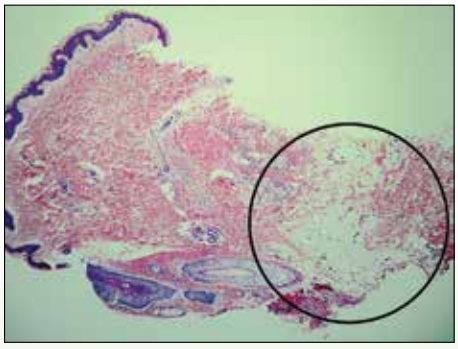
"We had patients we were successfully treating with BOTOX injections, but they would all ask about something permanent," Dr. Poindexter continued. "I had tried some of the other means, such as ultrasonic liposuction in the axilla, but without much success. A limiting factor in that for me was not

knowing the proper endpoint and fear of creating an issue, like skin burns or scarring that would have been worse than the original condition. When we received information on the miraDry technology and looked at the early data, it seemed like a nice fit. Then we tried it on a few people, including myself, and it was convincing."

Targeted microwave energy maximizes both efficacy and safety. This energy heats water in cells. While water is contained in all cells, the amount is much higher in sweat and odor glands compared to the fat tissue that surrounds them. The precisely selected 5.8 GHz frequency of the miraDry system provides the optimum depth of heating for sweat and odor glands. Energy is driven down from the surface and reflects off of the fat layer. During treatment the skin's surface is cooled with a proprietary hydroceramic cooling tip, creating a heat zone in excess of 60° C at only the interface of the dermis and fat, regardless of skin thickness. The epidermis, sensitive nerves and deeper structures are protected.



Human histology illustrating normal sweat glands before Tx



Absence of sweat glands six months after miraDry Tx

Photos courtesy of Nobuharu Kushikata, M.D.

Published studies have shown the treatment to be highly effective. Scientific data demonstrates 82% sweat reduction and more than 70% reduction in patients reporting problematic odor at two years. More than 30,000 miraDry treatments have been performed and patient satisfaction in commercial use has been reported as better than 90% – among the highest rate for all aesthetic procedures.

With a patient population that is 80% female and 20% male, Dr. Cox noted that though more women do the procedure, the men are probably the happiest with results. "The miraDry treatment has one of the highest rankings among all of our procedures," she reported. "Most of the time we give them two treatments, although sometimes we will do three. One treatment will eliminate about 70% of the sweat. Some patients only do one treatment and are happy. While it usually does not eradicate all the sweat, they are happy because the reduction in sweat makes it very tolerable for them."

miraDry is an easy, quick procedure that can be delegated and complications are practically non-existent, Dr. Cox added. "As an extra benefit, the treatment will remove a percentage of underarm hair and associated odor, which tends to make patients happy, as well," she said.

Future applications of this technology could conceivably include treatment of the hands, soles of the feet and other areas where people suffer from hyperhidrosis and nuisance sweat, stated Dr. Pozner. "The future of this device looks great. Envision all color hair removal, in addition to treating the hands and feet," he said.

MK0321.B

THE AESTHETIC GUIDE™

The Leading Aesthetic Practice Resource®

Changing Lives by Eliminating Hyperhidrosis

Hyperhidrosis is a disorder of the eccrine sweat glands, most often affecting the palms, soles and axillae, in which anxiety and other emotional or mental stimuli elicit excessive sweat. This chronic condition affects up to 4% of the global population with physical symptoms that include wetness, staining of clothes, odor, sweaty hands and clumsiness. When you include those who are bothered by their typical underarm sweat you soon realize the immense growth potential of this emerging market.

July/August 2014

Medical Insight, Inc.® • 130 Vantis #240, Aliso Viejo, CA 92656 • (949) 830-5409 • Facsimile: (949) 830-8944 • www.miinews.com

miraDry Technology Rewards
Patients and Practitioners

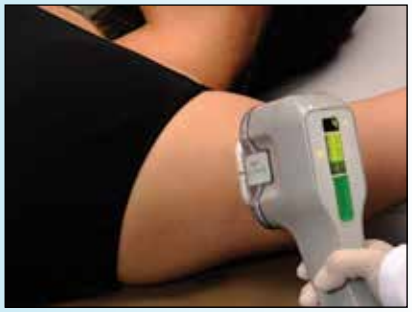
Anne Chapas, M.D.
Dermatologist
New York City, NY

Michael L. Maris, M.D.
Dermatologist
Dallas, TX

Eric S. Seiger, D.O.
Cosmetic Dermatologist
Fenton, MI

Christopher Khorsandi, M.D.
Plastic Surgeon
Las Vegas, NV

Susan Van Dyke, M.D.
Cosmetic Dermatologist
Scottsdale, AZ



miraDry treatment

By Jeffrey Frentzen, Executive Editor

Until recently, patients with axillary hyperhidrosis were limited to battling their excessive sweat with prescription-strength antiperspirants, repeated BOTOX injections or surgical removal of the sweat glands. However, a non-surgical solution, the handheld, energy-based miraDry® device from Miramar Labs, Inc. (Santa Clara, Calif.) requires no incisions or routine maintenance, and ensures long-term treatment of this indication.

With miraDry, practitioners deliver controlled microwave energy non-invasively to the region where the sweat glands reside, resulting in thermolysis of the glands. At the same time, a continuous cooling system protects the superficial dermis and keeps heat focused at the level of the sweat glands. Two treatments spaced three months apart are recommended for long lasting results.

According to Anne Chapas, M.D., a dermatologist in New York City, N.Y., the miraDry treatment has had a profoundly positive effect on the hyperhidrosis patient. "These patients are extremely embarrassed by their problem. It is not a socially pleasant type of problem to have. Multiple patients tell me they have to bring two shirts to work because they start sweating in the middle of a meeting. They suffer all the time."

The effects of a miraDry treatment can be seen almost immediately, expressed Michael L. Maris, M.D., a dermatologist in Dallas, Texas. "Not only can patients experience an immediate reduction, but results are long-term because the sweat glands do not regenerate. Published studies have revealed the treatment to be highly effective, with over 80% reduction in underarm sweat while delivering very high patient satisfaction."

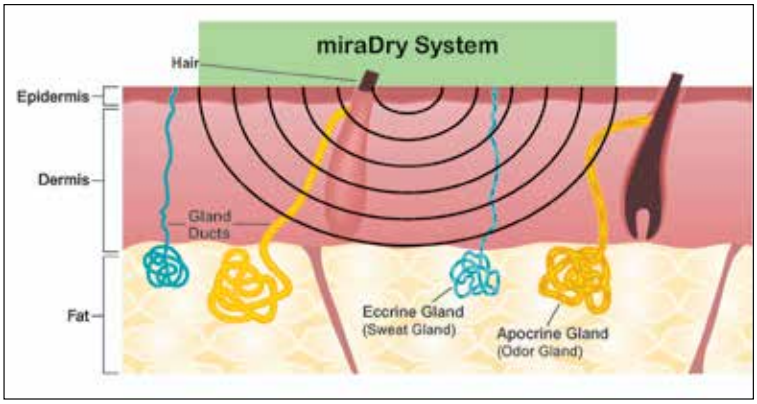
People with axillary hyperhidrosis, at last, have a permanent solution to their problem, said Eric S. Seiger, D.O., a cosmetic dermatologist in Fenton, Mich. "We keep busy with miraDry and do four, sometimes five treatments per week. I see people as young as 14-years-old to those in their 50s, and they come in embarrassed and devastated. They're looking for anything that can help them. Most of them have tried the

strongest prescription antiperspirants, and their life is severely altered by hyperhidrosis. They are extremely excited to get this treatment. It changes their life and represents a new beginning. To them, it's freedom."

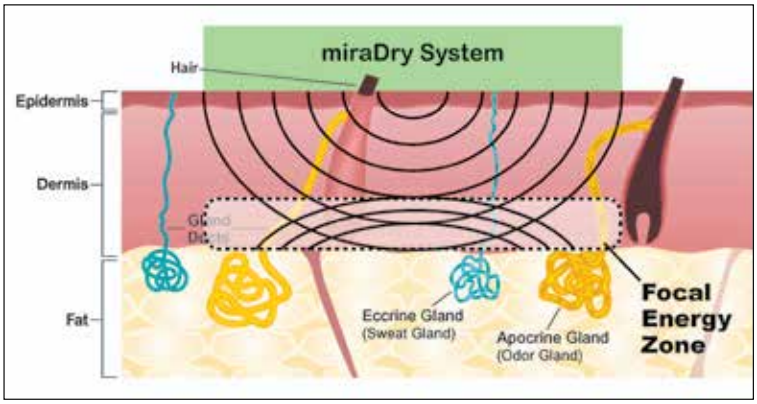
In Dr. Seiger's experience, the procedure takes about an hour. "Patients are very comfortable during treatment. Afterwards, there are a couple of days of swelling and soreness, but people go back to work the next day and experience instant relief from their sweating. Around three months out, 80% to 85% of patients begin to experience some sweating again and they come back for their second treatment. Most people achieve 80% clearance after two treatments, and that should last forever."

For Christopher Khorsandi, M.D., a plastic surgeon in Las Vegas, Nev., miraDry has been quite a good technology to have in the office. "People from all walks of life come to the office seeking treatment. We market it as a safe and effective long-term solution with minimal downtime and it works. Satisfaction has been close to 95% to 98%, which is as high as any procedure I know, and the side effects have been minimal," he shared.

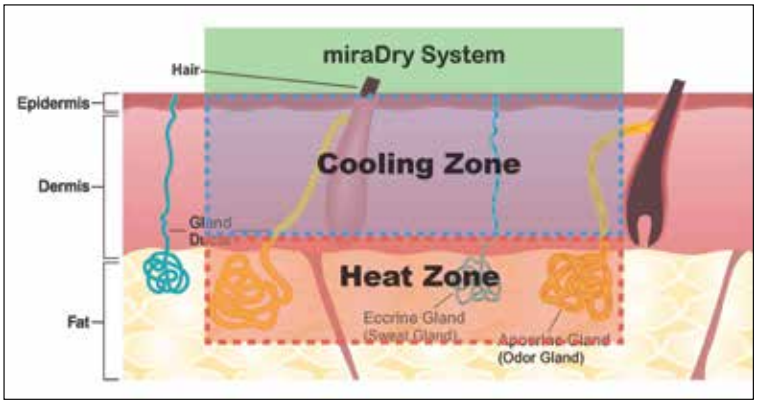
Interestingly, some of the side effects have actually been beneficial to patients, stated Susan Van Dyke, M.D., a cosmetic dermatologist in Scottsdale, Ariz. "It is very significant that miraDry treatments may also result in a reduction in underarm hair of all colors, including grey, as well as odor. Both apocrine glands and eccrine glands seem to be susceptible to the miraDry treatment."



miraDry delivers focused microwave energy to the dermal-fat interface region where sweat glands reside.



Energy becomes concentrated along the dermal-fat interface and creates a focal energy zone.



Continuous hydro-ceramic cooling system keeps heat zone at level of sweat glands.

Photos courtesy of Miramar Labs, Inc.

As Dr. Maris pointed out, the fact that treatment also effectively reduces underarm odor opens the door to a previously untapped market for miraDry providers. "Even though odor reduction is not an FDA cleared indication for miraDry, I've done several of these treatments. The efficacy rate is about as good as that for sweating, which has been really encouraging. One of my patients said her odor issues were very bothersome, a nine on a scale of ten. After the first miraDry treatment the number went down to one," he said.

Beyond the severe sufferers, there are also those that are affected by the nuisance of sweat (the "sweat-bothered"), who may not necessarily have hyperhidrosis, however, their underarm sweat is something that they want to eliminate, Dr. Khorsandi noted. "These include lawyers who have to wear a suit in and out of a courtroom, who don't want to show up looking flustered with underarm sweat stains. Hyperhidrosis can occur without the heat factor, sometimes triggered by anxiety levels. Specifically, here in Las Vegas, a lot of poker players come in for treatment. I have one guy who is a true hyperhidrosis poker player. He would prefer not to have to go in and out of the game to change shirts."

For anyone that has used strong antiperspirants to control excessive sweating, the miraDry treatment is a less chemically dependent and more holistic remedy, Dr. Maris highlighted. "Think about the chemicals one finds in deodorants and how we really don't know the lifelong effects of using those chemicals on your body. Although being bothered by sweat is not the same as dealing with the physical and emotional strain of hyperhidrosis, the treatment is the same and the outcomes are equally good," he said.

Like the severe sufferers, the sweat-bothered patient is extremely interested in their appearance, Dr. Van Dyke added. "They are interested in low risk, minimal or no downtime procedures to enhance their image. Since these miraDry patients are exposed to the other procedures that we offer as they wait in our lobby, during their consultation we ask about other cosmetic concerns. Not surprisingly the patients have other interests that we can address," she stated. "miraDry fits perfectly into our business model. It improves quality of life for the hyperhidrosis patient and also in the sweat-bothered patient, which is just about everyone that is concerned with their appearance."

"Since these miraDry patients are exposed to the other procedures that we offer as they wait in our lobby, during their consultation we ask about other cosmetic concerns. Not surprisingly the patients have other interests that we can address."

"I've seen a rise in the number of people coming in. When we first started using the device over a year ago, a majority of our patients heard about a 'procedure,' but in the first part of 2014, we have been getting calls asking for miraDry specifically."

Attracting patients with various levels of hyperhidrotic severity has been successful through the combination of both a practice's internal outreach and Miramar Labs' recent national campaign. "I've seen a rise in the number of people coming in," Dr. Chapas indicated. "When we first started using the device over a year ago, a majority of our patients heard about a 'procedure,' but in the first part of 2014, we have been getting calls asking for miraDry specifically."

Those looking to relieve their severe or bothersome sweating, "will seek us out using the Internet or some form of marketing or advertising," Dr. Seiger advised. "Once they are in our office, they may see other cosmetic procedures that we offer and become long-term patients. Then they turn around and send in their family members and friends."

"miraDry is so highly effective for hyperhidrosis patients, it really helps us to attract the patient with just nuisance sweating," Dr. Khorsandi stated. "Our substantial backlog of patients that have had success with miraDry, and their good word-of-mouth relaxes new patients who might otherwise think that a $3,000 investment in this treatment might be risky. We also have the positive stats and testimonials from established patients over the last year or so, which helps new patients feel better prior to treatment.

Considering miraDry's track record of efficacy and patient satisfaction, it is no surprise that practitioners are experiencing a spectacular return on investment (ROI). "Satisfied patients lead to profit," Dr. Maris stressed. "Owing to both word-of-mouth and my confidence that the procedure is likely to benefit the patient, I am probably a little bit more effective at selling the treatment. Moreover, even if the public is not convinced, one can look at the blogs that are written independently by patients that have had it done, and those are very positive. All of that translates into good business practice."

Other physicians agreed. "There is no other device like it on the market," Dr. Khorsandi emphasized. "It brings in patients that would not normally come up to the office, and when they arrive we offer a whole suite of different treatments. There are many times when I am grateful I have miraDry, when we perform three or four treatments in a day. That is revenue I would have never seen otherwise,

so miraDry has definitely added to my bottom line."

Similarly, for Dr. Van Dyke, miraDry has provided a completely new revenue stream. "My business goal is always to pay off any machine we buy within the first six months. We are right on track for doing that with miraDry. Patients want the treatment and it works, and it fits a niche that is not addressed adequately by anything else out there," she said.

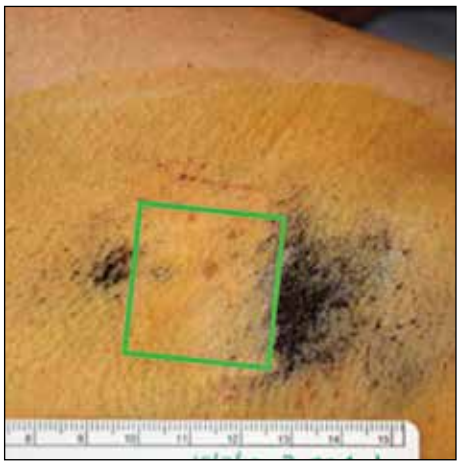


Image shows three year starch iodine test in axillary region. The inky areas show where the patient is still sweating, while the green box shows the treated area without sweat. This was taken three years after the patient received the miraDry treatment.

Photo courtesy of Miramar Labs, Inc.

In Dr. Maris's practice, miraDry is one of his best ROI experiences. "It doesn't require a lot of hands-on treatment time from me. This device is easy to use and the technology is safe, so I do a fair amount of delegating with much success," he stated. "The overhead from running it is not exorbitant and we have well-trained technicians, not to mention the extra income, which really helps a lot."

In Dr. Chapas opinion, the miraDry system holds impressive promise for the future, as well. "Like all new products, miraDry is still in its infancy and the company will be working on other indications in the future. This will also be very exciting when you consider other sweat-related issues not yet treatable. Not only will patients see us because they have underarm sweating issues, but also because of other issues, such as hand sweating and sweating in other body areas, and possibly acne and Hidradenitis suppurativa. These are the indications that the miraDry technology should someday be able to remedy."

"This device is easy to use and the technology is safe, so I do a fair amount of delegating with much succes. The overhead from running it is not exorbitant and we have well-trained technicians, not to mention the extra income, which really helps a lot."

THE AESTHETIC GUIDE®

The Leading Aesthetic Practice Resource™

Experts Explore Vast Potential of Microwave Technology

With the creation of new markets comes new opportunities. One novel approach in aesthetic medicine uses proven microwave technology to eliminate axillary sweat and odor glands to reduce both hyperhidrosis and osmidrosis. This modality also provides true color-blind axillary hair removal, but more importantly, researchers say these uses only scratch the surface of the full potential of this technology.

continued on page 3

July/August 2016
Circulation 25,000
www.miinews.com

Miramar Labs Creates New Markets with miraWave Therapy

By Kevin A. Wilson, Contributing Editor

With the introduction of its emergent flagship microwave technology, miraWave®, Miramar Labs, Inc. (Santa Clara, Calif.) is poised for unprecedented growth. The company's first device to utilize this modality is miraDry®, for permanent non-invasive axillary sweat, hair and odor reduction. Steve Kim, chief technology officer and founder of Miramar Labs shared, "In early 2007 we saw underarm sweat as a large, untapped global market, filled with opportunity. Controlling underarm sweat and odor is a multibillion dollar industry worldwide, but at that time therapies mostly consisted of underarm topical deodorants and antiperspirants. On the other end of the spectrum was surgery. That's a wide gulf between treatment offerings so we decided to actively pursue development of a non-invasive, energy-based modality to destroy sweat and odor glands permanently." With that vision, miraDry was created.

"We also wanted it to be affordable for patients and financially attractive to physicians, which meant strong profitability per procedure providing a high ROI and manageable costs overall. We're proud we were able to achieve those goals, Mr. Kim continued. "Physicians who obtain a miraDry device only need to perform about one treatment per week to pay for it within a year, and many do so more rapidly than that. Procedure profitability is further improved because the device is easy and safe enough for trained ancillary staff to operate."

The miraDry device was cleared by the FDA in 2011, followed by CE mark in 2013. In 2015, the miraDry device received FDA clearance for an expanded indication to include permanent hair removal for hair of all colors, leading the company to introduce a new procedure to the marketplace, miraSmooth®. Powered from the same device, this treatment allows practices to target the large hair removal audience with a unique product offering.

With continued development, miraWave technology has the potential to non-invasively treat hair, sweat and odor on other body regions. Additionally, physicians believe it may have more applications, suggesting a bright future for Miramar and early adopters of this powerful microwave technology.

Microwave Technology in Medical Aesthetics

Microwave energy was selected because it was proven, well understood and seemingly ideal. "Heat is the primary means by which controlled injury is induced non-invasively in aesthetic medicine," Mr. Kim explained. "We thoroughly investigated a variety of issues such as what tissue structures we wanted to affect, what we needed to avoid, and how to overcome whatever obstacles were presented. We worked with scientists that possessed expertise in all of the energy modalities (laser, RF, microwave, ultrasound) available to us to determine the best solution. Microwave energy was the clear winner because it is the only technology that automatically targets the interface between skin and fat where sweat and odor glands reside."

The difference between the way microwaves affect adipose tissue versus skin tissue causes the emitted energy to be reflected back toward the skin, colliding with oncoming energy waves to create peaks, which focus the effect

Steve Kim
Chief Technology Officer and Founder
Miramar Labs
Santa Clara, CA

Christine Dierickx, M.D.
Medical Director
Laser and Skin Center of Boom
Boom, Belgium

Jeremy A. Brauer, M.D.
Director of Clinical Research
Laser & Skin Surgery Center of New York
New York, NY

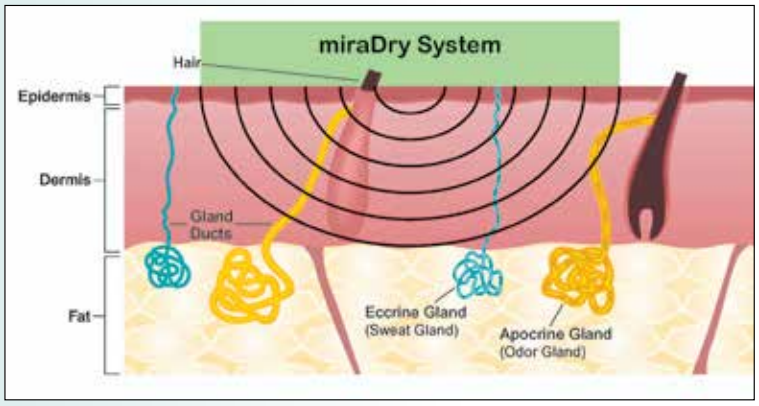
Louis P. Bucky, M.D.
Plastic Surgeon
Philadelphia, PA

Joshua Weitz, M.D.
Clinical Director
Dermatology Associates
Rochester, NY

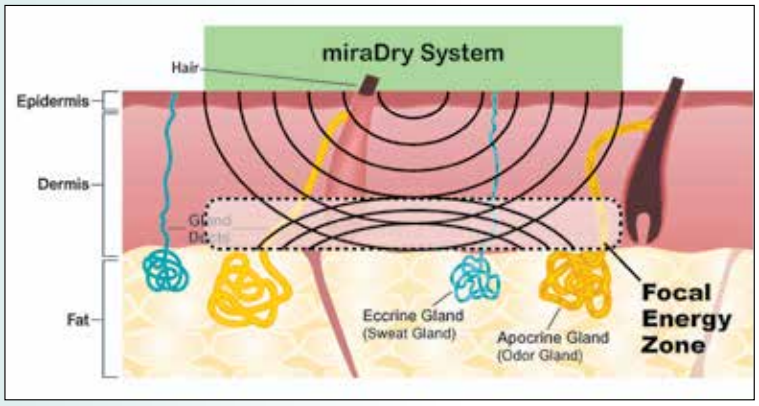
Cynthia Diehl, M.D.
Owner
Diehl Plastic Surgery
Raleigh, NC

Sheila Nazarian, M.D.
Founder
Nazarian Plastic Surgery
Beverly Hills, CA

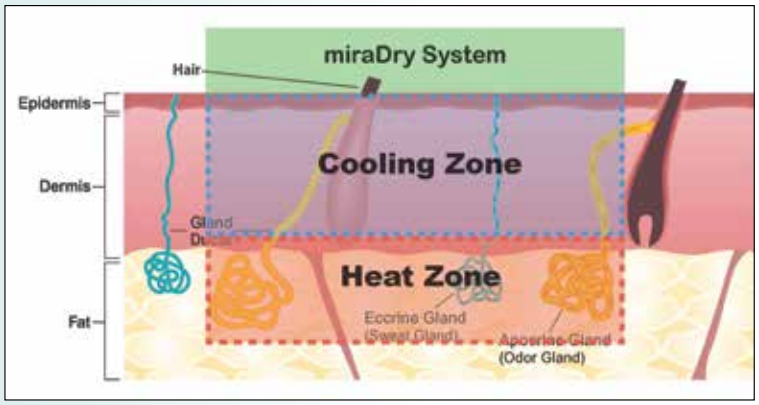
Rob Ellis
Vice President of Global Marketing
Miramar Labs
Santa Clara, CA



miraDry delivers focused microwave energy to the dermal-fat interface region where sweat glands reside.



Energy becomes concentrated along the dermal-fat interface and creates a focal energy zone.



Continuous hydroceramic cooling system keeps the heat zone at the level of sweat glands.

Photos courtesy of Miramar Labs, Inc.

appropriately. Hydroceramic contact cooling prevents thermal injury to the epidermis and the majority of the dermis, while allowing heat injury to be created in the shallow subcutaneous tissue. "For our sweat application, the goal was to raise the temperature of target cells to above 60° C, which causes instant cell death, without damaging the surface skin," Mr. Kim noted. "What we came up with is a device that will automatically focus the energy to that area, regardless of skin thickness, causing thermal necrosis of the apocrine and epocrine glands. This significantly reduces sweat and odor in patients leading to a very high satisfaction rate. We later found that we had permanent axillary hair removal as well."

Selectivity is a key contributor to the success of any medical treatment, and Miramar's miraWave therapy is no exception, according to dermatologist Christine Dierickx, M.D., medical director of the Laser and Skin Center of Boom (Boom, Belgium). "In hindsight it seems obvious to use microwave energy in this way. Microwave energy agitates water molecules, which creates heat. It will be more specific to water, and sweat glands contain more water than neighboring structures in the skin, so this modality will selectively heat sweat glands."

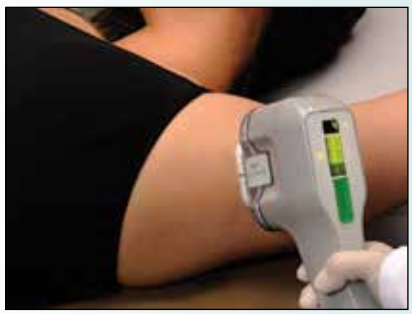
Depth of energy deposition is also important, according to Jeremy A. Brauer, M.D. director of clinical research at the Laser & Skin Surgery Center of New York (New York, N.Y.). "The miraDry device is optimized to deliver microwave energy directly to the depth where sweat glands and hair follicles reside."

According to Dr. Brauer the device is easy to use. "First you have to choose a template which best fits the patient's underarm area, and then use it to mark the area with temporary tattoos," he said. "These guide the operator. Once in place, we administer tumescent anesthesia, and can then safely begin the procedure, following the markings carefully to assure complete treatment based on whichever protocol we need – miraDry for sweat and odor or miraSmooth for hair removal." The result is permanent reduction in axillary sweat and odor, and/or permanent hair reduction regardless of hair color and skin type, most often in a single application.

For Louis P. Bucky, M.D., a plastic surgeon in Philadelphia, Penn., miraDry opens a new avenue of collaboration between plastic surgeons and their patients. "When people think 'plastic surgery' they think of appearance. This

technology provides us with another pathway to address not only the patient's appearance, but their self-image and well-being," he said. "Traditionally we do this through surgical correction, but these concerns can be strengthened by non-invasive solutions for sweat and odor, especially in that segment of the population affected by related disorders. It makes even more sense because some aspects of miraDry treatment, such as the use of tumescent anesthesia, are already familiar to plastic surgeons. Most notably, we are in the lifestyle treatment field; people want to not only look better, but feel better, and this is a prime example of how we can help them."

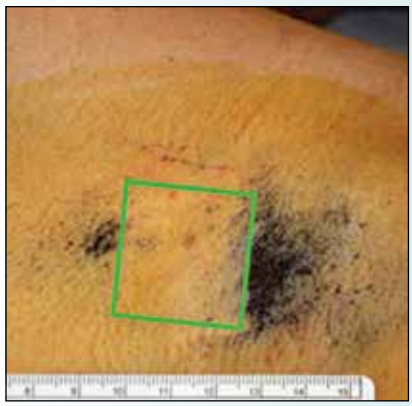
Joshua Weitz, M.D., clinical director at Dermatology Associates (Rochester, N.Y.) likened sweat and odor reduction to acne treatment wherein the lines between aesthetic and medical can be blurry except in the most severe cases. "Some people may have an obvious medical need, but for others it's a personal choice. And people are naïve not only to this technology, but to other therapeutic options available such as neurotoxins, oral preparations or prescription topicals."



miraDry treatment
Photo courtesy of Miramar Labs, Inc.

For Dr. Weitz, miraDry has been a home run for sweat and odor reduction. "We chose this technology for our office because it works so well, and we thought it had a lot of potential. Our experience has proven its value because it is so effective, and for patients it has had a real impact on quality of life. We're excited to see how this develops as more people become aware of the technology. Sweat and odor play a powerful role in social interaction, so reduction of these issues is important."

This growing global popularity of miraDry is also the result of a refinement in treatment protocols. "The safety and efficacy of miraDry have been there from the start, but the anesthesia protocol initially involved local infiltration using multiple needle sticks," Dr. Brauer explained. "Originally this technology was designed as a two-treatment protocol, so patients would get treated and then come back three months later for the second session. This worked, but introduction of anesthetic was complicated and time consuming, and therefore less than ideal. Additionally, we found that with higher energy levels we could get down to one treatment most of the time."



Starch iodine test in axillary region three years after miraDry Tx. Dark areas show where patient is still sweating. Patient is not sweating in treated area.
Photo courtesy of Larry Fan, M.D.

Now, with the Optimized Treatment Protocol (OTP) using high volume anesthesia (HVA), the treatment is even more tolerable. "The use of tumescent anesthesia has made a big difference; fewer needle sticks seems to cut down on the bruising we used to see. Making any treatment as close to painless and hassle free as possible is always a main goal for obvious reasons, and patients definitely prefer a single application over multiple sessions," Dr. Brauer added.

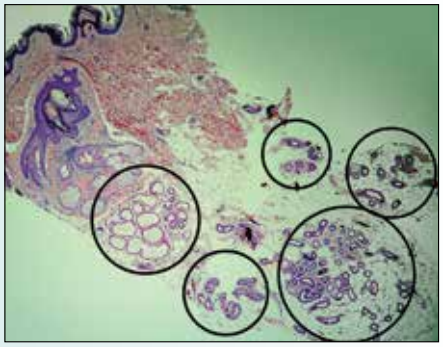
"The addition of HVA provides another measure of safety as well," Dr. Dierickx advised. "By using a tumescent method we inflate the area with a relatively large volume of solution, thereby creating a barrier between the skin we wish to treat aggressively and the sensitive underlying tissue, especially the lymph nodes and nerves that innervate the arm to provide sensation and motor function. This gives me added confidence that the chance of potentially injuring underlying tissue structures is minimized, thereby avoiding a temporary alteration of sensation, strength and motor function in the arm and hand. Up to now, using this protocol, every one of my patients has been satisfied with the procedure and the results."

Cynthia Diehl, M.D., owner of Diehl Plastic Surgery in Raleigh, N.C., described the cross section of patients that may comprise a typical market for miraDry. "You

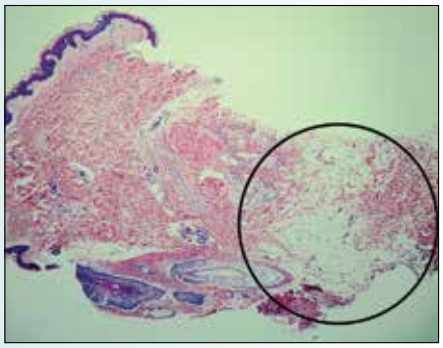
start with the ones who have real, obvious hyperhidrosis, who desperately need this sort of therapy to dramatically improve their quality of life. These people long to feel normal. Then we have professionals who are giving presentations and find underarm sweat distracting, or who are in close proximity to individuals such as patients all day and want to feel less self-conscious. We have people who just get sick of stained shirts or don't want to use aluminum-based or other chemical underarm products. Once this technology becomes further established I think even more people will become interested. Many of our patients come from word-of-mouth referrals."

While there is some recovery involved, patients may return to most normal activities within 24 hours, Dr. Diehl stated. "We're injecting 100 cc to 120 cc of tumescent fluid into each armpit so they feel a puffiness. As that subsides it reveals the inflammatory process, which is part of what demonstrates that the treatment worked; what patients call the lumps and bumps – somewhat tender like bruises. There is temporary reduction of sensation. Discomfort is manageable with OTC analgesia and ice. It may take four to six weeks for the lumps and bumps to fully resolve and a few months for sensation to normalize, but people don't seem to mind because it's only a single treatment, works so well, and offers permanent results."

Nevertheless, expectations management might be the easiest part of the miraDry experience, Dr. Diehl shared. "The success and satisfaction rate with this technology is remarkably high," she said. "With other aesthetic devices we have to overcome media and advertising hype so patients have a fair idea of what they can realistically expect. We simply do not have that problem with miraDry."



Human histology illustrating normal sweat glands before Tx



Absence of sweat glands six months after miraDry Tx

Photos courtesy of Nobuharu Kushikata, M.D.

A New Innovation in Permanent Hair Removal

Branded as miraSmooth, permanent, color-blind axillary hair removal with the miraDry device is in some ways a breed apart from laser or light-based hair removal, explained Dr. Brauer. With the latter technologies clinicians are depending on the principle of selective photothermolysis, which has been harnessed for numerous aesthetic and medical treatments over the past few decades. "To be effective you need a target chromophore, in this case pigment in the hair," he began. "Skin pigmentation may be a competing chromophore, especially in the case of darker skin types, so more careful deposition of energy is required and we often use a long pulsed 1064 nm Nd:YAG for this group of patients."

"When treating with microwave energy, we're relying on non-invasive deposition of energy affecting water molecules selectively so we're destroying hair follicles in any growth phase and hair or skin color are non-factors. Additionally, we usually need only one treatment," Dr. Brauer continued. "The downside is that the subcutaneous nodules and cords – the discomfort associated with this therapy – are a somewhat more involved recovery. Also, total time in office is often longer per session. Therefore, it might be looked at as a trade-off between lasers and light providing shorter, but more sessions for some skin and hair types with less than complete clearance, versus microwave energy providing permanent and more complete axillary hair removal for virtually anyone in one longer session, with somewhat more discomfort afterward."

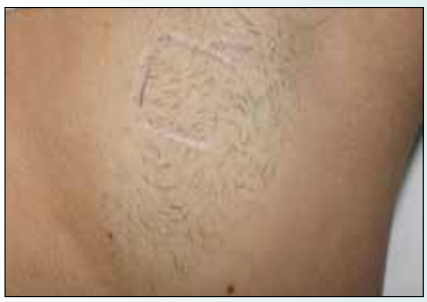
"Studies have shown that with laser hair removal, in a single treatment we may see 15% to 20% reduction," Dr. Dierickx reported. "And as hair diameter

and color is reduced over the course of several applications it becomes more difficult to treat. It is because of these and other factors that a patient may need up to ten sessions to achieve long-term hair reduction. Microwave-based hair removal has been shown to provide up to 70% reduction with a single treatment so apparently it can treat these follicles more thoroughly. In one or two sessions with microwave technology we achieve better results for any hair color or type than we can expect with laser- or light-based modalities in five to ten applications."

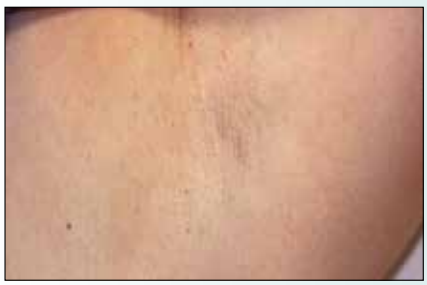
Female patient, age 39 four weeks after miraDry Tx of left underarm. Photo was taken immediately after a 30 minute stationary bike workout in heated room.

Photo courtesy of Mirimar Labs

According to Dr. Dierickx, in a study first presented by Dr. Brauer at the 2015 annual conference of the *American Society for Laser Medicine & Surgery* in Kissimmee, Fla., patients were recruited specifically for hair removal, rather than sweat and odor reduction, to investigate the effects of treatment on the axillary hairs. "In this study, typical treatment settings were applied: a single pass with energy levels between 3 and 4, using the original intradermal anesthesia protocol," Dr. Dierickx noted. "They found that hair reduction seemed dependent on the energy level chosen, meaning that more energy meant increased hair reduction." Dr. Dierickx performed a second study using the HVA protocol at the highest energy setting (5). "We also decided to do a double pass rather than a single pass because pictures from the first study showed that small linear areas were skipped when treating. Since it is difficult to place a pulse exactly next to the previous pulse and one may miss hair follicles, our second pass was made perpendicular to the first pass." To control any potential increase in incidence of side effects, a split axilla protocol was used in which one side was treated with a single pass, and the other with the double pass pattern. "What we found was excellent clearance of hair with no difference in side effects. Patients reported no more pain, swelling or inconvenience with the double pass side and at nine months out we've seen no regrowth of hair in the double pass side. And we included patients with very fine, light hair, which would have been poor candidates for laser or light-based hair reduction."



Underarm hair before Tx



One year after one miraSmooth Tx

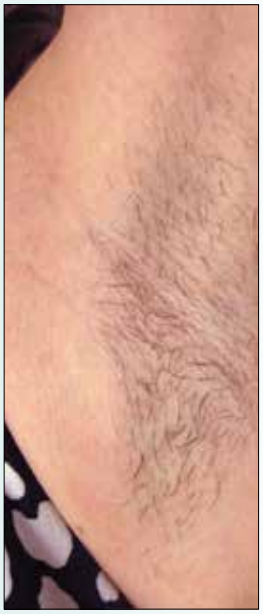
Photos courtesy of Miramar Labs

Expanding an Emerging Market

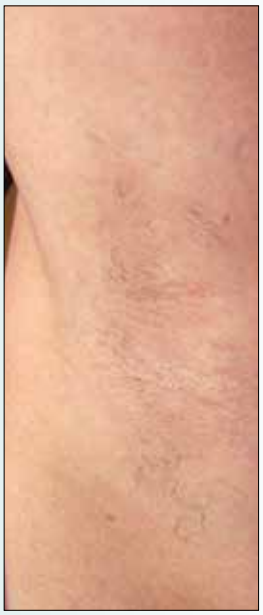
According to Sheila Nazarian, M.D., founder of Nazarian Plastic Surgery in Beverly Hills, Calif., there are financial advantages for physicians bringing this device into their office. "In addition to my medical training I was an economics major in college and hold a Master's Degree in medical management, because I've always been interested in business. I see the challenge with this technology as being one of building awareness," she explained. "This means marketing, which many of my colleagues are reluctant to do, but is essential to the success of this therapy. Efficacy is not the problem with these procedures, it is awareness."

Dr. Diehl agreed. "There are people looking for sweat reduction out there doing two neurotoxin treatments a year who could pay the same amount for one session with miraDry, and get permanent results. They just need to know that there is a great alternative. Strangely enough we're getting more referrals than you might expect because the results are so good, especially with the HVA protocol where we can use the highest energy levels in a single application."

Dr. Nazarian described a culture among plastic surgeons in which marketing is seen as less than classy. "It's almost as if having to market yourself suggests that you're not legitimately trained or unethical in some way," she revealed. "The rationale to overcoming this is simple. Who better than us to offer these treatments to patients? If we experts don't get the word out, others will, and they may be less qualified. We need to lead the way into this massive market and preserve its integrity if we're going to fully develop it. We must change with the times."



Underarm hair before Tx



One year after miraSmooth Tx

Photos courtesy of Miramar Labs

"In our practice we have signs up everywhere telling patients that miraDry can stop underarm sweat and odor, because we want to raise awareness," said Dr. Bucky. "In my experience people aren't really aware that this exists, but once they become aware they consider it, especially if they feel they have problems with sweat and odor. People are generally quiet about these sorts of issues because they are embarrassed or they don't think there's much that can be done, but our early adopter patients are ecstatic about the outcomes because in many cases they've been life changing. And results are permanent, unlike injectable neurotoxin, which works well, but requires maintenance at least every six months. If we were marketing this more heavily I think we'd be seeing a lot more patients asking about miraDry. The staff also appreciates the procedure because it's easy to perform and patients love the results."

For Dr. Nazarian the results of marketing have been visible. "We have done billboards and while the ROI is not as high as social media, it has been great for branding. Billboards have historically had a stigma, but we see this turning around. Sweat and odor problems are more embarrassing to a lot of people than visible aging, and easier to avoid discussing, so we needed to get the word out. Patients come from all walks of life, beyond actors and models, we've seen so many different types of professionals, from business people sick of sweat-soaked armpits during presentations and the stains that come with them, to people like dental hygienists or physicians who hover over patients and are conscious of their potential sweat and odor. These people won't know miraDry is available unless we tell them." Then there are the medical cases. "We had one girl who went through several changes of clothing daily in school because of sweating, going so far as to wear maxi pads under her arms. So this is a life changing and gratifying procedure that affects quality of life."

Return on investment is also excellent, Dr. Nazarian reported. "It doesn't take many treatments to pay off your cost outlay, and given the sky high rates of success and satisfaction we're seeing, if you put the word out there you can quickly move into profitability," she stated. "I paid off my device in four months of treatments, it's been that successful. If you are aggressive at all you should see profitability on the horizon."

The Future of miraWave Technology

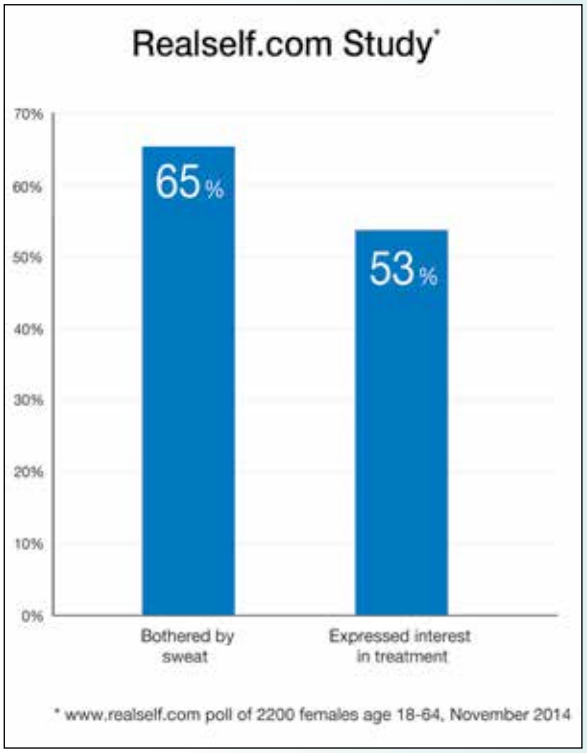
Having delivered the device as well as a valid and attractive business model, Mr. Kim suggested that more applications are being aggressively researched. "There are places all over the body where sweat, odor and hair might be successfully addressed using our technology," he suggested. "All we need to do is what we did before, study the anatomy, overcome obstacles, and do a better job than what's out there."

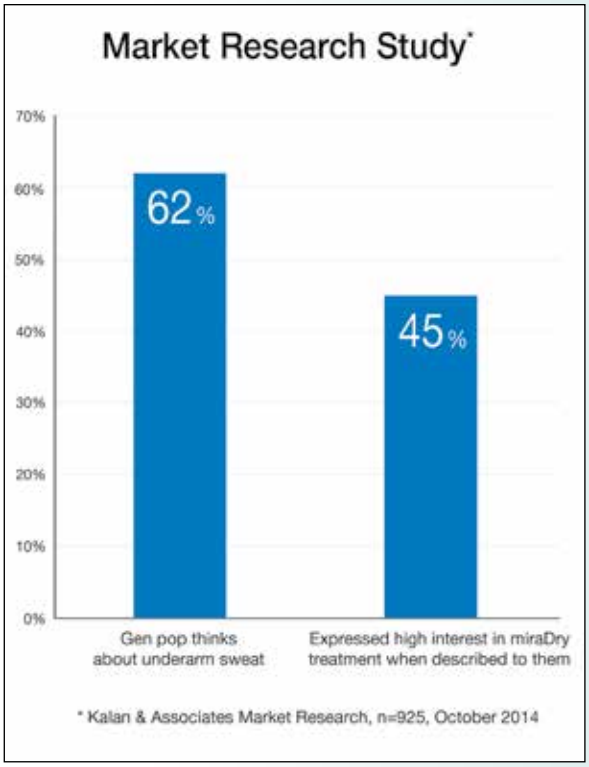
"I'm excited to be involved with the miraWave technology because of its potential in the global marketplace," said Rob Ellis, vice president of global marketing at Miramar. "In all my years in this industry I've seen few devices with miraWave's ability to shake up the industry. Not only does this modality do something well like nobody else, featuring technology no one else in aesthetic medicine is using, but it has already seen the hair removal indication added, which is further testament to what this technology may be able to do. We've envisioned a device that's easily expandable and have designed the current platform with that in mind. In the future we expect you'll be able to program in the indication and body area you want to treat, and the platform will modify the settings accordingly."

Dr. Dierickx is a believer in the potential of microwave technology for other uses in aesthetic medicine. "What we have is another mode of delivering heat energy, which is the backbone of many successful therapies we rely on today. The company is examining ways in which we may harness the technology differently to treat other indications and body areas. By manipulating the cooling protocol, for example, we may be able to change the depth at which we deliver energy to target sebaceous glands and treat acne, or target the skin to induce neocollagenesis. This is in addition to finding new ways to treat sweat glands and hair follicles on other body regions."

Patients in Dr. Nazarian's practice are eagerly awaiting further developments to the miraWave platform. "After seeing what miraDry did for them, many patients ask about using it for other body areas such as hand or foot sweat, or removal of hair all over the body," she stated. "Miramar will need to refine protocols and build new, larger microwave applicators, among other things, to make it work but when they do, patients are ready for it."

"As time goes by and awareness grows, I would wager that demand for miraDry will explode," Dr. Weitz speculated. "At our practice we're focused mostly on non-invasive modalities, maybe 70% medical, 30% aesthetic and miraDry has the highest percentage of satisfaction of anything we've ever offered. We perform a lot of treatments and our success rate to date is 99.4%, and there is no arguing against that."





THE AESTHETIC GUIDE®
The Leading Aesthetic Practice Resource™
JANUARY/FEBRUARY 2015

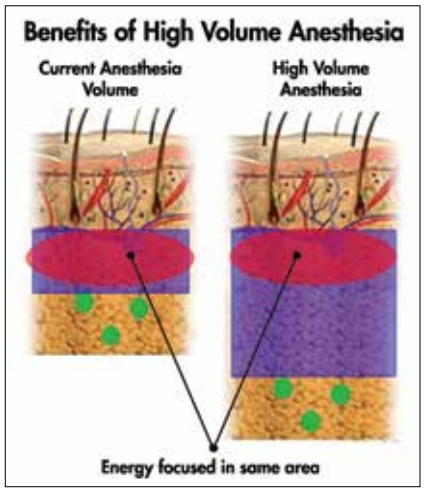
New miraDry Protocol

Stops Sweat in as Little as One Tx

Carolyn Jacob, M.D.
Dermatologist
Chicago, IL

Larry Fan, M.D.
Plastic Surgeon
San Francisco, CA

"With HVA and increased energy levels, some patients may only need one application to be happy with their results."



Increasing the volume of fluid injected in the target tissue creates a separation between skin and the nerves, better protecting the underlying structures, including the brachial plexus. This extra fluid has been proven to not impact efficacy.

Image courtesy of Miramar Labs, Inc.

By Jeffrey Frentzen, Executive Editor

The miraDry® device from Miramar Labs, Inc. (Santa Clara, Calif.), the only clinically proven, FDA cleared solution to permanently eliminate underarm sweat glands, is now being performed using a high volume anesthesia (HVA) approach. HVA enables the safe use of higher energy levels, delivering excellent patient satisfaction in as little as one treatment.

With the miraDry procedure, accurate, controlled microwave energy is delivered to the dermal-fat interface, effectively eliminating the sweat and odor glands. The new HVA approach delivers greater patient comfort and provides a larger safety buffer between the focal energy zone and sensitive nerves and deeper structures.

"We use a fanning technique to administer the HVA," expressed Carolyn Jacob, M.D., a dermatologist in Chicago, Ill. "With this approach, you can inject the anesthesia under the skin in only one or two small areas. This makes the treatment easier for the patient and saves time for the injector. There is no difference in the results patients see, but discomfort during the procedure is reduced because there are far fewer anesthesia injections at the beginning of the treatment," she said.

"After performing a study using ultrasound imaging to visualize the subcutaneous anatomy of the axilla, we compared the location and depth of the brachial plexus with standard injection anesthesia versus HVA," stated Larry Fan, M.D., a plastic surgeon in San Francisco, Calif. "With HVA, the nerves are pushed much deeper beneath the surface of the skin, adding another safety zone to the treatment. As well, side effects are decreased and the duration of underarm swelling, numbness and tingling also seems to be reduced."

Some patients in Dr. Fan's practice that previously underwent the miraDry procedure using the original anesthetic technique at a conservative energy level received a more aggressive follow-up using the HVA approach. "Every single patient in this group told me that the HVA treatment was easier and more comfortable, and recovery was significantly faster," he noted.

This treatment is very well received, has minimal complications and offers a very acceptable side effect profile, Dr. Fan advised. "While patient satisfaction with miraDry is already among the highest of the non-invasive procedures we offer, with the new protocol, patient satisfaction is even higher.

In addition, HVA provides physicians with the confidence to increase the energy level used during the procedure, allowing them to further tailor the treatment to patient needs. "With HVA and increased energy levels, some patients may only need one application to be happy with their results," Dr. Fan added.

MK0346.B

THE European
AESTHETIC
The Leading Aesthetic Practice Resource™
AUTUMN 2015
GUIDE™

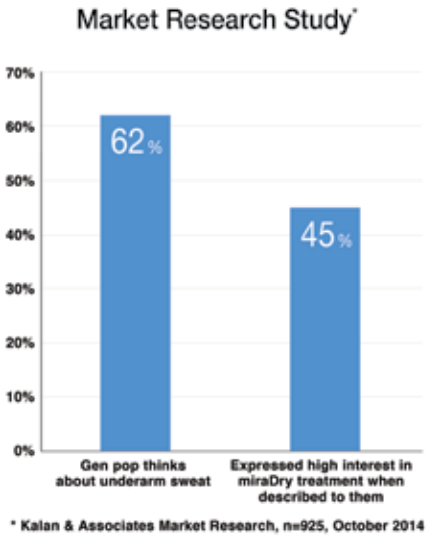
New Protocol Enhances miraDry

Sweat Reduction Outcomes

Professor Christoph Schick
Head of the Deutsches Hyperhidrosezentrum DHHZ
Founding Member
International Society of Sympathetic Surgery
Munich, Germany

Joshua Weitz, M.D.
Clinical Director
Dermatology Associates
Rochester, NY, USA

"With the new OTP, high volume anesthesia (HVA) and miraDry's highest energy levels are combined to safely decrease treatment time and side effects, while increasing patient satisfaction."



By Jeffrey Frentzen, Executive Editor

The sweat eliminating miraDry device from Miramar Labs, Inc. (Santa Clara, California, U.S.) – currently one of the most popular aesthetic procedures worldwide – now utilizes a new optimized treatment protocol (OTP) that provides an improved patient experience while maintaining the high efficacy and satisfaction rates the procedure is known for. In addition, the company has implemented a revised pricing structure that benefits a practice's bottom line.

miraDry is an FDA cleared and CE marked device that delivers non-invasive, localized microwave energy to destroy underarm sweat and odor glands, offering immediate and permanent results.

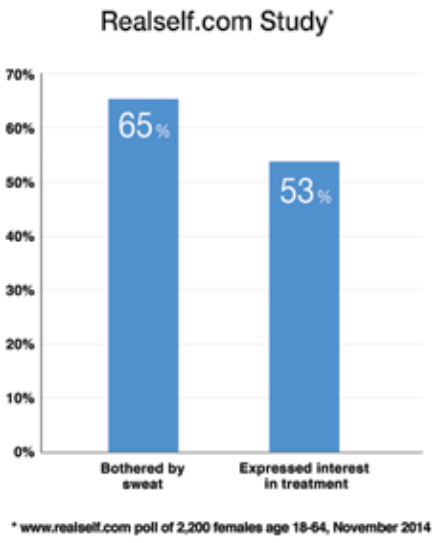
Adding the miraDry treatment to a physician's range of offerings has provided a safe, reliable solution for anyone – from people that sweat excessively to those who just don't want to deal with nuisance sweat, expressed Professor Christoph Schick, head of the Deutsches Hyperhidrosezentrum DHHZ in Munich, Germany, and founding member of the *International Society of Sympathetic Surgery*.

"miraDry uses a novel method that non-invasively achieves instant results, with no surgical intervention required," Prof. Schick stated. "The sweat glands are targeted with microwave energy and permanently destroyed by the resulting heat. Simultaneously, the unpleasant odor also disappears."

The technology is very impressive, Prof. Schick continued. "Three years ago I would never have thought that this technology was even possible, to heat tissue at depths of 4 mm to 5 mm without burning the surface of the skin."

With the new OTP, high volume anesthesia (HVA) and miraDry's highest energy levels are combined to safely decrease treatment time and side effects, while increasing patient satisfaction, expressed Prof. Schick. "The original protocol was far too complicated and took too long. Also, we had some large patients come to our clinic and would very often have to treat a big area, up to 140 mm or even 180 mm. Administering the anesthesia alone sometimes lasted more than 15 or 20 minutes. Utilizing HVA, or tumescent anesthesia, allows the procedure to go more quickly and the results have been superior," he advised.

Joshua Weitz, M.D., clinical director at Dermatology Associates in Rochester, New York, U.S., agreed, adding, "One thing that has really helped in terms of converting our patients to the miraDry procedure was the introduction of tumescent anesthesia. With the old method, we used a fairly complex template for delivering many injections of lidocaine in very small volumes barely beneath the surface of the skin. People would feel each little poke like a bee sting. Now that we have gone with the tumescent HVA method patients barely feel one, maybe two pokes.



"I feel what we're seeing with miraDry is just the tip of the iceberg and am looking forward to what the demand will be as patient awareness continues to increase."

Essentially we have now made the most uncomfortable portion of the procedure, the anesthesia delivery, very comfortable."

According to Prof. Schick, "By 'inflating' the area with a large volume of fluid more distance is created between the surface of the skin and the underlying structures, such as nerves, so nerve injury by heat is almost impossible. The procedure is now even safer. Even in very slim people."

Compared with the old method, the patient experience with the new OTP has been like night and day, said Dr. Weitz. "In the past, some patients would experience slight discomfort and downtime after the procedure. With the HVA method this is virtually a non-issue. Among the 50 plus patients we have treated in the last few months, only a small number have experienced very minimal downtime. The process has become quite simple."

Combining HVA with miraDry's highest energy settings has notably increased patient satisfaction, Dr. Weitz maintained. "Recovery time has been fantastic," he said. "You can treat most people at level five. For me, I can confidently tell patients that with the OTP we achieve excellent results after only a single treatment."

In conjunction with the value offered by the OTP, Miramar Labs' recently revised pricing recommendations based on reduced treatment time and added benefits for the patient, as well as the potential for increased patient volume and profitability for practices. "Before, we had patients that would balk at paying $3,000 for two treatments," reported Dr. Weitz. "Now, they don't bat an eye when you tell them that it's $1,900 for the first treatment, and we offer a slight discount for the second treatment."

To help practices more effectively attract new miraDry patients, Miramar Labs' offers marketing support via a new "miraDry Me" campaign that has also become very important, noted Dr. Weitz. "The improvements I've seen with OTP with respect to patient comfort and results are leading to more widespread interest among patients," he expressed. "Couple that with the new campaign designed to speak to everyone, and I've seen business improve fivefold and fully expect the volume to continue growing."

Dr. Weitz employs a combination of internal and external marketing, which has attracted new patients that are interested in miraDry treatments. "Once they contact us, we are able to successfully convert those consultations to treatments over 90% of the time," he stated. "I feel what we're seeing with miraDry is just the tip of the iceberg and am looking forward to what the demand will be as consumer awareness continues to increase."

#MK0455.A

miraDry Sweat Treatment
Attracts a Wide Spectrum of Patients

David Eccleston, M.D.
Aesthetic Physician
Birmingham, UK

Itzhak Vider, M.D.
Head of Medical OR
Aesthetic Medical Center
Herzliya, Israel

Adrian Krahenbuhl, M.D.
Dermatologist
Biel, Switzerland

"I was rendered almost entirely sweat-free after one application. I was so impressed, I decided then and there to acquire a machine for my practice, which has proven to be a very sound investment and extremely popular with patients."

By Jeffrey Frentzen, Executive Editor

As a permanent solution to embarrassing underarm sweat, odor or untidy deodorant stains, miraDry® from Miramar Labs, Inc. (Santa Clara, California, U.S.) will appeal to a wide-range of aesthetic patients. This energy-based device offers the only CE mark approved, non-invasive procedure for long lasting reduction of underarm sweat. miraDry uses precisely targeted microwave energy to destroy a patient's underarm sweat and odor glands. Since these glands do not regenerate, the effects of treatment are permanent. miraDry treatments target patients suffering from bothersome axillary sweating, hyperhidrosis patients, those who are looking to stop using deodorants, as well as the much larger population of patients that want to eliminate "nuisance" sweating and odor.

"When I first heard about miraDry I was intrigued," expressed David Eccleston, M.D., an aesthetic physician in Birmingham, U.K. "I have been treating excessive sweating very successfully with BOTOX from Allergan (Marlow, Buckinghamshire, U.K.) for many years. The main problem, however, was that the cost of treatment was unsustainable for many patients. As a result, there is a definite drop-off in follow-up appointments."

Upon further investigation, Dr. Eccleston was impressed with the high satisfaction scores among U.S. miraDry patients in both clinical trials and published reports from colleagues. "As a result, I tried the machine and underwent treatment myself in June 2014," he said. "I was rendered almost entirely sweat-free after one application. I was so impressed, I decided then and there to acquire a machine for my practice, which has proven to be a very sound investment and extremely popular with patients."

Expectations were high that miraDry would provide a permanent, long lasting solution to excessive sweating, noted Itzhak Vider, M.D., head of Medical OR at the Aesthetic Medical Center in Herzliya, Israel. "I was sure that this was a must-have in my clinic," he said. "For me it is not just another device. It is a game changer that has transformed how we work and treat both hyperhidrosis and those who suffer from unpleasant sweating. It is one of the major breakthroughs in the industry."

Adrian Krahenbuhl, M.D., a dermatologist in Biel, Switzerland, who has been offering patients a range of options to treat both hyperhidrosis and nuisance sweating agreed. "We used both surgical and laser-based solutions, as well as BOTOX injections, until I found miraDry," he shared. "To me it was clear that there was now a non-surgical treatment that was effective. I read the scientific literature and what I have seen after treating more than 40 patients is that there is almost no medical risk."

Patients are very happy with the results, noted Dr. Eccleston. "Patient satisfaction has been extremely high. In fact, of all the device-based procedures we offer, the satisfaction level has generally been higher with miraDry than with any other treatment."

The device is technically very easy to use and side effects are minimal, Dr. Eccleston added. "Successful outcomes rely on precise marking of the area to be treated by application of a transfer to the shaved axilla, over the hair bearing area," he said. "Patients are advised to shave this area three to five days prior to therapy in order to aid adherence of the transfer. If the transfer is not properly applied or smudged, accurate placement of the device's applicator becomes more difficult and treatment has the potential to be less effective."

Dr. Vider concurred. "Absolutely, it is quite easy. We give the patient local anesthetic and from then on it is quite simple. They don't feel anything. miraDry is much safer and easier than any alternative, with almost no downtime — and most of all — the results are improved."

The learning curve for the device is not steep either, Dr. Eccleston expressed. "Once the patient has been assessed medically for suitability and the initial local anesthesia is injected by physician or trained nurse, the procedure itself can be administered by a trained, non-medical staff member."

Treatment can be tailored to the patient's condition and new protocols utilize high volume anesthesia to separate the target area from sensitive underlying structures, providing a physical safety buffer and permitting the use of higher energy levels. Most patients see results in as little as one session.

"It is very common for patients to receive only one application," noted Dr. Krahenbuhl. "Only a minority of patients need a second treatment. It is extremely rare to perform a third, but it can happen in the most stubborn cases of extreme hyperhidrosis."

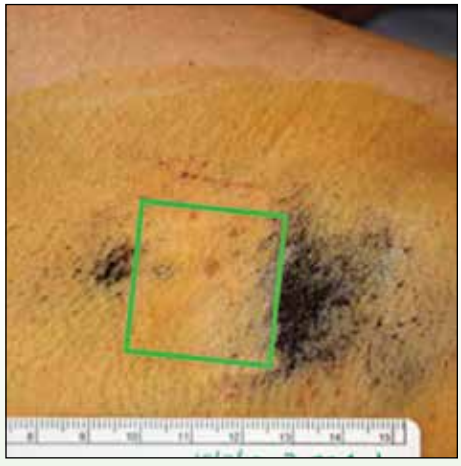
"I frontload the pricing so the patient pays more for the first treatment, less for the second, and if a third session is required, a nominal fee is charged to cover equipment disposable costs," Dr. Eccleston shared.

"It goes without saying that a physician who adopts miraDry into his or her practice will attract new patients," Dr. Vider declared. "Internal marketing and word-of-mouth initially brought them in, but we now do an extensive amount of advertising and we get a lot of new patients."

Dr. Krahenbuhl has also seen an increase in the number of consumers seeking relief from nuisance sweating. "We are considering the professional person who sweats too much and believe this will be a big market for us," he stated. "One such patient, a businessman, was so pleased with the result he sent over a bottle of champagne. In 2015, we want to go big with our marketing to this audience."

Future applications of this technology could conceivably include treatment of the hands, soles of the feet and other areas where people suffer from sweating, which is needed, Dr. Krahenbuhl opined. "I think Miramar Labs is working hard on this. It would open up an even bigger market."

"It goes without saying that a physician who adopts miraDry into his or her practice will attract new patients."



Starch iodine test in axillary region three years after partial miraDry Tx. Dark areas show where patient is still sweating. Patient is not sweating in treated area.

Photo courtesy of Larry Fan, M.D.

THE Asian
AESTHETIC
The Leading Aesthetic Practice Resource™
VOL. 10 2016
GUIDE™

miraDry for Underarm Odor

Produces the Sweet Smell of Success

Po-Han Huang, M.D.
Dermatologist
Executive Director
Taiwanese Dermatological Association
Kaohsiung City, Taiwan

Yung-Hsueh Huang, M.D.
Director
20 Skin Dermatology Clinic
Taiwan

"Most of my patients obtain about 70% reduction in odor and sweat after one treatment."

Po-Han Huang, M.D. treats patient for osmidrosis with miraDry's non-invasive microwave technology

Photo courtesy of Po-Han Huang, M.D.

By Anthony J. Varro, Contributing Editor

Already proven effective for eliminating excessive underarm sweat production and axillary hair removal regardless of hair color, the miraDry procedure from Miramar Labs (Santa Clara, California, U.S.) also significantly reduces underarm odor with technology that's safe, effective and most importantly, non-invasive. For patients with osmidrosis, we're very happy to have this non-invasive microwave technology," said Po-Han Huang, M.D., a dermatologist and executive director of the *Taiwanese Dermatological Association* in Kaohsiung City, Taiwan.

When asked about other treatment options for this indication, Dr. P.H. Huang advised, "Antiperspirants may lack effectiveness and require daily application. Botulinum toxin injections are painful, and the results are modest. Additionally, the heat generated by some of the high-intensity focused ultrasound and radiofrequency microneedling treatments can damage the epidermis. Among surgical options, some of my colleagues prefer using liposuction to extract the axillary sweat glands, but this procedure is very technique-dependent and can cause post-procedure problems including skin necrosis."

"miraDry's cooling system prevents epidermal damage," Dr. P.H. Huang pointed out. The procedure, which he performs under local anesthesia, takes about 20 minutes per axilla. Following a miraDry treatment, patients may experience minor swelling and bruising and temporary numbness or discomfort in the treated area.

According to Dr. P.H. Huang, it is impossible to know pre-procedure if a patient will need one or two treatments. "I usually suggest that patients consider one treatment at first and if bothersome odor persists two or three months later, patients may consider a second treatment," he shared. "Around 70% of my patients are satisfied with one procedure."

Recent Miramar surveys show that patients in China, Taiwan and Korea worry more about axillary odor than sweat. In Taiwan, for example, 45.5% of potential patients are very concerned about underarm odor, while 27.8% are very concerned about underarm sweat. Dr. P.H. Huang estimates that half of his miraDry patients come in for odor reduction, and half for sweat reduction.

"Whereas hyperhidrosis only bothers patients in hot environments or during exercise, for patients with malodor, it's a problem every minute of every day that people can smell from several feet away. I always advise patients that even normal people have some odor from the armpit, but after miraDry treatment, there is much less odor."

Yung-Hsueh Huang, M.D., director of 20 Skin Dermatology Clinic in Taiwan, said that 80% of his patients who undergo miraDry are concerned about odor and 20% worry about sweat. "Most of my patients obtain about 70% reduction in odor and sweat after one treatment. For people who are concerned with odor, I also give them some antiseptic wash. Their satisfaction is high – only 5% to 10% of my patients request a second treatment."

So far, Dr. P.H. Huang has treated approximately 50 patients for underarm odor. "Osmidrosis runs in families, so patients commonly refer relatives for treatment," he shared.

Likewise, in Dr. Y.H. Huang's practice, patients concerned with odor always refer family and friends for miraDry treatment. "What I like best about miraDry is that it's a non-invasive procedure that only requires local anesthesia and the side effects are minimal."

Overall, "miraDry is a very effective procedure that will safely destroy the sweat and apocrine glands," Dr. P.H. Huang concluded.

MK0542.A

The latest innovation in permanent underarm hair removal.

- Removes light and white color hair
- Eliminates underarm sweat
- Significant reduction after only 1-2 treatments

miraSmooth™

SMOOTH, DRY UNDERARMS

Article

Safety and Efficacy of Micro-focused Ultrasound Plus Visualization for the Treatment of Axillary Hyperhidrosis

 Mark S Nestor

 Hyunhee Park

Journal of Clinical and Aesthetic Dermatology 04/2014; 7(4):14-21.
Source: PubMed

ABSTRACT

Objectives: To evaluate the safety, efficacy, and durability of treating axillary hyperhidrosis with high-intensity micro-focused ultrasound plus visualization. Design: Two randomized double-blind, sham-controlled pilot studies. Measurements: For Study 1, the primary endpoint was response defined as ≥50-percent reduction in baseline sweat production as measured gravimetrically. For Study 2, the primary endpoint was response defined as a reduction of Hyperhidrosis Disease Severity Scale scores from 3 or 4 to 1 or 2. Secondary endpoints included changes in gravimetric and starch-iodine testing and patient satisfaction. Results: In Study 1, ≥50 percent of patients achieved a positive treatment response. In Study 2, the response rate at post-treatment Day 60 for micro-focused ultrasound plus visualization- (N=12) and sham-treated (N=8) patients was 67 and zero percent, respectively (p=0.005). Patients evaluated 12 months after treatment (N=11) demonstrated the long-lasting effectiveness of micro-focused ultrasound plus visualization for treating axillary hyperhidrosis. All but one patient in the micro-focused ultrasound plus visualization group were satisfied with their results while all sham group patients were dissatisfied (p=0.0001). Subjective reports of greatest improvement were sweat production (92%) and social embarrassment (83%). Adverse events were found to be mild and were resolved within a short timeframe. Conclusion: Micro-focused ultrasound plus visualization appears to be safe, effective, well-tolerated, and a long-lasting means for treating axillary hyperhidrosis.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 19, 2015

Miramar Labs Incorporated
Dr. Kathy O'Shaughnessy, Ph.D.
Vice President, Clinical/Regulatory/Quality Assurance
2790 Walsh Avenue
Santa Clara, California 95051

Re: K150419
Trade/Device Name: MiraDry System MD4000
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: OUB, NEY, MWY
Dated: May 5, 2015
Received: May 6, 2015

Dear Dr. O'Shaughnessy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150419

Device Name
miraDry System MD4000

Indications for Use *(Describe)*
The miraDry System MD4000 is indicated for use in the treatment of primary axillary hyperhidrosis plus unwanted underarm hair removal, and permanent reduction of underarm hair of all colors for Fitzpatrick skin types I – IV.

Permanent hair reduction is defined as long-term, stable reduction in the number of hairs regrowing when measured at 6, 9 and 12 months after the completion of a treatment regime.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

5. 510(k) Summary

GENERAL INFORMATION

Classification:	Class II (special controls)
Classification No.:	21 CFR 878.4400
Classification Name:	Electrosurgical cutting and coagulation device and accessories.
Product Code(s):	OUB, NEY, MWY
Common Name:	Instrument for Treatment of Hyperhidrosis System, Ablation, Microwave And Accessories System, Microwave, Hair Removal
Trade Name:	miraDry System MD4000
Submitter:	Miramar Labs, Inc. 2790 Walsh Avenue Santa Clara, CA 95051 USA Tel: 408-940-8700 Fax: 408-940-8795 FDA Registration No.: 3008082710
Contact:	Kathy O'Shaughnessy, PhD VP, Clinical/Regulatory/Quality
Date prepared:	06/16/15

INTENDED USE

The miraDry System MD4000 is indicated for use in the treatment of primary axillary hyperhidrosis plus unwanted underarm hair removal, and permanent reduction of underarm hair of all colors for Fitzpatrick skin types I – IV.

Permanent hair reduction is defined as long-term, stable reduction in the number of hairs regrowing when measured at 6, 9 and 12 months after the completion of a treatment regime.

PREDICATE DEVICES

The miraDry System MD4000 (K131162).

REFERENCE DEVICE

The Microwave Delivery System Model MMC-330 (K991456).

DEVICE DESCRIPTION

The miraDry System MD4000 is a microwave device designed to heat tissue located at the dermal- hypodermal interface where the axillary sweat glands and hair bulbs reside using a surface contact applicator. The miraDry System MD4000 consists of: the MD4000-MC Console; the MD4000-HP miraDry Handpiece; and a disposable, sterile MD4000-BT miraDry bioTip that snaps onto the Handpiece to provide a sterile protective cover.

As described in K131162, the miraDry System MD4000 also includes Class I components/accessories. The MD4000-TS template system is a required component for the miraDry treatment as well as the MD4000-PK priming kit. The MD4000-PK priming kit is required when the system is initially set up at a user facility. Optional accessories include an armrest and disposable ice packs.

The MD4000-MC Console is a software-driven device which contains circuit boards, a microwave generator, integrated vacuum and cooling systems, and an integrated touch-screen user interface.

The non-invasive miraDry Handpiece is specifically designed to deliver microwave energy to the skin at specified frequency and power levels. The proximal end of the Handpiece has a cable bundle and a console connector that supplies the energy and cooling to the Handpiece. The distal end has a sterile, disposable barrier, the miraDry bioTip, which contacts the patient.

SUMMARY OF SUBSTANTIAL EQUIVALENCE

The miraDry System MD4000 with the revised, expanded indication to include underarm hair removal is substantially equivalent to the miraDry System MD4000 as previously cleared for sweat reduction. The subject and predicate device have the same fundamental technology, design, and method of usage. A comparison of the two devices is shown in Table 1 below.

Table 1. Substantial Equivalence Comparison Table.

Characteristics	Predicate Device miraDry MD4000	Subject Device miraDry MD4000
510(k)	K131162	K150419
Device Class	II	II
Energy Type	Microwave	Microwave
Mode of Action	generation of localized heat	generation of localized heat
Product Code	NEY, OUB	NEY, OUB, MWY
Indications for Use	The miraDry System is indicated for use in the treatment of primary axillary hyperhidrosis. Note: The miraDry System is not indicated for use in the treatment of hyperhidrosis related to other body areas or generalized hyperhidrosis.	The miraDry System MD4000 is indicated for use in the treatment of primary axillary hyperhidrosis plus unwanted underarm hair removal, and permanent reduction of underarm hair of all colors for Fitzpatrick skin types I – IV. Permanent hair reduction is defined as long-term, stable reduction in the number of hairs regrowing when measured at 6, 9 and 12 months after the completion of a treatment regime.
Function	Heat absorption by tissue located at the dermal- hypodermal interface where the axillary sweat glands reside	Heat absorption by tissue located at the dermal- hypodermal interface where the axillary sweat glands and hair bulbs reside
Overall System structure	microwave source/amplifier, coolant supply system, operator interface, and microwave, electrical and coolant lines that connect to the applicator	microwave source/amplifier, coolant supply system, operator interface, and microwave, electrical and coolant lines that connect to the applicator
Key Components	Console, handpiece, disposable applicator tip	Console, handpiece, disposable applicator tip
Console Control Mechanism	electronic user interface	electronic user interface
Coolant usage	Delivers cooling to the skin surface	Delivers cooling to the skin surface

NON-CLINICAL TESTING

There was no additional non-clinical testing that was completed, as the device being used is the same as the cleared device (miraDry System MD4000, cleared under K131162).

CLINICAL TESTING

The safety and effectiveness of the clinical application of the miraDry System MD4000 for sweat reduction was demonstrated in prior clinical studies. The performance for underarm hair reduction was demonstrated in a clinical trial of 56 subjects.

The primary objective of this study was to quantify hair reduction in the axillae after treatment(s) with the miraDry System MD4000. The study device was used in the same manner as the commercially available technique cleared by the FDA for the treatment of primary axillary hyperhidrosis, as described in the User Manual.

The study was conducted at three private dermatology clinics in the United States. The study was initiated at the first site in September of 2012. Adult subjects seeking hair reduction in the axillae were considered for enrollment. Subjects were treated with the miraDry System MD4000 using the standard miraDry procedure in one or two treatment sessions 3 months apart.

Fifty-six subjects were enrolled in the study. The mean age was 33 years; 80% of the subjects were female and 88% were Caucasian. The majority of the subjects were of Fitzpatrick skin type I-IV. 23% (13/56) of the subjects completed only one treatment session; 5 of these 13 subjects declined a second session due to adverse events. The primary endpoint of this study was to show >30% reduction (baseline to 3 month, measured by hair counts) in >50% of subjects. There were 42 subjects assessable for this endpoint. The secondary endpoint was to show >30% reduction (comparing baseline to 12 months photos) to make a claim for permanent axillary hair reduction. Additional analyses used a blinded comparison of baseline to follow-up full-axilla photos by an independent physician reviewer to correctly identify which photo had more hair and score hair reduction at follow-up. Also, a subject assessment of overall satisfaction, odor rating and sweat ratings was determined at the follow-up visits. A summary of the results is presented in Table 2 below.

Table 2: Summary of Efficacy Results.

Efficacy measure	Follow-up visit time from the last treatment session			
	3 months	6 month	9 month	12 month
Hair count: % of subjects with >30% reduction [lower 95% CL]	**Primary:** 88.1% (37/42) [76.6%]	97.5% (39/40) [88.7%]	92.1% (35/38) [80.8%]	**Secondary:** 95.5% (42/44) [86.4%]
Hair count: Average reduction [std] Light hair subgroup (n)	66% [± 30%] 66% (n=12)	72% [± 29%]	75% [± 28%]	75% [± 27%] 72% (n=13)
Side-by-side axilla review: % of pairs having at least 26-50% reduction	74% (63/85)	78% (65/83)	78% (66/85)	89% (83/93)
Patient satisfaction with hair reduction: % of subjects rating “very satisfied” or “somewhat satisfied”	81% (38/47)	70% (31/44)	68% (30/44)	70% (33/47)
Odor self-assessment, Mean reduction 10pt scale	2.6 ± 3.0	2.8 ± 2.8	2.5 ± 2.8	2.4 ± 2.7
% of subjects with HDSS reduction to score of 1 or 2	92% (23/25)	96% (25/26)	96% (24/25)	89% (25/28)

Both the primary and secondary endpoints were met, since the percentage of patients with hair reduction of at least 30% was significantly higher than 50% at all follow-up timepoints.

All subjects experienced at least one (1) treatment-related adverse event (AE), 99% (324/326) of all AE’s were rated as mild in severity. Many subjects experienced the expected mild transient post-treatment effects; the most common were localized edema (55%), tingling or numbness in the treatment area (30%), vacuum acquisition marks (29%), bumps or lumps under the skin (29%) or discomfort or tenderness in the treatment area (26%). Other rarer treatment effects affecting more than the treatment area were noted in 18% of subjects (10/56), 75% of which were rated as mild. These included numbness or tingling in the arms (n=6 events); more extensive swelling in the adjacent area (e.g. arms) (n=4 events); and bruising outside the treatment area (n=2 events). One patient experienced unilateral ulnar neuropathy that was improving but not completely resolved at study exit. The types, rates and severity of the reported AE’s are substantially equivalent to those from the predicate device (MD4000-MC with the hyperhidrosis indication, K131162).

The modification to the Indications for Use statement has not altered the fundamental technology of the miraDry System MD4000.

CONCLUSION

As described in this 510(k) Summary, Miramar Labs Inc. considers the miraDry System MD4000 to be substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

October 31, 2016

Miramar Labs Incorporated
Ms. Kathy O'Shaughnessy
Consultant, Regulatory Affairs
2790 Walsh Avenue
Santa Clara, California 95051

Re: K160141
Trade/Device Name: miraDry System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: OUB, NEY, MWY
Dated: September 19, 2016
Received: September 20, 2016

Dear Ms. O'Shaughnessy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Jennifer R. Stevenson -A

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160141

Device Name
miraDry System

Indications for Use *(Describe)*
The miraDry System MD4000 is indicated for use in the treatment of primary axillary hyperhidrosis plus unwanted underarm hair removal, and permanent reduction of underarm hair of all colors for Fitzpatrick skin types I – IV.

Permanent hair reduction is defined as long-term, stable reduction in the number of hairs regrowing when measured at 6, 9 and 12 months after the completion of a treatment regime.

When used for the treatment of primary axillary hyperhidrosis, the miraDry System MD4000 may reduce underarm odor.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

1. 510(k) Summary

GENERAL INFORMATION

Classification:	Class II (special controls)
Classification No.:	21 CFR 878.4400
Classification Name:	Electrosurgical cutting and coagulation device and accessories.
Product Code(s):	OUB, NEY, MWY
Common Name:	Instrument for Treatment of Hyperhidrosis System, Ablation, Microwave And Accessories System, Microwave, Hair Removal
Trade Name:	miraDry MD4000 System
Submitter:	Miramar Labs, Inc. 2790 Walsh Avenue Santa Clara, CA 95051, USA Tel: 408-940-8700 Fax: 408-940-8795 FDA Registration No.: 3008082710
Contact:	Kathy O'Shaughnessy, PhD VP, Clinical/Regulatory/QA (Consulting)
Date prepared:	10/27/16

INDICATIONS FOR USE

The miraDry System MD4000 is indicated for use in the treatment of primary axillary hyperhidrosis plus unwanted underarm hair removal, and permanent reduction of underarm hair of all colors for Fitzpatrick skin types I – IV.

Permanent hair reduction is defined as long-term, stable reduction in the number of hairs regrowing when measured at 6, 9 and 12 months after the completion of a treatment regime.

When used for the treatment of primary axillary hyperhidrosis, the miraDry System MD4000 may reduce underarm odor.

PREDICATE DEVICE

The miraDry MD4000 System (K150419).

DEVICE DESCRIPTION

The miraDry MD4000 that is the subject of this 510(k) is identical to the device described and cleared in K150419, except for the proposed labeling changes that resulted in this 510(k) submission.

The miraDry MD4000 System is a microwave device designed to heat tissue located at the dermal- hypodermal interface where the axillary sweat and odor glands and hair bulbs reside using a surface contact applicator. The miraDry MD4000 System consists of: the MD4000-MC Console; the MD4000-HP miraDry Handpiece; and a disposable, sterile MD4000-BT miraDry bioTip that snaps onto the Handpiece to provide a sterile protective cover.

As described in K150419 and prior submissions, the miraDry MD4000 System also includes Class I components/accessories. The MD4000-TS template system is a required component for the miraDry treatment as well as the MD4000-PK priming kit and the MD4000-BT-DE demonstration bioTip. The MD4000-PK priming kit and the non-sterile "demo" bioTip are required when the system is initially set up at a user facility. Optional accessories include an armrest and disposable ice packs.

The MD4000-MC Console is a software-driven device which contains circuit boards, a microwave generator, integrated vacuum and cooling systems, and an integrated touch-screen user interface.

The non-invasive miraDry Handpiece is specifically designed to deliver microwave energy to the skin at specified frequency and power levels. The proximal end of the Handpiece has a cable bundle and a console connector that supplies the energy and cooling to the Handpiece. The distal end has a sterile, disposable barrier, the miraDry bioTip, which contacts the patient.

SUMMARY OF SUBSTANTIAL EQUIVALENCE

The miraDry MD4000 System described and cleared in 510(k) number K150419 serves as the predicate device for this premarket notification. The miraDry MD4000 System that is the subject of this 510(k) has the same intended use and technological characteristics as the device described and cleared in 510(k) number K150419. Furthermore, there have been no changes in design, material, chemical composition, energy source, or manufacturing process since FDA's clearance of K150419.

Substantial Equivalence Comparison Table

Characteristics	Predicate Device miraDry MD4000 K150419	Subject Device miraDry MD4000
Device Class	II	II
Energy Type	Microwave	Microwave
Mode of Action	generation of localized heat	generation of localized heat
Product Code	NEY, OUB, MWY	NEY, OUB, MWY
Indications for Use	The miraDry System MD4000 is indicated for use in the treatment of primary axillary hyperhidrosis plus unwanted underarm hair removal, and permanent reduction of underarm hair of all colors for Fitzpatrick skin types I – IV. Permanent hair reduction is defined as long-term, stable reduction in the number of hairs regrowing when measured at 6, 9 and 12 months after the completion of a treatment regime.	The miraDry System MD4000 is indicated for use in the treatment of primary axillary hyperhidrosis plus unwanted underarm hair removal, and permanent reduction of underarm hair of all colors for Fitzpatrick skin types I – IV. Permanent hair reduction is defined as long-term, stable reduction in the number of hairs regrowing when measured at 6, 9 and 12 months after the completion of a treatment regime. When used for the treatment of primary axillary hyperhidrosis, the miraDry System MD4000 may reduce underarm odor.
Function	Heat absorption by tissue located at the dermal-hypodermal interface where the axillary sweat (wetness and odor) glands and hair bulbs reside	Heat absorption by tissue located at the dermal-hypodermal interface where the axillary sweat (wetness and odor) glands and hair bulbs reside
Overall System structure	microwave source/amplifier, coolant supply system, operator interface, and microwave, electrical and coolant lines that connect to the applicator	microwave source/amplifier, coolant supply system, operator interface, and microwave, electrical and coolant lines that connect to the applicator
Key Components	Console, handpiece, disposable applicator tip	Console, handpiece, disposable applicator tip
Console Control Mechanism	Electronic user interface	Electronic user interface
Coolant usage	Delivers cooling to the skin surface	Delivers cooling to the skin surface

NON-CLINICAL TESTING

There was no additional non-clinical testing that was completed, as the device being used is the same as the cleared device (miraDry MD4000 System, cleared under K150419).

CLINICAL TESTING

In support of this 510(k), a prospective, split-patient, randomized, single center trial was conducted. Forty adult subjects with high underarm odor were enrolled. Subjects were treated in one underarm (randomly selected) with the miraDry MD4000 System using the standard miraDry procedure, which at the time of the study was two treatment sessions 3 months apart. The other underarm was untreated and served as the control.

The odor assessments were conducted by four blinded, trained odor assessors, where each assessor gave a score to each underarm between 0 (no malodor) and 10 (extremely strong malodor). Scores for each underarm were obtained by averaging the scores from the four judges. Patients also self-reported their odor scores and rated their satisfaction with the procedure. The mean subject age was 49 years; 63% of the subjects were female and 57% were African American, with the remainder Caucasian.

The study design and results are summarized in the table below.

Study Design	Prospective, split-patient, randomized, single center trial
Sample Size	40 patients – one underarm treated, one underarm untreated
Odor Assessment Method	Panel of 4 blinded, trained odor assessors; each underarm rated on a scale of 0 (none, no malodor) to 10 (extremely strong malodor) and averaged
Principal Eligibility Criteria	• Score of at least 5 in each underarm; less than a 2 point difference between underarms • Willing to comply with washout period instructions prior to each odor assessment • Willing to receive the miraDry treatments and available for the follow-up period
Follow-ups	1 month, 3 months and 6 months after last treatment
Endpoints	Primary: Percentage of the subjects that scored at least a 2 point lower odor score in the treated underarm compared to the untreated underarm (responders) when assessed1 month after treatment Secondary: • Statistically significant difference in % of subjects with at least a 2 point drop in underarm odor score in the treated underarm compared to the untreated underarm at 3 and 6 months. • Average difference in odor in the treated underarm compared to the untreated underarm at all follow-up visits. • Patient-rated satisfaction scores on odor specific questions, as measured at the follow-up visits that are 1, 3 and 6 months post final treatment

Effectiveness results

The results for the responder analysis are shown in the table below for the subjects that attended the study visits.

Table 1: Percentage of subjects with at least 2 point lower odor score in the treated underarm compared to the untreated underarm

	# of Evaluable subjects	Percentage of subjects with at least 2 point lower odor score in the treated underarm compared to the untreated underarm 1 month after treatment.
1 month after treatment	35	23/35 (66%)*
3 months after treatment	36	14/36 (39%)
6 months after treatment	36	13/36 (36%)

*p=0.09, indicating the proportion of subjects experiencing a 2 point difference (between the treated and untreated underarm) was not significantly greater than 50%.

The primary endpoint and a secondary endpoint were not met, since the percentage of patients with at least a 2 point lower score on the treated underarm compared to the untreated underarm was not statistically significant at the three time points. However, the treated underarm was scored as having lower odor at all time points.

Table 2: Average difference in odor in the treated underarm compared to the untreated underarm at all follow-up visits.

	Average difference in odor between the treated and untreated underarm (± 95%CI)	P value
1 month	2.84 (±0.73)	<0.0001
3 months	1.27 (±0.74)	0.0005
6 months	1.56 (±0.56)	<0.0001

The treated underarm was rated by judges as having lower odor scores than the untreated underarm at every time point. Therefore, although the primary endpoint of statistically significant responder rate of 2 point reduction in odor was not met, the study data demonstrate some reduction of underarm odor when used for the treatment of primary axillary hyperhidrosis.

	Finally, subjects were asked about their general satisfaction and if they would be willing to receive treatment for free on the untreated arm. In response to the general satisfaction question, 29/35 or 83% reported being at least somewhat satisfied. However, only 15/36 or 42% responded that they would like undergo treatment of the untreated underarm at no cost.
Safety results	About half the treated subjects reported expected post-treatment effects such as localized edema and discomfort (Grade 0 events). One patient reported a mild infection that cleared in 10 days; another patient reported pain likely due to an infection after the optional biopsy; this cleared in 12 days.
Histo-pathology results	An optional component of the study was to obtain small biopsies from each of the treated and untreated (control) underarms after the final follow-up visit (6 months post-treatment). A blinded histopathologist review of the available pairs with adequate samples found: (1) In 7/10 cases the control sample had more apocrine glands (2) In 8/10 cases the treated sample had a higher degree of fibrosis.

CONCLUSION

The changes in Indications for Use do not pose any new questions of safety or efficacy. As demonstrated through clinical testing, the subject device miraDry MD4000 System's safety and effectiveness are substantially equivalent to those of the legally marketed predicate device (K150419).

K103014

510(k) Summary

JAN 2 8 2011

General Information

Trade Name	miraDry System
Classification	21CFR 878.4400, Electrosurgical cutting and coagulation device and accessories Class II (special controls)
Product Code	NEY
Submitter	Miramar Labs, Inc. 445 Indio Way Sunnyvale, CA 94085 USA Tel: 408-940-8700 Fax: 408-940-8795
Contact	Kathy O'Shaughnessy, PhD VP, Clinical and Regulatory Affairs
Date prepared:	January 20, 2011

Indications for Use

The miraDry System is indicated for use in the treatment of primary axillary hyperhidrosis.

Note: The miraDry System is not indicated for treating hyperhidrosis related to other body areas or generalized hyperhidrosis.

Predicate Device

K082819	Miramar Labs' DTS G2 System

Device Description

The miraDry System is a microwave device designed to heat tissue located at the dermal- hypodermal interface where the sweat glands reside using a surface contact applicator. The miraDry System consists of: the DTS3000

Console; the miraDry Handpiece; and a disposable, sterile miraDry bioTip that snaps onto the Handpiece to provide a sterile protective cover.

The DTS3000 Console is a software-driven device which contains circuit boards, a microwave generator, integrated vacuum and cooling systems, and an integrated touch-screen user interface.

The non-invasive miraDry Handpiece is specifically designed to deliver microwave energy to the skin at specified frequency and power levels. The proximal end of the Handpiece has a cable bundle and console connector that supplies the energy and cooling to the Handpiece. The distal end has a sterile, disposable barrier, the miraDry bioTip, that contacts the patient.

Materials

All materials used in the manufacture of the miraDry System are suitable for this use and have been used in numerous previously cleared products. Patient-contacting materials have been demonstrated to be biocompatible.

Performance Testing

Product and animal testing was conducted to ensure conformance to product specifications, and equivalence to the predicate device. In particular, animal testing demonstrated that thermal zones created with the predicate device were similar to those created with the miraDry System.

The miraDry System has been shown to conform to the applicable requirements of the following:

- IEC 60601-1: (1988 + A1:1991 + A2:1995) Medical Electrical Equipment Part 1: General Requirements for Safety: Safety Requirements for Medical Electrical Systems
- IEC 60601-1-2: (2001+A1:2004) Medical Electrical Equipment Part 1-2: General Requirements for Safety: Electromagnetic Compatibility
- IEC60601-1-4:2000. Medical Electrical Equipment Part 1-4 General requirement for safety - Collateral Standard: Programmable electrical medical systems
- IEC60601-1-6:2004. Medical electrical equipment Part 1-6: General requirements for safety – Collateral Standard: Usability
- IEC 60601-2-2:2006. Medical electrical equipment Part 2-2: Particular requirements for the safety of High Frequency Surgical Equipment
- IEC 60601-2-6:1984. Medical electrical equipment Part 2: Particular requirements for the safety of microwave therapy equipment.

Clinical testing showed that the device provides a safe and effective means to treat axillary hyperhidrosis. A randomized, blinded study with 120 subjects with primary axillary hyperhidrosis was conducted. The study primary endpoint was met, which demonstrated a statistically significant difference in sweat

reduction efficacy between the treated subjects (n=81) and the subjects that received a sham treatment (n=39). Adverse events were generally mild in severity and all but one (persistent hyperhidrosis on the face) resolved.

Summary of Substantial Equivalence

The miraDry System is substantially equivalent to the predicate product for the following reasons:

1. The miraDry System has the same intended use as the legally marketed DTS G2 System, i.e., a localized and controlled heating of soft tissue.
2. The indication for use for the miraDry System is a specific indications for use within the "functional" indications for use for the DTS G2 System that were cleared by FDA, i.e., "The DTS G2 System is indicated for use for coagulation of soft tissue".
3. The materials used in the miraDry System, the device's methods of manufacturing and overall function are the same as the FDA cleared DTS G2 System.
4. While the miraDry System has the same intended use and basic technological characteristics as the predicate, the specificity of the miraDry System's indications for use prompted Miramar Labs to conduct a clinical study to ensure that the performance specifications of the device met user needs. On the basis of direct comparison with the predicate device and the results of preclinical and clinical testing, the miraDry System has been demonstrated to be substantially equivalent to the legally marketed DTS G2 System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Miramar Labs, Inc.
% Kathy O'Shaughnessy, Ph.D.
Vice President, Clinical and Regulatory Affairs
445 Indio Way
Sunnyvale, California 94085

JAN 28 2011

Re: K103014
Trade/Device Name: miraDry System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: OUB, NEY
Dated: December 10, 2010
Received: December 13, 2010

Dear Dr. O'Shaughnessy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K103014

1 Indications for Use

510(k) Number (if known):

Device Name:	miraDry System
Indications for Use:	The miraDry System is indicated for use in the treatment of primary axillary hyperhidrosis. Note: The miraDry System is not indicated for use in the treatment of hyperhidrosis related to other body areas or generalized hyperhidrosis.

X
Prescription Use
(Per 21 CFR 801 Subpart D)

OR

Over-The-Counter Use
(21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

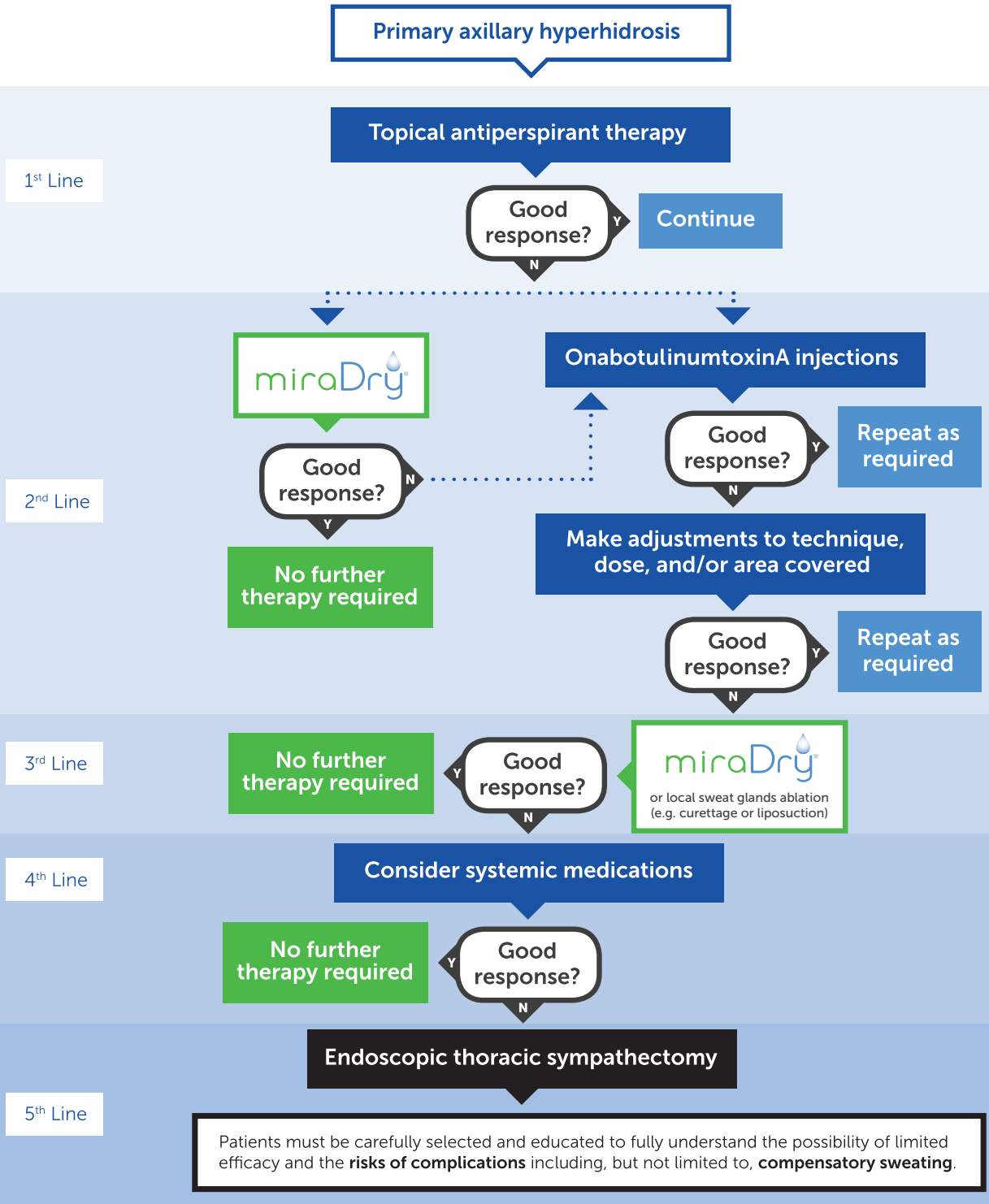
Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogden for mkm
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K103014

International Hyperhidrosis Society guidelines for treating excessive underarm sweating

This treatment pathway offers guidance to patients and physicians on the treatments available for primary axillary hyperhidrosis. If topical antiperspirants are found to be ineffective, miraDry® is a safe, effective and lasting 2nd line treatment option.



The International Hyperhidrosis Society (IHHS) is a global non-profit organisation that provides support for sufferers and clinical guidance for medical professionals. With over 50,000 subscribers, the IHHS is the largest hyperhidrosis support community in the world and is led by a team of research experts and medical specialists. The organisation is dedicated to research, education and awareness and is a recognised authority on hyperhidrosis within the medical community.

To see the IHHS treatment pathway for axillary hyperhidrosis in full, visit **www.sweathelp.org**

miraDry®

A lasting solution for excessive underarm sweat

What is miraDry?

miraDry is a treatment solution for excessive underarm sweat (axillary hyperhidrosis) that provides dramatic and lasting results after just two procedures*, with no further treatment required. The system works by delivering precisely controlled electromagnetic energy to the underarm, targeting and eliminating the sweat glands. Sweat glands do not grow back, so the effects of miraDry are long lasting.

In clinical studies, miraDry provided an average 82% reduction in sweat[1] and patients who are treated with miraDry frequently report a huge improvement in their quality of life. This breakthrough, life-changing treatment is now available in the UK, providing safe, effective and lasting relief from excessive underarm sweat.

- The first and only **FDA cleared** and **CE marked** device for the treatment of axillary hyperhidrosis.
- Installed in over **250 clinics** in the USA and worldwide.
- Over **20,000 patients** successfully treated.
- **2nd line treatment option** in the International Hyperhidrosis Society clinical guidelines.
- Brings **freedom** from the need for regular repeat procedures, without resorting to surgery.

To find out more about miraDry or to locate our nearest miraDry clinic, visit our website at **www.miraDry.co.uk**

Benefits

- A **dramatic reduction** of underarm sweat, with immediate and lasting results.
- **Non-invasive**, **non-surgical** treatment.
- **Quick procedure** performed in a clinic, with minimal to no downtime.
- **Toxin-free** treatment which does not require repeat procedures to maintain results.
- Secondary effects include a **reduction in odour** and underarm hair.

> "miraDry has a greater impact on people's lives than I ever expected. I didn't realise how much stress hyperhidrosis caused until my patients came back to tell me how much their lives had improved!"
>
> - Dr Tapan Patel
> PHI Clinic, Harley Street

Get in touch today on **info@miraDry.co.uk** or **01788 571 200**

www.miraDry.co.uk

miraDry is distributed in the UK by Aesthetic Business Partners LLP,
Unit 21, Sir Frank Whittle Business Centre, Great Central Way, Rugby, CV21 3XH.

1. Data on file

*Two treatments are recommended, however some patients may find that one treatment provides a sufficient result.

A very small number of patients may require more than two treatments.

An Alternative Method of Pain Management for Microwave Treatment of Primary Axillary Hyperhidrosis

William P. Coleman III, MD, W. Patrick Coleman IV, MD
Coleman Center for Cosmetic Dermatologic Surgery

Objective

A novel microwave device has been utilized widely for over 2 years to treat primary axillary hyperhidrosis [1-3]. The device works by heating the subdermal layer of the skin where the sweat glands are primarily located. Clinical studies to date and commercial use have employed injected stock solutions of local anesthetic for analgesia. This study was undertaken to determine if the use of tumescent anesthesia would provide similar pain management without negative effects on sweat reduction efficacy. The potential advantages include increased comfort for the patient during anesthesia administration and less trauma to the dermis in the treatment site.

Study Design and Methods

This study is a randomized, split-patient, unblinded study. Each patient was required at baseline to have significant axillary hyperhidrosis, defined as gravimetric sweat levels of greater than 50mg/5min in each axilla, with relatively symmetric sweat levels (within a factor of two). At the time of the first treatment session, subject's axillae were randomly assigned to be anesthetized with either of two methods. See Table 1 for a comparison of the two techniques.

Table 1. Different anesthesia methods compared

	Method 1 – Injection	Method 2 - Tumescent
Anesthesia used	1% lidocaine with 1:100000 epinephrine	0.2% lidocaine in buffered saline with 1:500000 epinephrine
Range of volumes (cc)	15 - 32	200 - 500
Method of infiltration	Injection with 30g needles at approx 1cm spacing, using manufacturer supplied grid	Blunt cannula using peristaltic pump

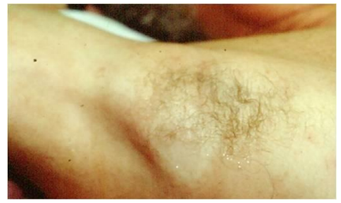
- The microwave device (miraDry System, Miramar Labs, Santa Clara, CA) allows the operator to choose between 5 different energy levels, where energy level 1 corresponds to 2.4sec of energy delivery per antenna and energy level 5 corresponds to 3.0sec of energy delivery.
- The energy levels selected for this clinical study were the same as used in clinical practice and were the same for both underarms.
- Subject pain scores (scale of 1 to 10, with 10 being the worst pain) were separately gathered for each underarm for the discomfort of anesthesia administration and the discomfort of treatment.
- Follow-up visits were scheduled at 1 month, 3 months, 6 months, 9 months and 12 months after the second treatment. Sweat levels were measured using the HDSS (Hyperhidrosis Disease Severity Scale) scores and gravimetric assessments.

Table 2. Subject demographics (n=17)

Characteristic	Distribution
Male	**9 (53%)**
Female	**8 (47%)**
Age (Average)	**32**
Baseline Gravimetric scores (ave) – Method 1 axilla	**204 mg**
Method 2 axilla	**191 mg**

Results

Figure 1.
Example of axilla after high volume anesthesia has been administered.



For the first treatment session, all patients were treated at energy level 3 with the first few superior rows kept at energy level 1 as is carried out in clinical practice. For the second treatment session, 60% of patients were treated at energy level 4 with the remaining 40% of patients treated at energy level 3.

Table 3. Average pain scores for each treatment session (n=17). 1 is no pain, 10 is severe pain.

	Treatment 1		Treatment 2	
	Score for anesthesia admin	Score for treatment	Score for anesthesia admin	Score for treatment
Injected Axilla	4.5	1.4	3.6	1.1
Tumescent Axilla	3.6	1.4	2.6	1.1

The efficacy results were similar for both methods, according to both gravimetric assessments and HDSS scores. See Tables 4 and 5 and Figure 2 for the results. The results for the 12 month visit are preliminary, there are still some patients scheduled.

Table 4. Efficacy results based on gravimetric measurements

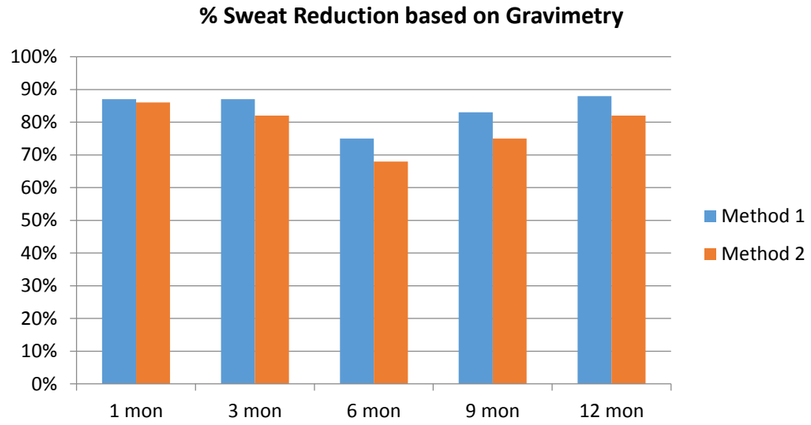
	% sweat reduction based on gravimetric measurements				
	1 month (n=14)	3 month (n=14)	6 month (n=13)	9 month (n=9)	12 month (n=7, partial)
Injected Axilla	**87%**	**87%**	**75%**	**83%**	**88%**
Tumescent Axilla	**86%**	**82%**	**68%**	**75%**	**82%**

Table 5. Efficacy results based on HDSS scores

	% with HDSS scores of 1 or 2*				
	1 month	3 month	6 month	9 month	12 month (Partial)
Injected Axilla	100% 13/13	100% 12/12	100% 10/10	89% 8/9	100% 7/7
Tumescent Axilla	100% 13/13	100% 12/12	100% 10/10	89% 8/9	100% 7/7

*Two patients self-rated as HDSS score of 2 at baseline, so they are not included. Not all patients completed the questionnaire.

Figure 2. Sweat reduction comparison between the two methods at each follow-up visit. The methods used to administer anesthesia gave equivalent results (within measurement error).



In addition to wetness reduction, patients self-reported odor assessments at baseline and follow-up visits. For patients who started with scores of 5 or more (on a 1 to 10 scale, with 10 being a severe odor problem), the average reduction in odor was 6.7 and 6.9 points for Method 1 and Method 2 respectively (at the 6 month follow-up visit, n=7 patients).

The general side effects reported were temporary swelling and some tenderness in the treated area which is consistent with previous commercial use of the device. In this series, 3 patients reported infection on the side that had injected anesthesia and were managed with short-term antibiotics. This is a higher rate than has been seen with commercial use of the device. The authors theorize that the tumescent approach decreases the risk of infection by eliminating multiple needle sticks throughout the treatment field. Tumescent anesthesia has also been shown to reduce infections in liposuction although the mechanism is debated

Conclusions

The results of this study demonstrate that the two methods of anesthesia provided similar comfort management and efficacy. This provides supportive evidence for physicians who want to use different anesthesia approaches. The results seem to be stable through a full year of follow-up. It is possible that there may be ways to optimize the microwave treatment by utilizing a higher volume of anesthesia with higher energy levels that may improve the results further.

References

1. Glaser DA, Coleman WP, Fan LK, et al. A Randomized, Blinded Clinical Evaluation of a Novel Microwave Device for treating Axillary Hyperhidrosis: the DRIUP Study (Dermatologic Reduction In Underarm Perspiration). Dermatol Surg 2012; 38: 185-191.

2. Hong HC-H, Lupin M, O'Shaughnessy KF. Clinical Evaluation of a Microwave Device for Treating Axillary Hyperhidrosis. Dermatol Surg 2012; 38: 728-735.

3. Lupin M, Hong HC-H, O'Shaughnessy KF. Long-term Efficacy and Quality of Life Assessment for Treatment of Axillary Hyperhidrosis With a Microwave Device. Dermatol Surg 2014; 40: 805-807.

This research was funded by Miramar Labs, Inc.
Presented at the 2014 American Society of Dermatologic Surgery Annual Meeting
Nov. 6-9, 2014. San Diego, CA
Used with permission from all abstract authors

Evolution of a New Treatment Modality for Primary Focal Hyperhidrosis

Stacy R Smith, MD | Affiliation: Volunteer Faculty, UCSD Division of Dermatology

Introduction

Hyperhidrosis is a condition of excess perspiration. While no specific diagnostic criteria exist to differentiate "normal" amounts of sweating from those individuals with a bona fide medical illness, in most cases, patients complaining of excess sweating have substantial symptoms and findings. These include persistent sweating, dripping or soaking moisture at rest, inability to perform certain daily functions such as handling paper due to wetness on the hands or vastly accelerated garment deterioration due to wetness. Hyperhidrosis may exist due to diseases or medications such as hyperthyroidism or anti-depressive agents and, in these cases, is known as secondary hyperhidrosis. Primary hyperhidrosis is diagnosed when no underlying medical condition or causative medication is found. Primary hyperhidrosis is typically a focal condition most commonly involving the axillae and reported to occur in 1.4% of the US population, although the prevalence is probably under-reported due to the social stigma of the disease.[1]

To date, no ideal treatment for focal hyperhidrosis exists. Current treatments have various limitations. High strength topical antiperspirants available over the counter or via prescription all contain aluminum salts which are at best, modestly effective for true medical hyperhidrosis and have been associated with some risks when used long term.[2,3] Botulinum toxin injections show good efficacy but last less than 12 months and are a painful procedure. Systemic anticholinergic agents have a broad array of side effects and limited efficacy.[4, 5] Various surgical procedures have their own specific morbidities such as scars, pain and importantly, compensatory hyperhidrosis.[6]

The ideal treatment for hyperhidrosis would be focally deliverable, non-invasive, long-acting and with minimal adverse effects. A technology based on focused heating of sweat gland tissue using microwave energy has been developed and refined for clinical use. The engineering, pre-clinical and clinical work conducted to develop this product will be reviewed here.

Technology

A microwave-based technology has been developed and optimized which implements several features in its design to precisely deliver energy to the depth of the sweat glands. An integrated vacuum system lifts the skin and underlying tissue a few millimeters into the treatment chamber. During the treatment cycle (consisting of energy delivery time and post-cool time) cooling fluid flows through a chamber in contact with the skin, protecting the epidermis and upper dermis from excess heating (see Figure 1). Structures deeper than the sweat glands are protected from heat injury due to the limited penetration depth of microwave energy. Limited penetration is achieved by tailoring the frequency and antenna structure such that the radiated microwave energy is focused at the dermal/hypodermal interface.

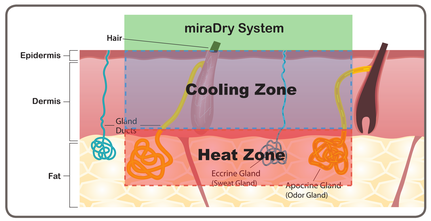


Figure 1. The miraDry System creates a heat zone at the level of the sweat glands and a protective cooling zone at the dermis.

Pre-Clinical Studies

Multiple pre-clinical studies were conducted in the Yorkshire porcine model. All studies used the belly/flank of the pig as the target area; there are no eccrine (sweat-producing) glands but the dermis and subcutaneous fat allowed safety evaluation of the various tested devices and settings as well as confirmation of the depth of penetration and heat zone. Multiple interations varying the power output as well as the antennae that transmit the microwave energy were tested to arrive at a combination that produced a well-controlled zone of heat injury at the correct depth.[7]

Figure 2 shows a representative result of testing with the system approximately one week after energy was applied. The dark areas show the zone with the bulk of the damage, indicating that the energy indeed is concentrated at the dermal/hypodermal interface. There is no sign of damage to the epidermis or upper dermis.

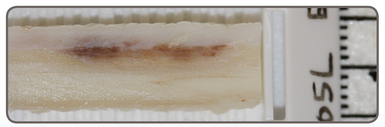


Figure 2. Effect of energy delivery on porcine model.

Procedure

To perform the treatment, subjects receive infiltrative local anesthesia in a grid pattern to the entire axilla. The treatment is provided via serial placement of the handpiece, with an active area of approximately 10mm by 30mm. After placement of the handpiece, the treatment cycle is activated. Upon activation, a vacuum is created which gently draws the skin against the thin ceramic treatment plate. Chilled fluid passes behind the plate providing cooling to the superficial levels of the skin. Sensors ensure that the skin is in close apposition to this cooling surface. Microwave energy is then applied non-invasively in a very directed fashion via multiple antennae within the handpiece. The energy is delivered over approximately 30 seconds followed by a 20 second post-cool period. Upon completion, the vacuum is released and the cessation of the audio signal indicates the end of the treatment cycle. The handpiece is then moved by the operator to the next adjacent treatment area and the process is repeated.

Based on the clinical testing described below, two procedure sessions approximately 3 months apart are recommended for optimal efficacy results.

Clinical Studies

A series of clinical studies have been conducted to systematically demonstrate the safety and efficacy of the procedure, as well as to optimize the device and procedure for clinical use. All studies had very similar key inclusion/exclusion criteria which included:

- Adults only
- All subjects were required to have HDSS=3 or 4 (see Table 1)
- Aside from the feasibility study, the studies required gravimetric readings of at least 50mg of sweat / 5 min in each axilla
- No botulinum toxin injections in the axillae within the 6 months prior to enrollment

Table 1. Hyperhidrosis Disease Severity Scale (HDSS) Definition

The question asked is: How would you rate the severity of your hyperhidrosis?

HDSS Value	Definition
1	My underarm sweating is never noticeable and never interferes with my daily activities
2	My underarm sweating is tolerable but sometimes interferes with my daily activities
3	My underarm sweating is barely tolerable and frequently interferes with my daily activities
4	My underarm sweating is intolerable and always interferes with my daily activities

Table 2. Subject Demographic Comparison

		Feasibility Study (n=28)	Randomized Study (n=81 treated)	miraDry Study (n=31)
Age:	Median	34 years old	33 years old	33 years old
	Range	19 to 49	18 to 83	18 to 65
Gender:	Female	57%	53%	74%
Race:	Caucasian	77%	84%	87%
BMI:	Median	25.6	26.5	24.8

Feasibility Study

After pre-clinical studies had identified an optimal design with demonstrated safety, a human feasibility study was undertaken to gain efficacy information.[7] The first phase involved a small number of subjects that were treated in a small area in one axilla to demonstrate (via the starch-iodine test) local sweat elimination. The second phase (utilizing a modified device and handpiece with a larger active area, see Figure 3), was a titration study to treat full axillae; the goal was to optimize the device settings and establish methods to measure efficacy prior to a definitive efficacy study being conducted. The second phase study was conducted at 6 sites in the US; subjects were treated with one to three procedure sessions over 2 months. A total of 28 subjects were enrolled, treated and followed for three months post treatments. Major findings from the study include:

- Device settings that demonstrated efficacy with appropriate safety parameters were identified
- A reduction to an HDSS score of 1 or 2 in 82% of subjects (measured 30 days post-treatment)

Randomized Study

The device used and the settings determined from the prior study procedure were then implemented in a large, randomized sham-controlled study at 7 sites in the US.[8,9] A total of 120 subjects were randomized (81 in the active treatment group and 39 in the sham treatment group). Treatments were conducted in one to three procedure sessions, typically spaced 2 weeks apart. Subjects in the sham group were followed for 6 months. Subjects in the active group were followed for 12 months. The major findings from the study were:

- A reduction to an HDSS score of 1 or 2 in 89% of subjects (measured 30 days post-treatment) in the active group, and a statistically significant difference between active and sham group was seen ($p<0.001$)
- HDSS efficacy in the active group was relatively stable from 3 months (74%) to the last study visit at 12 months (69%)
- Gravimetric assessments (weight of sweat) also showed stability in efficacy from 3 to 12 months
- The procedure was well tolerated and a strong safety profile was established

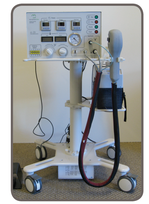


Figure 3. Investigational version of the miraDry System used in Feasibility and Randomized studies.

miraDry Study

Based on findings from the pre clinical animal studies as well as the two human clinical trials, a commercial version of the device, named the miraDry System (see Figure 4), was developed that added software control and automatic safety features. The energy delivery through the handpiece microwave antennas was also improved to eliminate potential gaps between the heated regions under each antenna.

Figure 4. Commercial miraDry System used in the miraDry study.

The miraDry procedure using the commercial device was tested in 2 sites in Canada in a single-group study of 31 subjects. These subjects were treated in one to three procedure sessions, with procedure sessions now being held two to three months apart. At the time of this writing, efficacy and safety data are available for up to 3 months post-treatment.[10] Subjects will be followed for 12 months. The major findings from this study were:

- A reduction to an HDSS score of 1 or 2 in 90% of subjects (measured 30 days post-treatment)
- The procedure and device improvements have stabilized the efficacy seen at later time points compared to prior studies; the last reported efficacy was 94% at 3 months post-treatment
- The average reduction in amount of sweat produced (measured by gravimetric assessment) was 82%.
- Patient satisfaction tracks very closely with efficacy and has been reported at >90%

A compilation of efficacy results for the three reported studies can be seen in Table 3 and plotted over time in Figure 5. The most recent miraDry study with the optimized device and procedure show greater than 90% efficacy.

Table 3. Comparison of HDSS Score Reduction Results for Three Reported Studies

Study	Reference	30 days	3 months	6 months	12 months
Feasibility	Kaminer	23/28=**82%**	18/28=**64%**	not available	not available
Randomized	Kilmer	72/81=**89%**	60/81=**74%**	54/81=**67%**	56/81=**69%**
miraDry	Lupin	28/31=**90%**	29/31=**94%**	(pending)	(pending)

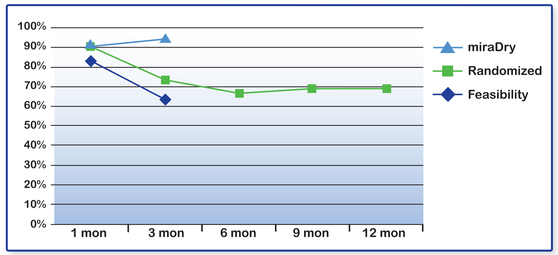


Figure 5. Percentage of subjects that had HDSS scores of 1 or 2 at the indicated follow-up visits for each study.

Finally, the safety data across all three clinical studies has been very good. Almost all subjects noted the expected mild, temporary swelling and discomfort in the treatment area post-treatment with an average duration of approximately one week; altered sensation in the treatment area can last several months. Treatment-related effects were apparent very soon after a procedure and have almost entirely been transient. Table 4 lists the side effects with incidence >5% of subjects seen in each study. Only interim data from the miraDry commercial device study is available as the study is still ongoing.

Table 4. Most Common Adverse Events in Each Study

Category	# of subj (%)	Severity (events)
Feasibility Study (n=28)		
Numbness or altered sensation outside treatment area	10 (36%)	10 mild, 3 moderate
Compensatory hyperhidrosis	2 (7%)	1 mild, 1 moderate
Randomized Study (n=81)		
Numbness or altered sensation outside treatment area	8 (10%)	8 mild, 1 moderate
Axillary pain requiring Rx medication or soreness	5 (6%)	4 mild, 1 moderate, 1 severe*
miraDry Study (n=31)		
Numbness or altered sensation outside treatment area	12 (39%)	16 mild
Edema in limb or chest	8 (26%)	5 mild, 3 moderate
Skin: Irritation or rash	3 (10%)	3 mild
Tenderness in arms	3 (10%)	3 mild

* One subject elected bedrest after the procedure which required a severe rating.

Conclusion

Primary focal hyperhidrosis remains a difficult clinical problem. Through deliberate engineering, study and clinical analysis, a novel device using microwave energy has been developed. This device focuses the energy at a specific depth and uses topical cooling to preserve the more superficial layers of skin. Clinical studies have shown:

- Significant overall efficacy with improvement at each stage of device development
- A highly acceptable safety profile with mild, generally self-limited changes
- An easy to perform clinical procedure
- The possibility that the improvement in hyperhidrosis may be long-lived compared to existing therapies

References

1. Strutton DR, Kowalski JW, Glaser DA, et al. US prevalence of hyperhidrosis and impact on individuals with axillary hyperhidrosis: results from a national survey. J Am Acad Dermatol 2004;51:241-8.
2. Exley C. Does antiperspirant use increase the risk of aluminium-related disease, including Alzheimer's disease? Mol Med Today 1998;4:107-9.
3. Graves AB, White E, Koepsell TD, et al. The association between aluminum-containing products and Alzheimer's disease. J Clin Epidemiol 1990;43:35-44.
4. Kim WO, Kil HK, Yoon KB, et al. Treatment of generalized hyperhidrosis with oxybutynin in post-menopausal patients. Acta Derm Venereol 2010;90:291-3.
5. Bajaj V, Langtry JA. Use of oral glycopyrronium bromide in hyperhidrosis. Br J Dermatol 2007;157:118-21.
6. Dumont P. Side effects and complications of surgery for hyperhidrosis. Thorac Surg Clin 2008;18:193-207.
7. Kaminer MS, Coleman WP, Fan LK et al. First Clinical Use of a Novel Microwave Device for Treatment of Axillary Hyperhidrosis. In: American Society of Dermatologic Surgeons 2010 Annual Meeting. Chicago, IL; 2010.
8. Glaser DA, Coleman WP, Fan LK, Kaminer MS, Kilmer SL, Nossa R, Smith SR. A randomized, blinded clinical evaluation of a novel microwave device for treatment of axillary hyperhidrosis. In: American Society of Dermatologic Surgeons Annual Meeting. Chicago IL; 2010.
9. Kilmer S, Coleman WP, Fan L, Glaser DA, Kaminer M, Nossa R, Smith SR. A randomized, blinded clinical study of a microwave device for treatment of axillary hyperhidrosis. In: The 31st Annual Conference of the American Society for Laser Medicine and Surgery. Grapevine TX; 2011 (late breaking).
10. Lupin ML, Hong C-H, O'Shaughnessy KF. A multi-center evaluation of the miraDry System to treat subjects with axillary hyperhidrosis. In: The 31st Annual Conference of the American Society for Laser Medicine and Surgery. Grapevine, TX; 2011.

Presentation funded by Miramar Labs.
S. Smith is a consultant for Miramar Labs.

Cosmetic Boot Camp 2011, Aspen, CO

First Clinical Use of a Novel Microwave Device for Treatment of Axillary Hyperhidrosis

Michael S. Kaminer, MD[1]; William P. Coleman III, MD[2]; Larry K. Fan, MD[3]; Suzanne L. Kilmer, MD[4]; Steve W. Kim[5]; Robert N. Nossa, MD[6]; Kathryn F. O'Shaughnessy, PhD[5]; Perry H. Solomon, MD[7]

[1] Department of Dermatology, Yale University Medical School, New Haven, CT and SkinCare Physicians, Chestnut Hill, MA; [2] Department of Dermatology and Plastic Surgery, Tulane University Health Sciences Center, New Orleans, LA and Coleman Cosmetic Dermatologic Surgery Center, Metairie, LA; [3] Bay Area Center for Plastic Surgery, Oakland, CA; [4] Laser and Skin Surgery Center of Northern California, Sacramento, CA; [5] Miramar Labs, Sunnyvale, CA; [6] The Dermatology Group Northern New Jersey, Verona, NJ; [7] Bridges Medical Clinic, San Ramon, CA

Introduction

Primary focal hyperhidrosis is a disorder of excessive, bilateral, and relatively symmetric sweating that can occur in focal areas of the body, very commonly in the underarms.[1] It is characterized by uncontrollable sweating that is more than is needed for thermal regulation of the body.

Hyperhidrosis can have significant psychological and social effects on patients and negatively impact their quality of life.[2]

Current therapy options' include temporary over-the-counter treatments and prescription anti-perspirants, longer-lasting but still temporary botulinum toxin injections, as well as invasive sympathectomy and liposuction/curettage surgery. Although each has its merits, the potential for a long lasting, non-invasive, effective device holds promise.

A new non-invasive microwave device for treatment of primary axillary hyperhidrosis has been explored and tested in feasibility studies.

Objectives

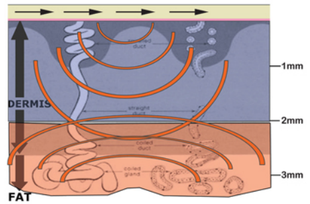
The objectives of this study were to demonstrate a safe and effective local treatment for primary axillary hyperhidrosis with prototype devices; and develop a treatment protocol for full axillary treatment with demonstrated clinical benefit.

Methods

Device Description

The microwave devices being tested in this study were designed to focus microwave energy at the dermal/subdermal interface in the location of the apocrine and eccrine sweat glands. The sweat glands are especially susceptible to microwave energy due to their high ionic water content.

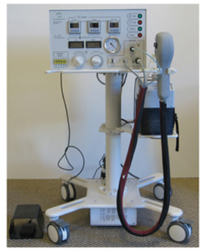
The molecular rotation of the sweat gland molecules in the presence of microwaves causes localized heating, which in turn leads to irreversible thermal necrosis of the sweat glands. The handpiece portion of the device incorporates a vacuum suction feature to lift and localize the treatment area and provide stability during the energy delivery phase. The vacuum lift feature along with the design of the microwave antenna (including the choice of an optimal frequency of operation) helps protect the deeper critical structures in the axilla. Additionally, an active hydro-ceramic cooling system integrated into the handpiece that is in direct thermal contact with the skin prevents damage to the upper and mid dermis. Local anesthesia injections were used for patient comfort, but the device itself is non-invasive.



▲ *Schematic view of the interaction of the Applicator with the tissue in the axilla. The cooling fluid on the surface of the skin creates a cooler (blue) zone, while the microwave energy penetrating into the dermis causes heating at the dermis/ fat interface (light red zone).*

The microwave system consists of four major components:

1. Generator: The Generator contains electric circuits, circuit boards and an ingrated control panel and provides generation of microwave energy at 5.8GHz, up to 100 Watts set by the user in 5 Watt increments, generation of vacuum set by the user, user settings of pre-cool, energy delivery, and post-cool durations in sub-second increments and display of the skin and coolant temperatures.
2. Chiller/Circulator: The Chiller/Circulator is a solid-state chiller designed to chill water in its reservoir and pump the water through inlet and outlet ports on the back of the unit. It is used to create fluid flow through the Applicator cooling chamber to protect the skin from thermal damage.
3. Isolation Transformer: This component provides isolation of the AC mains to the equipment as part of the patient safety system.
4. Applicator: The applicator includes a vacuum acquisition chamber, a surface cooling feature, four microwave antennas which can be activated sequentially, and thermocouple temperature sensors to monitor skin and cooling fluid temperatures. Not shown is the disposable snap-on head that provided a protective barrier between the patient and the Applicator.



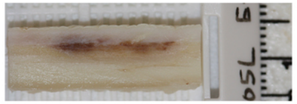
▲ *Second generation study device used for the treatments described in this study*

Over the course of the study, adjustments were made to the power and time settings used and the extent of the axilla that was treated in a single session as one of the goals of the study was to determine appropriate device settings and treatment protocol for a larger study.

Pre-Clinical Experience

Many animal studies were performed to confirm the safety of the device and that the energy can be focused in the dermal-hypodermal interface. The animal model used was the Yorkshire pig. The belly/fore flank area of the pig where the dermal thickness is in the range of 1-2mm was utilized as the test area. Energy dosage studies were performed, with animal survival out to several time-points (1 wk, 1 month, and 3 months). A range of energy levels demonstrated consistent thermal damage to the tissue in the dermal-hypodermal interface and showed a high safety profile.

The conclusions made from the studies were that the therapy is safe and that it would be appropriate to initiate human clinical studies with the energy levels developed from the pre-clinical experience.



◄ *Cross-section of porcine skin showing localized hematoma reaction in the dermal-hypodermal interface due to the microwave therapy. The area of hematoma reaction correlates well to histologic evidence of thermal damage to the tissue in the area.*

Study Design

This was a prospective, multi-center, non-randomized single-group feasibility study. IRB approval was obtained for this study and all subjects gave informed consent. The study was conducted in two stages.

The first stage used a prototype device (not shown) to treat small areas of the axilla in one treatment session. In this first stage, efficacy was qualitatively measured using the starch-iodine test and safety information was recorded.

The second stage used a device with the same technology as in the first step, modified to more easily treat larger areas of the axilla. Subjects' full axillae (hair bearing area) were treated in multiple sessions (ranging from one to four) with slightly different device settings. Local anesthetic injected throughout the axilla was used to provide pain management. Subjects were followed for a minimum of 90 days after their final treatment session to establish the safety and efficacy of the treatment. Efficacy was measured by Hyperhidrosis Disease Severity Scale and gravimetric assessments (standardized weighing of sweat produced) and safety information was recorded.

Hyperhidrosis Disease Severity Scale (HDSS) definition. The question asked is: How would you rate the severity of your hyperhidrosis?

HDSS Value	Definition
1	My underarm sweating is never noticeable and never interferes with my daily activities
2	My underarm sweating is tolerable but sometimes interferes with my daily activities
3	My underarm sweating is barely tolerable and frequently interferes with my daily activities
4	My underarm sweating is intolerable and always interferes with my daily activities

Subjects

For both steps of the study, subjects were males and females at least 18 years of age diagnosed with primary axillary hyperhidrosis, as evidenced by all of the following:
- Subjects were required to have an HDSS of 3 or 4
- Bilateral primary axillary hyperhidrosis

Subjects were excluded if they met any of the following conditions:
- Prior endoscopic thoracic sympathectomy, liposuction or other surgery for axillary hyperhidrosis
- Axillary injection of botulinum toxin within 180-days preceding the treatment
- Topical treatments for axillary hyperhidrosis within 14 days immediately preceding the treatment
- Oral anticholinergic medication use or cholomimetic medication within the last 6 months or planned use during

Efficacy Outcomes

For the first stage of the study where only small areas were treated, efficacy was qualitatively determined from reviewing the starch-iodine photos.

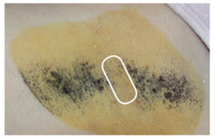
For the second stage of the study, more global efficacy measures were used after the full axilla was treated. The primary efficacy measure was the Hyperhidrosis Disease Severity Scale (HDSS) questionnaire. A positive outcome was defined as a subject that rated themselves with an HDSS score of 1 or 2 at the 30-day follow-up visit (relative to the last treatment session). Last-observation-carry-forward was used to replace missing values for missed visits.

A gravimetric assessment was also used as a second, quantitative efficacy measure. The gravimetric assessment is a test that uses standard filter paper to absorb underarm sweat over a 5-minute period at room temperature while the patient is at rest. The filter paper is weighed before and after and the amount of sweat produced is measured in milligrams.

Safety Outcomes

Safety data was collected for all enrolled subjects throughout the study. These data included subject-rated pain ratings after each treatment session, evaluation of the axilla condition immediately post-treatment by the physician, and adverse events. Expected treatment effects that were minor in severity and in the treatment region were recorded separately from adverse events.

Results



First Stage Results – Local Efficacy

In the first stage of the study, fifteen subjects were enrolled at two sites. Small areas in the axilla ranging from size 1 to 3 cm^2 were treated in one treatment session. An example of the starch-iodine test from one subject shows the treated area has remained without sweat for 14 months after the one treatment session.

◄ *Starch-iodine test taken 14 months after treatment in the indicated area. The black areas indicate still-active sweat glands. The lack of sweat in the treated area is apparent.*

Second Stage Results – Full Axilla Treatment

In the second step of the study, thirty subjects were enrolled at six sites. Subject demographics are summarized in Table 1 below.

Patient Demographics and Characteristics

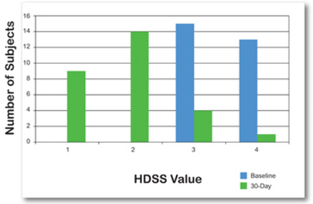
Age		Ethnicity	N (%)
Median	34 years old	Caucasian	23 (77%)
Range	19-49	Hispanic / Latino	6 (20%)
		African American	1 (3%)
Gender	**N (%)**	**Body Mass Index**	
Male	13 (43%)	Median	25.6
Female	17 (57%)	Range	20.2 – 40.8

Efficacy

There were 28 subjects that completed all treatments and were available for post-treatment follow-up HDSS efficacy measurements. Of these 28 subjects, 20 had baseline gravimetric values of at least 50 mg in each axilla, allowing a post-treatment evaluation of efficacy using the gravimetric assessments.

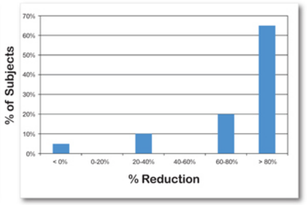
- For the primary efficacy analysis, 23/28=82% of the subjects were classified as responders (their HDSS scores dropped to 1 or 2 at the 30 day follow-up visit).
- The efficacy reduced slightly by the final 90-day visit; 18/28=64% had HDSS score of 1 or 2. Further investigation identified improvements that could be made to the procedure and the device to improve the long-term efficacy.
- The average HDSS score dropped from 3.5 at baseline to 1.9 at the 30-day follow-up visit and 2.1 at the 90-day follow-up visit.
- Gravimetric assessment values showed a similar trend. The median reduction in produced sweat was 83% at the 30-day follow-up visit and 74% at the 90-day final follow-up visit. If one defines success as achieving at least a 50% reduction in sweat, at the 30 day follow-up visit the efficacy was 80% (16/20); at the 90-day visit the efficacy was 75% (15/20).

HDSS Distribution



▲ *Distribution of HDSS scores for efficacy group of 28 subjects at baseline (blue bars) and at the 30-day follow-up visit (green bars). The overall efficacy (number of subjects with scores of HDSS=1 or 2) was 82%.*

% Reduction in Axillary Sweat at 30 Day Visit

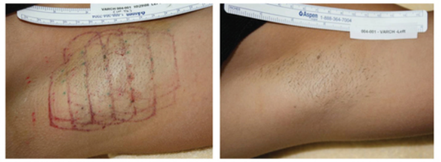


▲ *Percentage of subjects from the gravimetric assessment group (n=20) with the indicated reduction in sweat, as measured by gravimetric assessment at the 30-day follow-up visit.*

Safety

Safety data showed that the treatments were well tolerated and that adverse events were generally mild. In the first stage of the study, where only small areas were treated, there were no adverse events recorded.

In the second stage, averaging over all subjects and treatment sessions, the average pain rating was 1.5 out of 10 on a scale of 0 to 10, with 0 being no pain at all and 10 being the worst pain the subjects could imagine. 88% of subjects experienced a pain rating of 3 or less during the procedure.



▲ *Example of most common post-treatment immediate effect, bruising (due to vacuum acquisition of tissue) and healing 4 days later.*

All subjects were evaluated immediately post-treatment by the investigator. The most common treatment effects noticeable in the axilla included: bruising (77%), soreness due to procedure position (49%), redness (25%) and edema in the treatment area (21%). These were all expected, relatively mild, transient effects. An example of a post-treatment subject's axilla is shown above, with the photo on the left taken immediately post-treatment and the one on the right taken four days later, showing that all the effects have healed.

There were no reports of device-related serious adverse events or unanticipated adverse device effects during the study. There were a total of 24 adverse events, where 6 were judged by the investigator as not being related to the device or procedure. Treatment-related adverse events included: numbness, tingling, or sensitivity in treatment limb (43% of subjects treated, n=13); altered sweating elsewhere (7%, n=2), blisters (3%, n=1), infection due to ingrown hair (3%, n=1) and decreased sensitivity in treatment area (3%n=1). All events resolved.

Conclusions

The study demonstrated a highly feasible microwave-based non-invasive treatment for primary axillary hyperhidrosis.

A larger study would need to be performed to determine predictable efficacy and the duration of such treatments. This study provided data for the appropriate device settings and treatment session optimization for such a study. Some improvements for the device and procedure were identified and have been implemented in the next generation device to increase the long-term efficacy.

References

1. Hornberger J, Grimes K, Naumann M, et al. Recognition, diagnosis, and treatment of primary focal hyperhidrosis. J Am Acad Dermatol 2004; 51:274-286.
2. Strutton DR, Kowalski JW, Glaser DA, and Stang PE. US prevalence of hyperhidrosis and impact on individuals with axillary hyperhidrosis: Results from a national survey. J Am Acad Dermatol 2004; 51: 241-248.

Study funded by Miramar Labs, Sunnyvale, CA

Michael Kaminer and WP Coleman III are consultants for Miramar Labs and are members of Miramar Labs' Scientific Advisory Board.

American Society for Dermatologic Surgery 2010 Annual Meeting.

Bye-bye Busch

11. August 2015 07:05; *Akt: 11.08.2015 07:05*

Nie wieder Achselhaare dank Mikrowellen

Die einen lieben sie und lassen sie wachsen, andere unternehmen alles, um sie loszuwerden: Achselhaare. Für Letztere gibt es nun eine neue Lösung.

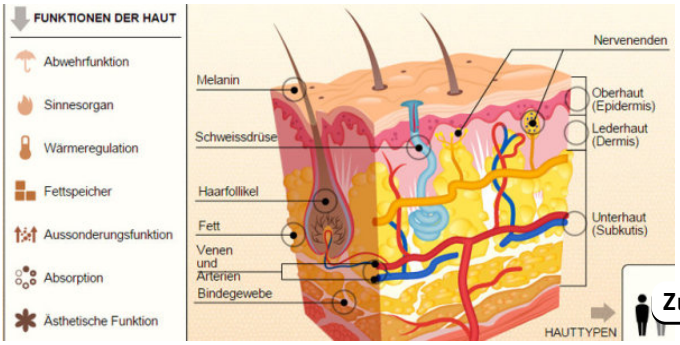
Miley Cyrus liebt Haare. Auch solche unter den Achseln. Zwar ist sie damit nicht allein, aber nach wie vor versuchen viele Frauen (und Männer) alles, um sie loszuwerden. Das Problem: Wer sich das Achselgestrüpp nicht weglasern oder mithilfe von Blitzlampen entfernen lässt, ärgert sich schon kurz darauf wieder über Stoppeln. Doch auch die dauerhaften Methoden sind nicht für jeden geeignet (siehe Box).

Abhilfe verspricht eine neue, nicht invasive Methode aus den USA, die soeben von der US-Behörde FDA zugelassen wurde. Anders als alle bisherigen Methoden soll MiraSmooth auch jenen helfen können, bei denen Laser und Blitzlampen an ihre Grenzen stossen. Denn laut Mitteilung des Herstellers spielt die Farbe der Pigmente von Haar und Haut keine Rolle.

Positive Nebenwirkung

Ganz neu ist das Verfahren jedoch nicht. Vielmehr handelt es sich um eine Weiterentwicklung der MiraDry-Methode, die bereits seit zwei Jahren gegen übermässiges Schwitzen, die sogenannte Hyperhidrose, eingesetzt wird. Dabei werden die Schweissdrüsen – ebenfalls durch Mikrowellen – dauerhaft zerstört und dann vom Körper abgebaut.

Den Anwendern fiel dabei auf, dass nach der Prozedur nicht nur das Schwitzen, sondern auch die Achselhaare weniger wurden – die neue Idee war geboren.



Zur Infografik »

(fee)

So funktionieren Laser- und Blitzlampen-Enthaarungen

Laser arbeiten mit genau definierten Wellenlängen und Lichtintensitäten. Bei der Blitzlicht-Epilation hingegen wird hochfrequentes Licht auf die Haut «geblitzt». Damit sollen die Haarwurzel so geschädigt werden, dass keine Haare mehr nachwachsen. Allerdings werden dabei – anders als beim Lasern – nicht nur die einzelnen Haare, sondern ganze Hautpartien behandelt.
Das Problem: Beide Methoden wirken nur auf wachsende Haare und viele der Haare am Körper sind im Ruhezustand. Zudem eignen sie sich nicht für alle Anwender. So sollte die Haut möglichst hell, die Haare aber dunkel sein. Denn das dunkle Haar absorbiert die Lichtenergie, leitet sie in die Tiefe und der Haarfollikel wird durch das Haar selbst verkocht und geht zugrunde. Ist der Teint selbst dunkel, besteht die Gefahr, dass auch die Haut das Licht absorbiert. Dann können Entzündungen und Verbrennungen die Folge sein.

51 Kommentare

Die beliebtesten Leser-Kommentare

Sumsum am 11.08.2015 07:40 via

246
22

Gut,aber...

Ausgabe Frühjahr 2015

Gesund|leben

Heuschnupfen:
Was wirklich hilft und wie sich vorbeugen lässt

Herz-Kreislauf-Probleme:
Erschöpft und schlapp? Welche Rolle das Wetter spielt

Fitness-Test:
So verbessern Sie in wenigen Schritten Ihre Beweglichkeit

Frühjahrsmüdigkeit

Eine Laune der Natur?

Wie Sie dem Phänomen die Stirn bieten

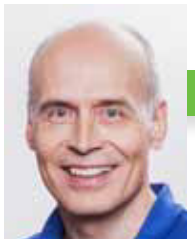
Gesund leben

ADVERTORIAL

Wenn Schwitzen zur Belastung wird

Was der Kelkheimer Dermatologe Dr. Rainer Jokisch Hyperhidrose-Betroffenen rät

Schwitzen ist eine lebenswichtige Funktion für unseren Körper, denn damit kühlt er die Haut und auch das Innere des Körpers. Für manche Menschen wird das Schwitzen allerdings zum Problem. Sie leiden an einer übermäßigen Schweißproduktion, auch „Hyperhidrose" genannt. Menschen, die davon betroffen sind, schwitzen verstärkt und ausbruchsartig – unabhängig von Wärme, Kälte, Tages- oder Jahreszeit. Die Angst, das Schwitzen nicht kontrollieren zu können, verstärkt den Effekt. Der Schweiß wird zu einer starken Belastung für sie selbst und das gesamte Umfeld, mit allen unangenehmen Begleiterscheinungen wie Geruch, schwitzigen Händen, Flecken auf der Kleidung. Neue Untersuchungen haben gezeigt, dass von übermäßigem Schwitzen Betroffene eine ähnlich starke Minderung ihrer Lebensqualität erleiden wie Tumorpatienten. Oft leiden die Betroffenen still, schämen sich, sind frustriert, weil sie sich von ihrem übermäßigen Achselschweiß in vielen Bereichen des Lebens gestört fühlen. Für viele ist dieser Zustand eine Belastung: Angst bei der Arbeit, Verlegenheit bei sozialen Kontakten sowie Einschränkung der Freizeitaktivitäten.



Der **EXPERTE**

Dr. med.
Rainer Jokisch

ist Facharzt für Dermatologie mit der Zusatzbezeichnung Phlebologe und der Qualifikation „Diploma in aesthetic laser medicine".

Herr Dr. Jokisch, worum handelt es sich bei miraDry, dem neuen Hyperhidrose-Verfahren aus den USA?
miraDry ist ein neues, nicht-invasives und klinisch erprobtes Verfahren gegen übermäßiges Achselschwitzen (axillare Hyperhidrose) und starken Schweißgeruch. Es basiert auf einer sicheren Mikrowellen-Technologie und ist die einzige Thermolyse-Methode, die eine FDA-Zulassung und ein CE-Zeichen besitzt. miraDry stellt eine hochwirksame Alternative zu den bisherigen Behandlungsmöglichkeiten dar, weil es erstmals sofortige und dauerhafte Ergebnisse liefert. Es gibt fast keine Ausfallzeiten und nur minimale Nebenwirkungen. Viele Patienten empfinden es als äußerst positiv, dass sich die Behaarung unter den Achseln reduziert und gleichzeitig die Geruchsdrüsen verschwinden.

Wie funktioniert miraDry?
Während der einstündigen Behandlung werden die Schweißdrüsen mit präzise gesteuerter elektromagnetischer Energie (Mikrowellen) bestrahlt. Die entstehende Hitze von ca. 60°C wird durch ein hydrokeramisches Kühlsystem direkt auf die Hautschicht gelenkt, in der die Schweißdrüsen sitzen. Nach ein paar Sekunden setzt die Zellthermolyse ein und die Schweißdrüsen samt ihrer Versorgungsnerven sterben ab. Da sich einmal zerstörte Schweißdrüsen nicht wieder regenerieren, sind die Ergebnisse von miraDry bleibend.

Inwiefern ist miraDry anders als die bisherigen Therapiemöglichkeiten?
Bei den herkömmlichen Behandlungsmethoden wurden die Schweißdrüsen meist nur vorrübergehend ausgeschaltet oder im Rahmen eines chirurgischen Eingriffs und den damit verbundenen Risiken entfernt. miraDry bietet Hyperhidrose-Patienten erstmals eine nichtoperative und dauerhafte Lösung für ihr übermäßiges Schwitzen. In zahlreichen klinischen Studien wurde gezeigt, dass miraDry die Schweißproduktion signifikant und nachhaltig reduziert und damit die Lebensqualität der Betroffenen enorm verbessern kann.

Wie läuft die Behandlung ab?
Das miraDry-Verfahren wird ambulant in unserer Arztpraxis durchgeführt und dauert in der Regel eine Stunde. Vor der Behandlung wird der zu behandelnde Achselbereich markiert und mit einem lokalen Anästhetikum betäubt. Nun wird das Handstück nach einem definierten Protokoll abschnittweise über den markierten Bereich geführt. Dabei wird die Haut angesaugt, die Energie abgegeben und anschließend 20 Sekunden lang gekühlt. Das miraDry-Verfahren kommt gänzlich ohne chirurgische Einschnitte aus. Im Anschluss an die Behandlung kühlen wir die Achseln mit Kühlpacks und empfehlen unseren Patienten Ibuprofen gegen die Schmerzen einzunehmen.

Ist das Verfahren schmerzhaft?
Die meisten Patienten empfinden wenig oder keinen Schmerz, da das zu behandelnde Hautareal vorher lokal betäubt wurde. Auf einer Skala von 1 (= kein Schmerz) bis 10 (= starker Schmerz) bewerten die Patienten miraDry mit einer Durchschnittsnote von 2.

Welche Ergebnisse kann man erwarten?
Sofort nach der Behandlung spüren die Patienten eine deutliche Schweißreduktion. Da die Schweißdrüsen durch die Mikrowellen dauerhaft zerstört wurden, sind die Ergebnisse von Dauer. Eine kürzlich durchgeführte Studie belegt, dass miraDry das Schwitzen um durchschnittlich 82% reduziert. Ein positiver Nebeneffekt: Mehr als 30% der Patienten verlieren die Behaarung unter den Achseln. Außerdem verschwindet der unangenehme Achselgeruch (Bromhidrose), da die Geruchsdrüsen ebenfalls zerstört werden. Da jeder Patient einzigartig ist, können die Ergebnisse wie bei jedem medizinischen Eingriff variieren.

Wie viele Behandlungen sind notwendig?
Für ein optimales Ergebnis sind zwei Behandlungen im Abstand von 3 Monaten notwendig.

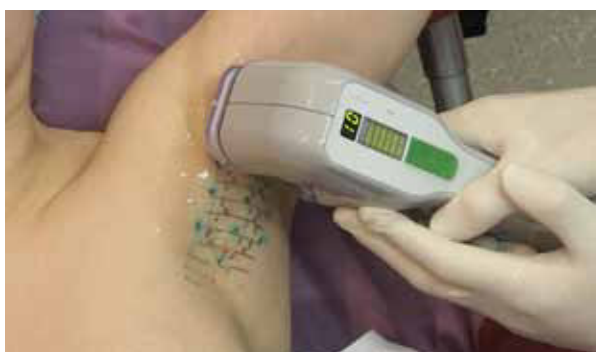
Wie lange muss sich der Patient nach der Behandlung schonen?
Die meisten können sofort nach der Behandlung wieder ihren gewohnten Tätigkeiten nachgehen. In der Regel gibt es lediglich eine kurze bis gar keine Ausfallzeit. Wir empfehlen unseren Patienten, ihre sportlichen Aktivitäten erst nach ein paar Tagen wieder aufzunehmen.

Welche typischen Nebenwirkungen gibt es?
Lokale Schmerzen, geringe Schwellungen, Blutergüsse und Taubheitsgefühl der Haut sind normale Nebenwirkungen, die nach kürzester Zeit ganz von selbst wieder verschwinden.

Braucht man die Schweißdrüsen unter den Achseln nicht?
Nein, nicht wirklich. Der Körper besitzt über vier Millionen Schweißdrüsen, von denen sich nur etwa 2 % unter den Achseln befinden. Wenn diese 2 % beseitigt werden, hat das keinen Einfluss auf die Fähigkeit des Körpers, sich selbst zu kühlen.

Mehr Informationen zur Hautmedizin Kelkheim, Frankenallee 1, Kelkheim am Taunus, unter 0 61 95/67 72-3 00

praxis@hautmedizin-kelkheim.de sowie unter www.hautmedizin-kelkheim.de oder www.hot-without-sweat.de



Für wen ist das miraDry-Verfahren geeignet?

- ☺ Patienten mit einer diagnostizierten axillären Hyperhidrose
- ☺ Patienten, die unter ihrem Achselschweiß leiden
- ☺ Patienten, die peinliche Achselschweißausbrüche haben
- ☺ Patienten, die mehrmals täglich ein starkes Antitranspirant-Deo verwenden müssen
- ☺ Patienten, die sich über großen Schweißflecken auf der Kleidung ärgern
- ☺ Patienten, die unter unangenehmen Schweißgeruch kurz nach dem Duschen leiden

- ☹ Für Patienten mit Herzschrittmachern und anderen elektronischen Implantaten, die eine zusätzliche Sauerstoffversorgung benötigen oder die eine Unverträglichkeit gegen die Betäubungsmittel Lidocain und Epinephrin haben, ist das Verfahren nicht geeignet.

DERMA*forum*
Zeitung für Dermatologie und Allergologie

KIRCHHEIM

FÄD
Forum Ästhetische Dermatologie

EINE SPEZIALAUSGABE VON DERMA*forum* FÜR ÄSTHETIK UND KOSMETOLOGIE Nr. 5 – Mai 2015 19. Jahrgang

Nicht invasives Thermolyse-Verfahren

Mit Mikrowellen gegen Achselschweiß

Dr. med. Rainer Jokisch, Kelkheim, stellt ein neues Verfahren zur Behandlung der Hyperhidrosis axillaris und der Bromhidrose vor.

Ein neues, nicht invasives, klinisch erprobtes Verfahren (miraDry), das auf der kontrollierten Applikation von Mikrowellen basiert, ist die derzeit einzige Thermolyse-Methode, die eine FDA-Zulassung und ein CE-Zeichen besitzt sowie von der International Hyperhidrosis Society und dem Deutschen Hyperhidrosezentrum DHHZ empfohlen wird. Ziel der Behandlung ist die thermische Schädigung ekkriner und apokriner Schweißdrüsen zur dauerhaften Reduktion axillärer Schweißproduktion. Das Verfahren ist im Gegensatz zu den Radiofrequenz-Verfahren nicht invasiv und unter Lokalanästhesie (keine Tumeszenz-LA) auch schmerzfrei. Es stellt eine hochwirksame Alternative zu den bisherigen Behandlungsmöglichkeiten dar, weil es erstmals sofortige und dauerhafte Ergebnisse liefert. Das Mikrowellen-Verfahren füllt damit die bestehende Lücke zwischen konservativer Behandlung und Operation.

Zerstörte Schweißdrüsen – bleibende Ergebnisse

Das zu behandelnde Areal entspricht der Ausdehnung der axillären Behaarung, weshalb sich die Patienten fünf Tage präoperativ zuletzt rasieren sollten. Die Haarstümpfe sind dann die Orientierungspunkte. Vor Behandlungsbeginn wird mit einer Abziehfolie das Behandlungsmuster auf die axilläre Haut übertragen. Damit ist jeder einzelne Betäubungspunkt und jede einzelne Behandlungsstelle für das Bio-Tip exakt auf der Haut festgelegt. Idealerweise werden beide Axillen mit Lidocain 1 %/Adrenalin 1:100.000 und kurzen 4 mm/30G Kanülen betäubt und eine Einwirkzeit von mindestens zehn Minuten beachtet. Während der Behandlung wird das Handstück nach einem von der gewählten Abziehfoliengröße abhängigen, definierten Protokoll abschnittweise über den markierten Bereich geführt. Bei jedem einzelnen Behandlungszyklus wird eine Fläche von 10 x 30 mm behandelt. Da sich einmal zerstörte Schweißdrüsen nicht wieder regenerieren, sind die Ergebnisse der Behandlung bleibend.

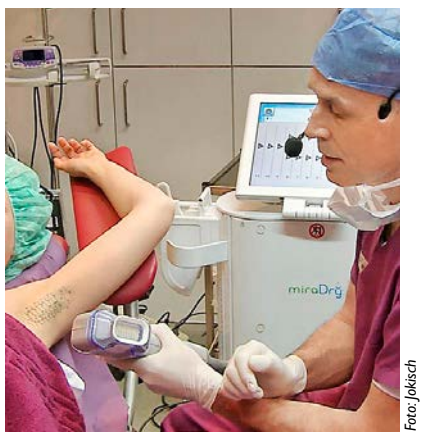


Foto: Jokisch

Dr. med. Rainer Jokisch bei der Anwendung des Thermolyse-Verfahrens

Fokussierte Zufuhr von elektromagnetischer Energie

Die Funktionsweise des Systems beruht auf der fokussierten Zufuhr von elektromagnetischer Energie (Mikrowellen) der Wellenlänge 5,8 GHz. Die Energie wird entlang des Haut-Fett-Bindegewebes und wasserreicher Adnex-Strukturen (Schweißdrüsen) konzentriert, da Mikrowellen auf Dipole wirken. So erklärt sich die bevorzugte Wirkung auf ekkrine, aber auch apokrine Schweißdrüsen (Bromhidrosis = übermäßiger Schweißgeruch). Durch entstehende Interferenzen intensiviert sich die Energie und bildet auf diese Weise eine fokale Energiezone. Das kontinuierlich hydrokeramische Kühlsystem begrenzt die Wärmezone auf den Bereich der Schweißdrüsen, deren Moleküle durch die Mikrowellen in Schwingungen versetzt werden. Die entstehende Hitze von über 60 °C zerstört die Schweißdrüsen und die innervierenden postsynaptischen Fasern des Sympathikus-Nervs irreversibel. (Zellthermolyse).
Bei mehr als 30 % der Patienten tritt nach der Behandlung eine Haarwuchsreduktion im Achselbereich auf. Alle Patienten fühlen sich erleichtert durch das Verschwinden des unangenehmen Schweißgeruchs (Bromhidrosis), da die apokrinen Schweißdrüsen ebenfalls zerstört werden. Mögliche Nebenwirkungen wie vorübergehende Rötungen, blaue Flecken, Druckempfindlichkeit, Schwellungen oder ein leichtes Taubheitsgefühl in den Fingern klingen nach kurzer Zeit von selbst ab. Für gewöhnlich treten keine Hämatome auf und die Bewegungsfreiheit wird nicht beeinträchtigt.

82 % Reduktion nach zwei Behandlungen

Eine klinische Langzeit-Studie bestätigt, dass das Verfahren das Schwitzen bereits nach zwei Behandlungen im Abstand von drei Monaten um ca. 82 % reduziert. Insgesamt zeichnet sich nach Studienlage in den Ergebnissen auch nach drei Jahren eine erfreulich hohe Zufriedenheit der Patienten ab. Die Kosten für zwei Behandlungen beider Axillen liegen bei ca. 2.600 €.
Das Mikrowellen-Verfahren kann die axilläre Schweißproduktion in einem hohen Prozentsatz von über 80 % dauerhaft reduzieren. Es dürfte deshalb zukünftig die Notwendigkeit operativer Methoden zumindest infrage stellen. Gerade auch für unsere bisher BTX-behandelten Hyperhidrosis-Patienten ist es eine interessante Alternative. Unsere initialen Behandlungsergebnisse decken sich mit den in Studien berichteten positiven Ergebnissen. *jt* ◆

Weitere Informationen unter www.hot-without-sweat.de und www.european-aesthetics.com.

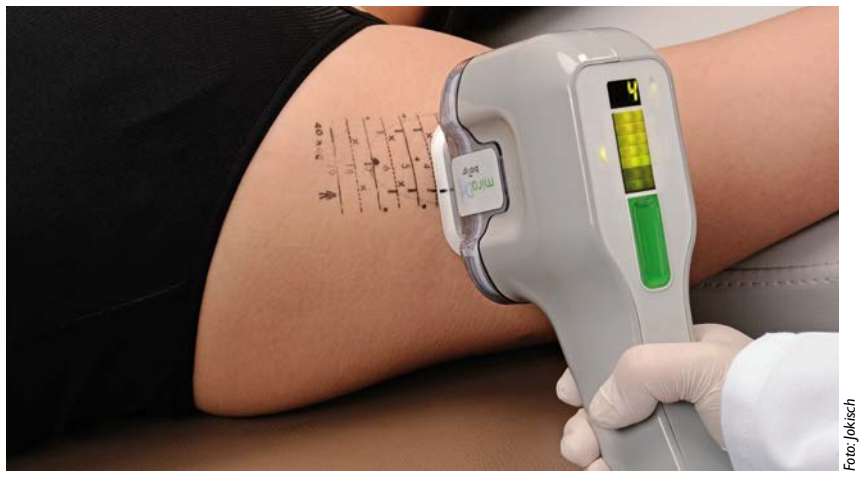


Foto: Jokisch

Der Dermatologe führt das Handstück nach einem definierten Protokoll abschnittsweise über das Hautareal.


Foto: Jokisch

Dr. med. Rainer Jokisch

„Viele unserer Hyperhidrose-Patienten wünschen sich eine schmerzfreie, anhaltende und wenig invasive Behandlung mit kurzen Erholungszeiten. Das vorgestellte Verfahren ist eine perfekte Lösung für diese Anforderungen und liefert für Arzt und Patient überzeugende Ergebnisse. Wir sind stolz, die erste und bisher einzige dermatologische Praxis in Deutschland zu sein, die das hochwirksame Thermolyse-Verfahren anbietet, dessen Sicherheit und Effizienz durch zahlreiche Studien klinisch erwiesen sind. Meiner Meinung nach ist es eine gute Erweiterung des Behandlungsspektrums bei Hyperhidrosis axillaris.“

Moderne Strategien der Narbentherapie

Bei richtiger Indikation einfach anzuwenden

Die heute möglichen und gängigen Methoden zur Behandlung von atrophen Narben, hypertrophen Narben und Keloiden erläutert Priv.-Doz. Dr. med. Gerd G. Gauglitz, München.

Narben können in Abhängigkeit von Lokalisation, Ursache, Heilungsverlauf und individueller Disposition in unterschiedlichen Formen auftreten. Heutzutage unterscheidet man üblicherweise reife, unreife, atrophe, hypertrophe Narben und Keloide. Letztere sind häufig mit Juckreiz und expansivem Wachstum assoziiert und können neben teils signifikantem Spannungsgefühl und Schmerzen, auch zu kosmetischen und psychischen Problemen führen. In den letzten Jahren wurde das Spektrum etablierter Verfahren zur Behandlung überschießender Narben, wie zum Beispiel Kryotherapie, intraläsionale Steroide und Druckverbände durch die Einführung neuerer Techniken (Laser, 5-Fluorouracil, u. a.) erweitert. Für den bestmöglichen Therapieerfolg werden diese heute zunehmend miteinander kombiniert.
Besonders die Anwendung eines gepulsten Farbstofflaser (PDL) hatte sich in den letzten Jahren bei fri-

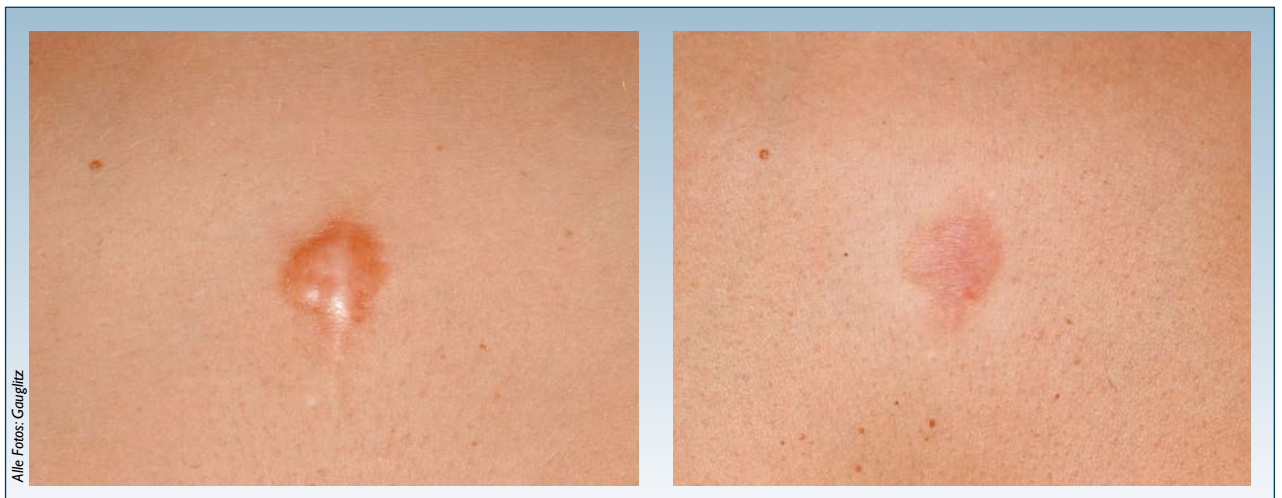

Foto: privat

Priv.-Doz. Dr. med. Gerd G. Gauglitz

Bitte lesen Sie weiter auf Seite II ▶

▶ Fortsetzung von Seite I „Bei richtiger Indikation einfach anzuwenden“

schen, noch geröteten hypertrophen Narben und Keloiden als erfolgreich erwiesen. Der Wirkmechanismus des PDL beruht auf einer selektiven Photothermolyse von Hämoglobinmolekülen, die einen mikrovaskulären Schaden und eine koagulative Nekrose verursacht und letztlich zu einer Gewebshypoxie führt. Melanin ist dabei das kompetitive Chromophor, sodass diese Therapie bei dunkelhäutigen Menschen nicht bzw. schlecht wirksam ist. Das Verfahren muss in mehreren Sitzungen alle vier Wochen wiederholt werden. In verschiedenen Studien zeigte sich eine gute Effektivität mit bis zu 75%igen Ansprechraten bei minimaler Morbidität. Meiner Erfahrung nach erscheint die anfängliche Kombination mit intraläsionalem Triamcinolonacetonid und Kryotherapie zur Abflachung der Keloide sinnvoll, da der Farbstofflaser nur relativ oberflächlich penetriert.



Alle Fotos: Gauglitz

Abb. 1: Keloid: Ausgangsbefund und Endergebnis nach drei Kombinationsbehandlungen mit Vereisung und intraläsionaler Triamcinolon-Acetonid-Injektion, gefolgt von vier Behandlungen mit Farbstofflaser

Blutgefäße selektiv entfernen

Mit neueren Lasergeräten spezifischer Wellenlänge sollen selektiv Blutgefäße entfernt werden. Der Nd:YAG-Laser (Nd:YAG) zeigte dabei Ansprechraten von 36–47%. In einer Studie an 17 Keloid-Patienten flachten fast 60% der Keloide nach einer Sitzung mit dem Nd:YAG-Laser ab. Diese Patienten blieben bei den Nachuntersuchungen nach 18 Monaten bis zu fünf Jahre frei von Keloiden. Eine vorsichtige Indikationsstellung (kleinere Keloide und hypertrophe Narben aufgrund der begrenzten Eindringtiefe des Lasers) und umfassende Beratung des Patienten ist unumgänglich, da es bei diesen Verfahren zu vergleichsweise schwerwiegenden Nebenwirkungen wie beispielsweise Pigmentstörungen, lang anhaltenden Rötungen und Narben-Neubildung kommen kann. Wie auch bei den vorhergehenden Verfahren sind meist mehrere Sitzungen über einen Zeitraum von mehreren Monaten notwendig.

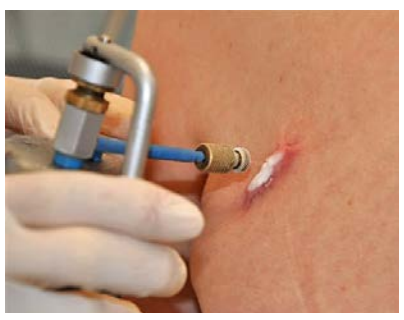


Abb. 3: Kryotherapie

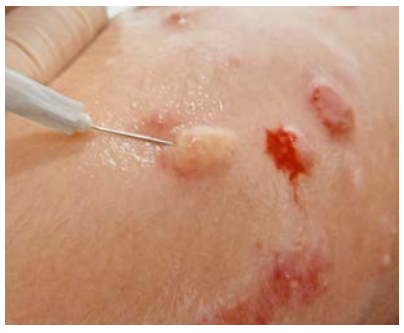


Abb. 4: Injektionen

Basierend auf zahlreichen Studien und der aktualisierten internationalen Leitlinie werden neben Farbstoff- und Nd:YAG-Laser erstmals fraktionierte Laser zur Verbesserung von hypertrophen (Verbrennungs-) Narben empfohlen. Ein Behandlungsansatz, der schon seit längerer Zeit zur Behandlung von atrophen (Akne-)Narben erfolgreich eingesetzt wird.

Bei der fraktionalen Lasertherapie (FL) dringen die Laserstrahlen bis in die Lederhaut ein, um dort tausende von winzigen, mikroskopischen, vertikalen Licht-Säulen zu bilden, die thermische Änderungen verursachen. Diese kleinen Gewebsschädigungen stimulieren die Bildung von neuen Kollagenfasern und die behandelten, geschädigten Zellen werden abgestoßen. Dadurch, dass zwischen den geschädigten Arealen intakte Hautstrukturen erhalten bleiben, ist eine schnellere Heilung mit weniger Nebenwirkungen, deutlich kürzeren Ausfallzeiten und geringeren Schmerzen möglich. Auch hier wird prinzipiell zwischen der ablativen (AFL) und nicht ablativen fraktionalen Lasertherapie (NFL) unterschieden. Nach einer NFL sieht man Schuppung und bronzeartige Verfärbung, die etwa eine Woche nach der Behandlung beendet ist. Bei der AFL dauert die Abheilung etwas länger und kann mit kleinen Blutungen und serösem Exsudat verbunden sein. Sowohl die AFL als auch die NFL werden in erster Linie bei Altershaut (Oberflächenbeschaffenheit, Elastizität, feine Falten, Pigmentverschiebungen) und zur Behandlung von Aknenarben eingesetzt. Seit einiger Zeit werden AFL (in erster Linie der fraktionierte CO_2-Laser aufgrund der größeren Eindringtiefe) zur Verbesserung von großflächigen überschießenden Narben nach Verbrennungen oder Verbrühungen eingesetzt. In der aktuellen Studienlage zeigt sich eine zunehmende Evidenz in Bezug auf die deutliche Verbesserung der Narbenqualität und die Reduktion von Kontrakturen durch dieses Verfahren.Diese Veränderungen beruhen wahrscheinlich auf relativ komplexen Veränderungen verschiedener Zytokin- und Wachstumsfaktorkonzentrationen und einer Wiederherstellung der ursprünglichen(physiologischen)Kollagenarchitektur.

Nach allen Laserbehandlungen ist die neu gebildete Haut auch nach Monaten sehr lichtempfindlich. Daher sollte dem Patienten die regelmäßige Anwendung eines Sonnenschutzmittels, das sowohl vor UVA- und UVB-Bereich (LSF 50 oder 50+) schützt, empfohlen werden. Eine systemische Infektionsprophylaxe (Aciclovir® und Breitspektrum-Antibiotikum) sollte vor einem klassischen „Skin-Resurfacing“ sowie bei größeren Behandlungsarealen durch AFL immer erfolgen.

Pathologische Narben

Hypertrophe Narben imponieren als rötliche Bindegewebswucherungen, die die Grenze der ursprünglichen chirurgischen oder Verletzungswunde nicht überschreiten, wie z. B. Tätowierung (Abb. 2a) und drittgradige Verbrennungen (Abb. 2b). Keloide überschreiten charakteristischerweise die Grenze der ursprünglichen Verletzungswunde und erscheinen als derbe, wulstige, gerötete Tumoren (Abb. 2c). Besonders häufig betroffen ist die Partie neben den Ohrläppchen, die vordere Brustregion und die Schulterpartie, z. B. nach ausgeprägter Akne (Abb. 2d). Atrophe Narben imponieren klinisch als Substanzverlust (Abb. 2e).

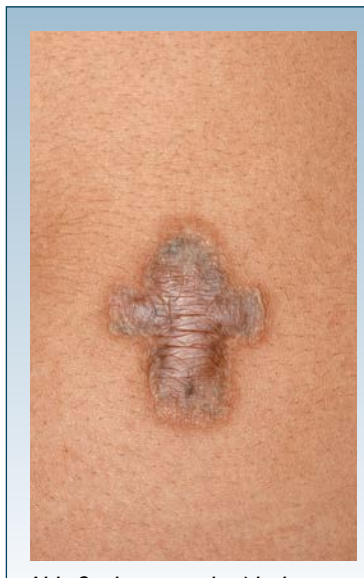


Abb. 2a: hypertrophe Narbe – Tätowierung

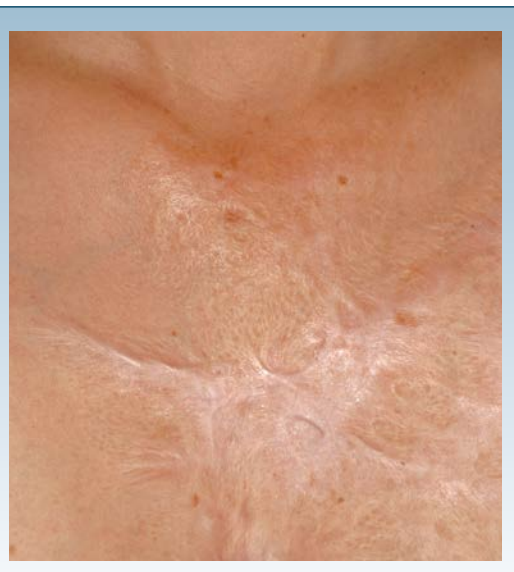


Abb. 2b: hypertrophe Narbe – drittgradige Verbrennung

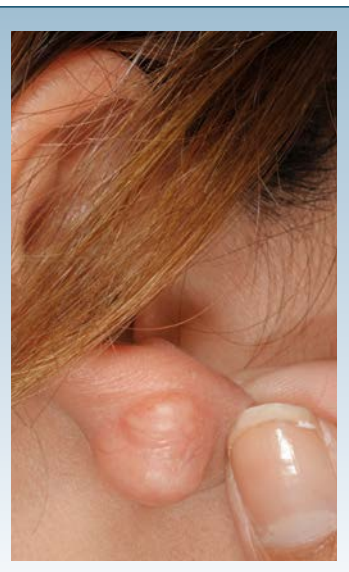


Abb. 2c: Keloid – wulstiger, geröteter Tumor am Ohrläppchen

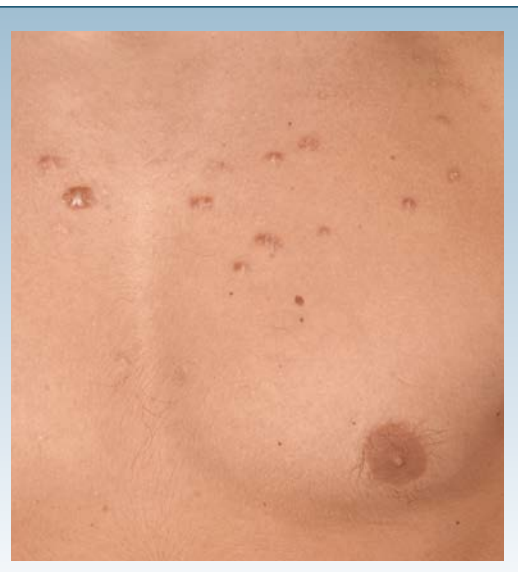


Abb. 2d: Keloid – Akne

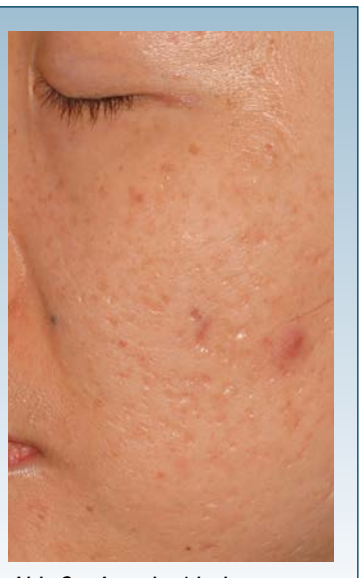


Abb. 2e: Atrophe Narben

Ausblick

Die Therapie überschießender Narben gestaltet sich weiterhin schwierig. Ziel der Narbenbehandlung bleibt es, Größe, Ausdehnung und Volumen der überschießenden Narbe zu reduzieren und Beschwerden wie Juckreiz, Schmerzen und Spannungsgefühl zu verringern. Die meisten der in den aktualisierten, internationalen Leitlinien vorgestellten Methoden zur Behandlung von hypertrophen Narben und Keloiden können bei richtiger Indikation relativ einfach angewendet werden. Neben etablierten Verfahren (Kryotherapie, intraläsionale Kortikosteroide, operative Verfahren) zeigen heute neuere Verfahren wie beispielsweise der Gebrauch von 5-Fluorouracil gute Erfolge. Eine besondere Beachtung finden (ablative) fraktionierte Laser, welche vor allem bei hypertrophen Verbrennungsnarben laut aktuellen Studien zu einer deutlichen Verbesserung der Narbenqualität und einer Reduktion von Kontrakturen führen können. Ihr Einsatz bei aktiven Keloiden sollte aber weiterhin mit größter Zurückhaltung erfolgen. *jt* ◆

Wenn Sie mehr über Laserverfahren zur Narbentherapie erfahren möchten, besuchen Sie die Vortragsreihe „Haar‘ige Narben“ am Samstag, den 13. Juni 2015 ab 16:05 Uhr auf der 24. Jahrestagung der DDL in Trier. Ausführliche Informationen zur Anmeldung, zu den Vortragenden und vielem mehr auf www.ddl-jahrestagung.de

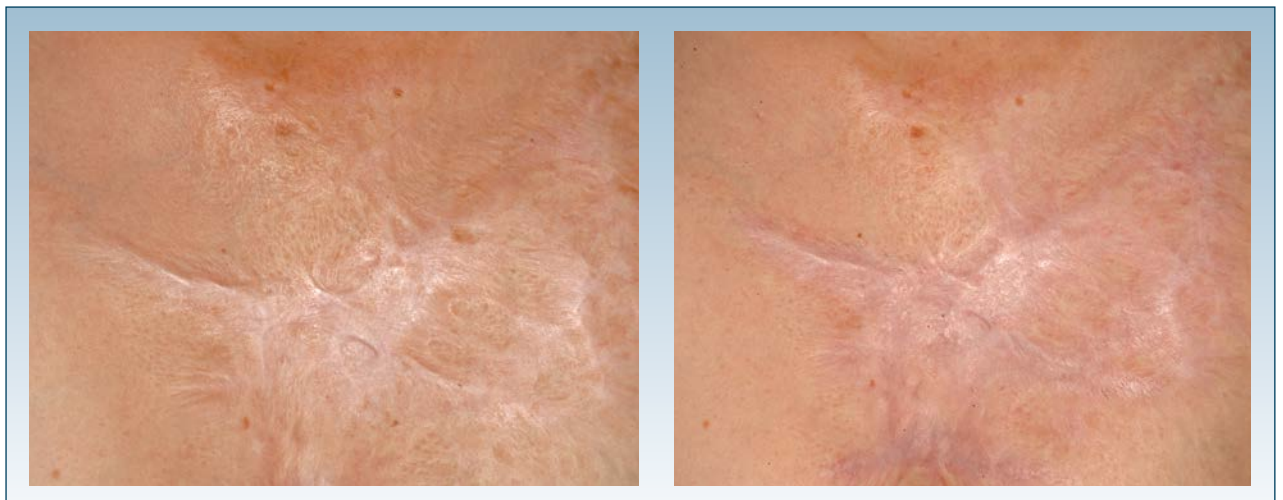


Abb. 5: Verbrennungsnarbe dritten Grades: Ausgangsbefund und Endergebnis nach drei Monaten, zwei Behandlungen mit fraktionalem Er: YAG-Laser

miraDry: die dauerhafte Lösung bei übermäßigem Schwitzen und starkem Schweißgeruch

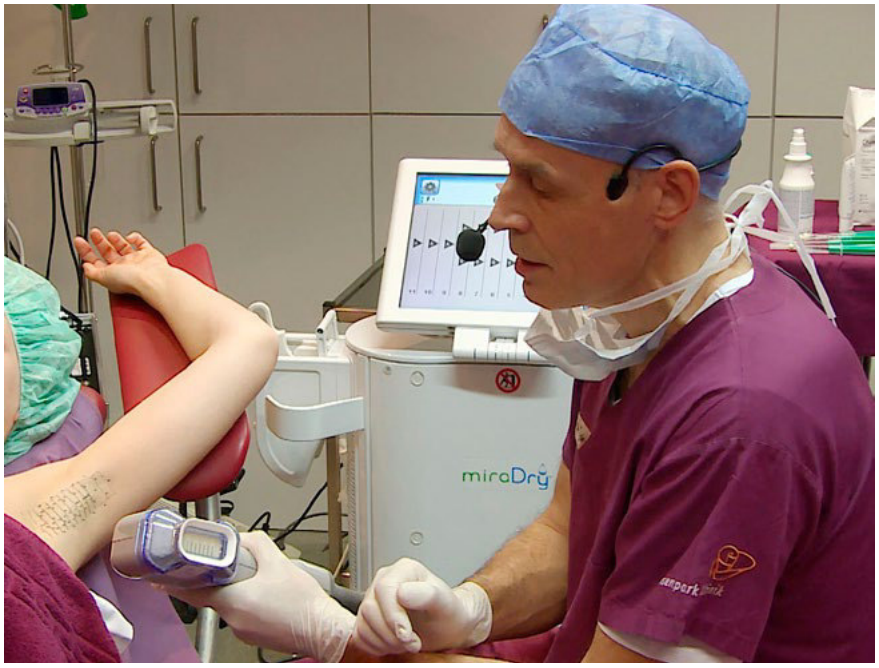
Neu in Deutschland und exklusiv in der Hautmedizin Kelkheim

Nach langjähriger klinischer Forschung entwickelte Miramar Labs die miraWave™-Technologie, die miraDry zugrunde liegt. Dieses auf Mikrowellen basierende Verfahren wird bereits erfolgreich in zahlreichen medizinischen Bereichen eingesetzt. In der Dermatologie wird sie vor allem zur Behandlung des übermäßigen Schwitzens (axilläre Hyperhidrose) angewendet. Das miraDry-System ist die einzige Thermolyse-Methode, die eine FDA-Zulassung für die USA und ein CE-Zeichen für den deutschen Markt besitzt.

Schwitzen ist für viele ein ganz natürlicher Vorgang, doch für andere wird es zum Problem: Sie leiden unter übermäßigem Achselschweiß (axilläre Hyperhidrose) und produzieren die 4- bis 5-fache Menge an Schweiß wie gesunde Menschen. Seit Kurzem gibt es erstmals eine nicht-operative und dauerhafte Lösung: miraDry. Im Gegensatz zu den herkömmlichen Behandlungsmethoden liefert miraDry sofortige Ergebnisse und erfordert keinen chirurgischen Eingriff.

Die Hautmedizin Kelkheim ist die erste und einzige Praxis in Deutschland, die ihren Hyperhidrose-Patienten das bahnbrechende miraDry-Verfahren aus den USA anbietet. Dabei werden die Schweißdrüsen mit gezielter elektromagnetischer Energie (Mikrowellen) bestrahlt und durch die entstehende Hitze dauerhaft zerstört. Gleichzeitig verschwindet auch der unangenehme Schweißgeruch, da die Geruchsdrüsen ebenfalls zerstört werden.

Dr. Jokisch während einer miraDry-Behandlung

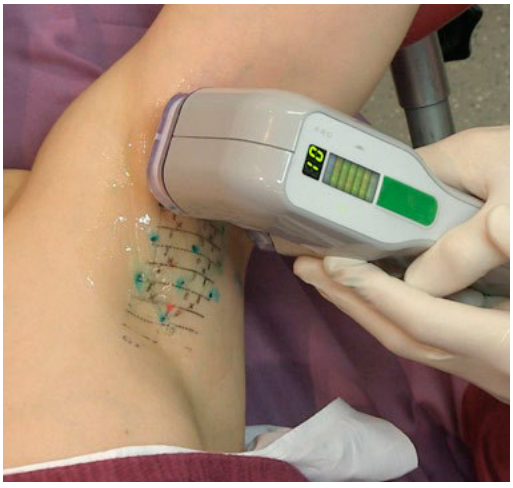


„Das Krankheitsbild des übermäßigen Schwitzens begegnet uns in unserer Praxis täglich. Um das Leid der Betroffenen zu lindern und dem Patientenwunsch nach einer sicheren und schnellen Behandlung mit dauerhaften Ergebnissen nachzukommen, haben wir uns für das nicht-operative und klinisch erprobte miraDry-Verfahren aus den USA entschieden. Schon kurz nach der Sitzung reduziert sich das Schwitzen spürbar und nach 2 Behandlungen wird die Schweißmenge dauerhaft auf ein Normalmaß gesenkt. Wir freuen uns, dass wir unseren Patienten mit miraDry ein großes Stück Lebensqualität zurückgeben können."

Endlich dauerhaft schweißfrei dank Mikrowellen!

Auf das zu behandelnde Areal werden vorübergehend Markierungen angebracht, um die Behandlung zu leiten. Anschließend wird die Haut desinfiziert und mit einem lokalen Anästhetikum betäubt. Der Arzt setzt nun das Handstück abschnittsweise auf die markierten Bereiche. Dabei wird jedes Mal die Haut leicht angesaugt und so für die Energiezufuhr stabilisiert. Dann dringen die Mikrowellen zielgerichtet in das Gewebe ein und führen

dort zu einer Thermolyse, d.h. es entsteht eine kurze aber intensive Hitze, die die Schweißdrüsen samt ihrer Versorgungsnerven ein für alle Mal zerstört. Gleichzeitig schützt ein kontinuierliches hydrokeramisches Kühlsystem die obere Hautschicht und begrenzt die Wärme auf den Bereich der Schweißdrüsen. Da sich einmal zerstörte Schweißdrüsen nicht wieder regenerieren, sind die Ergebnisse von miraDry bleibend.



Nach der Behandlung werden die Markierungen entfernt und die Achseln mit Kühlpacks gekühlt. Der gesamte Arztbesuch nimmt im Allgemeinen 60 Minuten in Anspruch. Die eigentliche Behandlung dauert ca. 40 Minuten.

Sofortige Ergebnisse

Meist spüren die Patienten schon kurz nach der Sitzung eine deutliche Reduzierung des Schweißes. Eine aktuelle Studie bestätigt, dass miraDry das Schwitzen bereits nach zwei Behandlungen um ca. 82% reduziert. Da sich einmal zerstörte Schweißdrüsen nicht regenerieren, ist das Ergebnis effektiv und dauerhaft. Insgesamt sind zwei Behandlungen im Abstand von 3 Monaten nötig. Das miraDry-System kann leider nicht für die Behandlung von Hyperhidrose in anderen Körperbereichen, einschließlich Händen und Füßen, verwendet werden. Die Kosten für 2 Behandlungen beider Achseln liegen bei 2.500€.

Positive Nebeneffekte

Kein Schweißgeruch mehr: Alle Patienten sind sehr erleichtert, dass nach der miraDry-Behandlung auch der unangenehme Schweißgeruch (Bromhidrose) verschwindet, weil die Geruchsdrüsen ebenfalls zerstört wurden.

Keine Achselbehaarung mehr: In der Hautschicht der Schweißdrüsen liegen auch die Wurzeln der Achselhaare. Daher reduziert sich bei vielen Patienten nach der Mikrowellen-Behandlung die Behaarung im Achselbereich deutlich.

Mögliche Nebenwirkungen wie vorübergehende Rötungen, blaue Flecken, Druckempfindlichkeit, Schwellungen oder ein leichtes Taubheitsgefühl in den Fingern klingen nach kurzer Zeit von selbst ab. Der Patient kann sofort nach dem Arztbesuch wieder seine Arbeit aufnehmen und nach einigen Tagen auch wieder Sport treiben.

miraDry – effizient, sicher & geprüft

miraDry ist ein neues, nicht-invasives und klinisch erprobtes Verfahren gegen übermäßiges Achselschwitzen (axilläre Hyperhidrose) und starken Schweißgeruch. Es basiert auf einer sicheren Mikrowellen-Technologie und ist die einzige Thermolyse-Methode, die eine FDA-Zulassung und ein CE-Zeichen besitzt. miraDry wurde bereits über 30.000 Mal in den USA sowie im asiatisch-pazifischen Raum, in Kanada und in Mexiko erfolgreich durchgeführt. Experten schätzen, dass ca. 1-2% der Deutschen unter Hyperhidrose leiden – eine enorme Nachfrage! Zahlreiche Langzeit-Studien von führenden Dermatologen der USA belegen die Sicherheit und Wirksamkeit von miraDry. Außerdem empfehlen die International Hyperhidrosis Society und das Deutsche Hyperhidrosezentrum DHHZ miraDry zur Behandlung der primären axillären Hyperhidrose bei Erwachsenen ab 18 Jahren.

Mehr Informationen unter www.hot-without-sweat.de oder www.hautmedizin-kelkheim.de

Das miraDry-System

Lästige Schweißflecken sind Vergangenheit – ganz ohne Operation!

28. April 2016 14:05

Lästige Schweißflecken sind Vergangenheit. - © HdS

Schwitzen ist eine effiziente Methode der Natur, um den Körper zu kühlen. Etwa zwei Millionen Schweißdrüsen schützen den Körper vor Überhitzung, die meisten davon sitzen in Achselhöhle, Handfläche und Fußsohle.

Egal, ob heißer Sommertag, anstrengende Sportaktivitäten oder stressige Situationen an der Arbeit: Man kommt unweigerlich ins Schwitzen, häufig verbunden mit unangenehmem Körpergeruch und steigender Unsicherheit. Man fühlt sich in seiner Haut nicht mehr wohl, das Wohlbefinden sinkt

Die Intensität der Schweißabsonderung ist von Mensch zu Mensch verschieden. Wenn der Schweiß aber, speziell im Achselbereich, in Strömen den Körper hinunterläuft und kaum mehr aufzuhalten ist, liegt ein ernstes Problem vor. Eine Überstimulation der Scheidrüsen wie im Fall von Hyperhidrose, emotionalem Schwitzen oder Schwitzen in den Wechseljahren kann eine enorme Belastung sein.

Dauerhafte Schweißreduktion durch ein neues Verfahren

Diese einzigartige Behandlung gegen Schwitzen in den Achselhöhlen ist ein non-invasives, das heißt nicht-chirurgisches Verfahren, das die Schweißdrüsen in den Achseln dauerhaft beseitigt und somit eine echte Alternative zu aluminium-versetzten Deos und Antitranspiranten, sowie zu operativen Eingriffen.

Wie funktioniert das Verfahren?
Zuerst werden die Achselhöhlen örtlich betäubt, um die Behandlung angenehmer zu gestalten. Eine Narkose ist nicht nötig. Danach werden mittels eines „Handstücks“ präzise kontrollierte elektromagnetische Energie in den Bereich der Schweißdrüsen in den Achseln geleitet. Durch mehrfache, genaue Platzierung kann die Behandlung exakt an die Bedürfnisse des Patienten angepasst werden.

Wie lange hält die Behandlung?
Die Schweißdrüsen werden durch die elektromagnetischen Strahlen permanent beseitigt und die Wirkung ist sofort nach dem Eingriff spürbar. Die Reduzierung der Schweißbildung nach der ersten Sitzung beläuft sich zwischen 80 und 90%. Sollte, wie in seltenen Fällen eine zweite Behandlung nötig sein, kann diese nach drei Monaten wiederholt werden.

Leserreporter
Feedback

Tschüss Achselschweiss – eine neue Behandlung hilft

Lifestyle Am 1. Februar eröffnet Dr. med. Mandana Péclard die Praxis am Paradeplatz für Medizin, Haut, Laser und Ästhetik. Sie bietet eine schweizweit einzigartige Anti-Schwitz-Behandlung an. **Von Ginger Hebel**

Die letzten Lasergeräte werden montiert, es riecht nach frisch gestrichenen Wänden. Am Montag eröffnet die Ärztin Mandana Péclard an der Kappelergasse 16 ihre eigene Praxis, die Praxis am Paradeplatz. Sie bietet etwas an, was schweizweit einzigartig ist: eine Mikrowellen-Behandlung gegen Achselschweiss. «Übermässige Schweissproduktion ist ein grosses Problem bei Männern und Frauen», sagt die gebürtige Iranerin. Leidende sind Männer in Kaderpositionen, die sich für die Schweissränder auf ihren Hemden schämen, aber auch Frauen, die gerne Seidenblusen tragen, auf denen sich Schweissringe besonders gut bemerkbar machen. «Manche stört die starke Schweissproduktion, andere der Geruch», sagt Mandana Péclard. Es gibt bereits Möglichkeiten, wie man dem Schwitzen unter den Armen den Kampf ansagt: mit Botox zum Beispiel (das «Tagblatt» berichtete). Auch Mandana Péclard bietet das an. Neu aber führt sie in ihrer Praxis die Mikrowellen-Behandlung MiraDry durch. Die Achselhöhle wird lokal betäubt, Mikrowellen erhitzen die Schweissdrüsen unter den Achseln und eliminieren sie, positiver Nebeneffekt: Dadurch verschwinden auch die Achselhaare. Die nichtinvasive Behandlung dauert rund eine Stunde und kostet zwischen 2500 und 3000 Franken. «Es kann zu Schmerzen, blauen Flecken oder Schwellungen kommen, die nach einigen Tagen jedoch abklingen», sagt Péclard. Als Mitglied der amerikanischen Lasergesellschaft ist sie auf die neue Technologie aufmerksam geworden.

Mandana Péclard sagt in der Praxis am Paradeplatz Schweissdrüsen den Kampf an. *Bild: GH*

> «Übermässige Schweissproduktion ist ein grosses Problem.»
> **Mandana Péclard** | Ärztin

Péclard hat sich auf Dermatologie spezialisiert und kennt sich mit Hautkrankheiten und Hautproblemen bestens aus. Neben Ekzemen sei Akne die häufigste Hautkrankheit, unter welcher Zürcherinnen und Zürcher leiden. «Betroffen sind nicht nur Personen in der Pubertät. Viele Erwachsene leiden an der sogenannten Spätakne.» Sie behandelt viele Frauen, die mit Ende dreissig erstmals Akne bekommen, oft sei dies hormonell bedingt. In ihrer Praxis wird sie Akne- und Narbenbehandlungen mit Laser anbieten, aber auch Cool Sculpting, Fettbekämpfung mit Kälte sowie ästhetische Behandlungen wie Botoxinjektionen gegen Mimikfalten. Botulinum Toxin schwächt die Muskulatur und entspannt die Haut, wodurch Falten verschwinden. Weil sich Botox im Körper abbaut, sollte eine Behandlung nach etwa vier bis sechs Monaten wiederholt werden. «Die Konkurrenz im Botox-Bereich ist sehr gross geworden, es gibt verschiedene Arten von Botox, wodurch ein Preisdumping entsteht», sagt Péclard. Wie erklärt sie sich manch maskenhaftes Botox-Gesicht? «Viele übertreiben es schlicht und einfach.» Sie weiss, dass viele Leute etwas machen lassen, oft seien es kleine ästhetische Behandlungen wie zum Beispiel mit Ultraschall, um das Gesicht zu straffen. Mandana Péclard: «Nicht nur Falten machen alt, auch die Konturen. Mit dem Alter wird die Haut schlaffer und beginnt zu hängen.» Die 46-Jährige geht mit dem Älterwerden gelassen um. «Wir werden alle älter. Wenn nicht das Gesicht altert, dann der Hals, die Haare, die Hände, die Stimme, da kann man nichts machen. Aber man kann schauen, dass man länger frisch wirkt und besser altert.»

praxis@peclard.net

Ratgeber

Wie enteise ich am schnellsten mein Auto?

«Ich brauche morgens oft fast eine Viertelstunde, bis ich die Scheiben meines Autos freigekratzt habe. Gibt es irgendwelche Tricks, wie ich sie schneller enteisen kann?», fragt Carlos M.

Kaum, ausser sie legen sich eine handelsübliche Abdeckfolie oder eine programmierbare Standheizung zu. Letztere kostet allerdings um die 2500 Franken und kommt darum für viele nicht infrage. Abgesehen davon, ist diese Methode nicht gerade umweltfreundlich, da die Heizung rund einen halben Liter Benzin pro Stunde verbraucht. Die Abdeckfolie ist zwar wesentlich günstiger, aber durch das ständige Auf- und Zudecken auch aufwendiger in der Handhabung und isoliert zudem nur die Frontscheibe.

Mit den ebenfalls im Handel angebotenen Enteisersprays ist man nur in Kombination mit einem Eiskratzer etwas schneller. Besprühen allein reicht meist nicht, weil die Eisschicht in der Regel zu dick ist und sich darum nicht ganz auflöst. Ums Kratzen kommt man also kaum herum. Allerdings gibt es bei Eiskratzern in Sachen Qualität teilweise grosse Unterschiede, wie ein Test von uns gezeigt hat. Achten Sie beim Kauf darauf, dass der Kratzer zwecks Kraftübertragung gut in der Hand liegt, biegsame Klingen vorweist, aber trotzdem aus widerstandsfähigem Material besteht (Nachzulesen in der Rubrik Testberichte auf www.tcs.ch).

Was Sie auf keinen Fall tun sollten, ist, heisses Wasser über die Scheiben zu giessen. So eliminieren sie zwar das Eis, bringen mit hoher Wahrscheinlichkeit aber auch die Scheibe zum Bersten. Ebenfalls abzuraten ist von der Methode, das Auto im Leerlauf warmlaufen zu lassen. Das nützt nichts, wenn es schnell gehen soll. Vor allem aber ist es per Gesetz verboten. **SB**

Daniel Ballmann (27), Experte Produktetest beim TCS, weiss Rat. *Bild: zvg*

Hyperhidrose

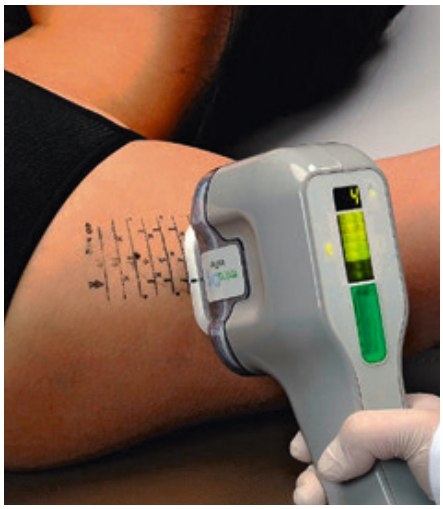
Dauerhafte Lösung gegen Achselschweiss

Eine übermässige Schweissbildung kann für Betroffene sehr unangenehm und belastend sein. Das neue, nicht invasive Verfahren miraDry reduziert übermässiges Achselschwitzen und starken Schweissgeruch dauerhaft.

Schwitzen ist eine lebenswichtige Funktion für unseren Körper: Etwa vier Millionen Schweissdrüsen sondern bei Wärme oder körperlicher Aktivität pro Stunde zwischen einem Deziliter und zwei Litern Schweiss ab, kühlen so die Haut und das Innere des Körpers und beugen damit der Überhitzung vor. Manche Menschen schwitzen aber deutlich stärker, unabhängig von Temperatur oder körperlicher Anstrengung. Sie leiden an einer übermässigen Schweissproduktion, auch Hyperhidrose genannt. Betroffen sind meist bestimmte Körperstellen, in der Regel Hände, Füsse oder Achselhöhlen, manchmal auch das Gesicht. Dieses starke Schwitzen kann zu einer starken psychischen und sozialen Belastung werden – nicht zuletzt auch wegen der unangenehmen Begleiterscheinungen wie Geruch, schweissnassen Händen oder Flecken auf der Kleidung.

Medikamente oder Operation

Dermatologen unterscheiden zwischen der angeborenen (primären) und der sekundären Hyperhidrose. Im letzteren Fall tritt sie als Folge einer anderen Grunderkrankung wie Diabetes, Übergewicht oder einer Schilddrüsenüberfunktion auf. Auch die Wechseljahre sowie die Einnahme von Medikamenten oder psychische Belastungen können mögliche Auslöser für das übermässige Schwitzen sein. Wird die Grunderkrankung erfolgreich behandelt, bessert sich meist auch die gestörte Schweissregulierung. Doch auch primäre Hyperhidrose lässt sich behandeln; bislang waren allerdings die Therapiemöglichkeiten auf temporäre medikamentöse Optionen wie Antitranspirantien oder das Spritzen von Botulinumtoxin zur vorübergehenden Deaktivierung der Schweissdrüsen sowie dauerhafte operative Verfahren wie die Schweissdrüsen-Saugkürettage oder die Laserlipolyse beschränkt.



Innovative Behandlung

Seit einem Jahr verwenden einige Dermatologen in der Schweiz das neue nichtoperative Verfahren miraDry, welches eine dauerhafte Achselschweissreduzierung ohne chirurgische Einschnitte ermöglicht. miraDry ist ein sicheres, klinisch getestetes und von der amerikanischen Arzneimittelzulassungsbehörde FDA zugelassenes Verfahren, welches bei Erwachsenen ab 18 Jahren indiziert ist. Die Behandlung wird ambulant in der Praxis des Dermatologen durchgeführt. Für ein dauerhaftes und gutes Ergebnis werden zwei Anwendungen im Abstand von drei Monaten empfohlen. Ein Behandlungstermin dauert etwa eine Stunde.

So wirkt miraDry

Vor dem Verfahren werden die zu behandelnden Stellen mit einem lokalen Anästhetikum betäubt, anschliessend setzt der Arzt das miraDry-Handstück abschnittsweise auf die vorher markierten Bereiche. Dabei wird jedes Mal die Haut leicht angesaugt und so für die Energiezufuhr stabilisiert, dann dringt elektromagnetische Energie zielgerichtet in das Gewebe ein und führt dort zu einer Thermolyse, das heisst, es entsteht eine kurze, aber intensive Hitze, welche die Schweissdrüsen samt ihrer Versorgungsnerven ein für alle Mal zerstört. Gleichzeitig schützt ein Kühlsystem die obere Hautschicht und begrenzt die Wärme auf den Bereich der Schweissdrüsen.
Während der Behandlung verspüren die meisten Patienten einen Druck und ein leichtes Ziehen auf der Haut sowie ein Gefühl von Wärme. Leichte Schmerzen, Rötungen oder Schwellungen sind normal und klingen üblicherweise innerhalb weniger Wochen ab. Die normalen Alltagsaktivitäten können Patienten direkt im Anschluss nach der Behandlung wieder aufnehmen, nach einigen Tagen dürfen sie wieder Sport treiben. In der Regel bemerken die Patienten schon kurz nach der Sitzung, dass sie weniger schwitzen und auch weniger Schweissgeruch verströmen. Klinische Studien belegen, dass miraDry das Schwitzen um über 80 Produzent reduziert.

Die Auskunftsperson
Thomas Schneiter, Dr. med.
Facharzt FMH für Dermatologie
und Venerologie
Fähigkeitsausweis Lasermedizin SGML/FMCH

Praxis:
Ästhetik Burgdorf
Poststrasse 6, 3400 Burgdorf
Tel. 034 422 00 01
info@aesthetik-burgdorf.ch
www.ästhetik-burgdorf.ch

Extra:
Website von miraDry mit weiteren Infos

NEUE METHODE: MIT MIKROWELLEN GEGEN SCHWITZEN

FÜR IMMER trockene Achseln

NIE MEHR SCHWITZEN Vor allem in der warmen Jahreszeit wird starkes Schwitzen unter den Achseln zur Qual. Eine neue Technologie nutzt Mikrowellen, um Schweißdrüsen dauerhaft zu entfernen.

BERATUNGSGESPRÄCH

Aufklärung. Dr. Jasmin Darabnia erklärt den genauen Ablauf der Behandlung. Die Zerstörung der Schweißdrüsen durch Mikrowellen ist nicht schmerzhaft und weist auch nach mehreren klinischen Tests keine schädlichen Nebenwirkungen oder Risiken auf. Das Gerät ist sowohl am US- als auch am europäischen Markt zugelassen.

Dunkle, nasse Flecken unter den Armen, unangenehmer Schweißgeruch (Bromhidrose) – vor allem in der warmen Jahreszeit beginnen wir vermehrt zu schwitzen. Das ist auch gut so, denn Schwitzen ist ein ganz natürlicher Vorgang unseres Körpers um sich bei hohen Temperaturen oder körperlicher Belastung abzukühlen. Nicht alle Menschen schwitzen gleich stark. Während für den Einen herkömmliche Antitranspirante ausreichen, um Schweiß und Geruch in den Griff zu bekommen, leidet der Andere unter vermehrter Schweißproduktion und ständig nassen Flecken unter den Armen. Eine in Österreich relativ neue Methode verspricht, Schweißdrüsen dauerhaft und schmerzfrei zu reduzieren.

Mikrowellen-Technik

Das nicht invasive, klinisch erprobte Verfahren aus den USA basiert auf dem kontrollierten Einsatz von Mikrowellen. Mittels gezielter elektromagnetischer Energie werden die Schweiß- und Duftdrüsen in der Achsel behandelt und durch Hitze dauerhaft zerstört. „Die Behandlung ist für alle Patienten geeignet, die unter übermäßigem Schwitzen, der sogenannten Hyperhidrose, unter der Achsel leiden“, erklärt Dr. Jasmin Darabnia, Fachärztin für Allgemeinmedizin und Spezialistin für ästhetische Medizin. „Für etwa ein Drittel aller Österreicher kann das häufige und ausgeprägte Schwitzen das Alltagsleben beeinträchtigen.“ ➔

ENDLICH SCHWEISSFREI

Dauerhaft trocken. Keine hässlichen Schweißflecken mehr unter den Achseln! Ein neues Verfahren verwendet Mikrowellen, um die Schweißdrüsen dauerhaft zu reduzieren.

Artner, beigestellt

NUN AUCH IN ÖSTERREICH

DR. ROLF BARTSCH:
Facharzt für plastische, ästhetische und rekonstruktive Chirurgie
1190 Wien, Sieferingerstr. 36
1220 Wien, Donau City Str.7/52.Stock
Tel.: 01/3287337 0
www.worseg-clinics.com

DR. JASMIN DARABNIA:
Fachärztin für Allgemeinmedizin
1010 Wien, Schottengasse 7/5
Tel.: 01/236 13 36
www.medspa.cc

DR. ANDREAS DOBROVITS:
Facharzt für plastische, ästhetische und rekonstruktive Chirurgie
1010 Wien, Kärntner Straße 51
Tel.: 01/358 28 98
www.kuzbari.at

DR. CARLO HASENÖHRL:
Facharzt plastische, ästhetische und rekonstruktive Chirurgie
6020 Innsbruck, Brucknerstr. 1a
Tel.: 0512 587766-0
1010 Wien, Elisabethstr. 15/2/8a
Tel.: 01/3695977-0
www.excellentbeauty.com

DR. JASMIN DARABNIA
Ärztin für Allgemeinmedizin, Spezialistin für ästhetische Medizin, www.medspa.cc

GEZIELT ERHITZT Mit gezielter elektromagnetischer Energie (Mikrowelle) werden die Schweißdrüsen dauerhaft zerstört.

Ablauf der Behandlung

Die Patientin nimmt in Rückenlage auf der Behandlungsliege Platz. Dann wird der zu behandelnde Bereich unter dem Arm gründlich desinfiziert und mit einer speziellen Schablone vermessen. Vier Markierungspunkte begrenzen den Achselbereich. An diesen Punkten setzt Dr. Darabnia mit dem Skalpell millimeterkleine Hautschnitte. Diese dienen dazu, die Achsel mittels einer Kanüle von vier Seiten mit einem Lokalanästhetikum zu unterspritzen. „Durch das Betäubungsmittel ist die Behandlung nahezu schmerzlos. Die Flüssigkeit brauchen wir auch zum Verdampfen der Drüsen", erklärt Dr. Darabnia. Nun wird mit einer Art Abziehfolie das Behandlungsmuster auf die Haut übertragen und dadurch jede einzelne Behandlungsstelle exakt festgelegt. Dr. Darabnia setzt das Handstück des Gerätes auf jedem einzelnen Marker an. Die Haut wird leicht angesaugt, Thermowellen dringen zielgerichtet ins Gewebe ein und die entstehende Hitze (Thermolyse) lässt Schweiß- und Duftdrüsen verdampfen. Ein integriertes Kühlsystem schützt die Haut vor Verbrennungen. Linie für Linie arbeitet die Ärztin den vorgezeichneten Bereich ab. Danach wird die Achsel mit einem Eisbeutel gekühlt.

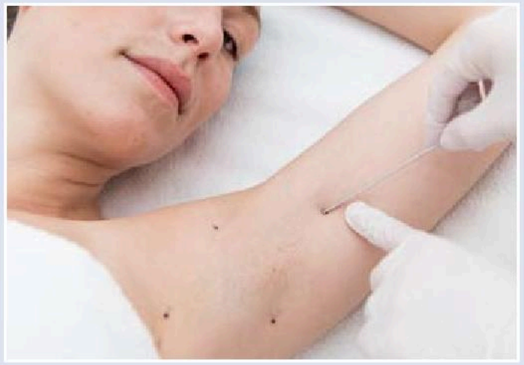
DIE TECHNIK

4everDry. Durch gezielte elektromagnetische Energie – wie bei einer Mikrowelle – werden die Schweißdrüsen erhitzt und dauerhaft zerstört. Die Behandlung ist weitgehend schmerzfrei.

STEP BY STEP SCHWEISSFREI

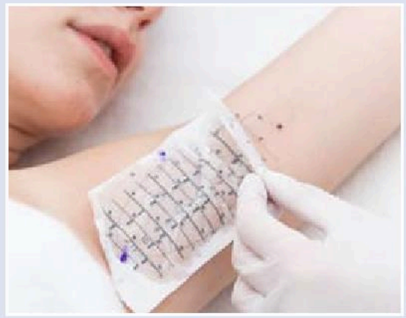
1. AUSMESSEN

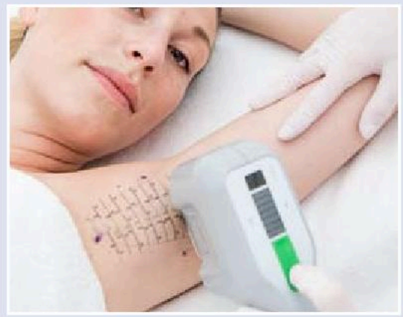
Vorbereiten. Nach sorgfältiger Desinfektion wird die Größe des zu behandelnden Bereichs mithilfe einer speziellen Schablone ausgemessen und mit vier Punkten markiert. Anhaltspunkt ist der Haarkranz der Patientin.



2. LOKALE BETÄUBUNG

Schmerzfrei. An den markierten Stellen werden mit dem Skalpell einige Millimeter kleine Hautschnitte gesetzt. An diesen Einschnitten wird die Achsel über einer Kanüle von vier Seiten mit einem Lokalanästhetikum „unterfüttert". Durch die Betäubung ist die Behandlung schmerzfrei.





3. RASTER ANBRINGEN & BEHANDELN

Ablauf. Mit einer Art Abziehfolie wird das Behandlungsmuster auf die Haut übertragen. Dadurch ist jede einzelne Behandlungsstelle exakt festgelegt. Die Marker zeigen, wo genau und wie oft das Handstück platziert werden muss. Danach wird ein Kontaktgel aufgetragen, die Haut laut Markierung abschnittsweise angesaugt und die Schweißdrüsen durch die Hitze der Mikrowellen verdampft.

4. KÜHLEN

Nachsorge. Nach der Behandlung wird die behandelte Stelle mit einem Eisbeutel gekühlt. Am selben Tag sollte wegen der Wundheilung nicht geduscht werden. Sport, Sauna und Dampfbad für maximal eine Woche meiden.

Nie mehr schwitzen dank der **4everDry-Methode**:

DIE FAKTEN ZUM EINGRIFF

DIE METHODE

Mikrowellen Mit gezielter elektromagnetischer Energie (Mikrowellen) werden die Schweißdrüsen bestrahlt und durch die entstehende Hitze dauerhaft verdampft. Gleichzeitig schützt ein eingebautes Kühlsystem die oberste Hautschicht und ermöglicht somit eine sehr sichere Handhabung. Ein positiver Nebeneffekt ist neben der Reduktion der Duftdrüsen eine Verminderung der Achselbehaarung, da sich die Wurzeln der Achselhaare in der selben Hautschicht befinden, wie die Schweißdrüsen und durch die Mikrowellen zerstört werden.

ABLAUF DER BEHANDLUNG

Schonend Die Behandlung wird in Rückenlage durchgeführt. Nach sorgfältiger Desinfektion der zu behandelnden Stelle wird die zu behandelnde Zone in der Achselhöhle mit einer Schablone ausgemessen, markiert und mittels Lokalanästhesie betäubt. Danach wird mit einer Art Abziehfolie ein Behandlungsmuster auf die Haut übertragen und das Handstück des Gerätes abschnittsweise auf die markierten Bereiche angesetzt. Die obere Hautschicht wird leicht angesaugt und die Schweißdrüsen mit den Mikrowellen erwärmt. Die durch die Hitze verdampften Drüsen werden vom Körper abgebaut. Durch ein eingebautes Kühlsystem wird die Haut vor Verbrennungen geschützt. Nach der Behandlung sollte die behandelnde Stelle mit einem Eisbeutel gekühlt und anstrengende Sportarten, Sauna oder Dampfbad für rund eine Woche vermieden werden. Die Behandlung dauert etwa 60 bis 90 Minuten.

RISIKO UND NEBENWIRKUNGEN

Risikoarm Die Behandlung erfolgt unter lokaler Betäubung und ist daher nahezu schmerzfrei. Nach der Behandlung kann es zu Schwellungen, Rötungen und der Bildung kleiner Knötchen kommen, die jedoch nach kurzer Zeit von selber wieder verschwinden. Äußerst selten kann eine Sensibilitätsstörung auftreten, in der Regel gibt es aber keine bis maximal eine kurze Ausfallzeit. Für Patienten mit implantierten Geräten, externer Sauerstoffversorgung oder Problemen mit Lokalanästhesie ist der Eingriff nicht geeignet.

ERGEBNIS & KOSTEN

Dauerhaft Über 80 Prozent der Schweißproduktion kann dauerhaft reduziert werden. Um die Ergebnisse zu maximieren, sind maximal 2 Behandlungen erforderlich. Kosten der Behandlung: 2.600 Euro.

Effektive Methode

Gleich nach der Behandlung ist eine Reduktion des Achselschweißes erkennbar. „Die Schweißproduktion kann um bis zu 80 Prozent dauerhaft reduziert werden", so die Expertin. Sind die Schweißdrüsen einmal zerstört, bilden sie sich nicht wieder nach. Ist es schädlich, den natürlichen Vorgang des Schwitzens durch Reduzierung der Schweißdrüsen zu behindern? „Nein", so die Ärztin. „Wir haben unter der Achsel nur einen geringen Prozentsatz an Schweißdrüsen im Vergleich zum ganzen Körper." Es kommt durch die Reduzierung der Schweißdrüsen unter den Achseln auch nicht zu einem vermehrten Schwitzen an einer anderen Körperstelle und Angst vor schädlichen Mikrowellen braucht man ebenfalls nicht haben, beruhigt Dr. Darabnia. Diese Methode wurde in mehreren klinischen Studien getestet und weist keine schädlichen Nebenwirkungen oder Risiken auf. Lediglich leichte Schwellungen, Rötungen, Hämatome oder Knötchenbildung können vorübergehend auftreten. „Positiver Nebeneffekt neben der Reduktion der Schweiß- und Duftdrüsen ist die Verminderung der Achselbehaarung. Da sich die Wurzeln der Achselhaare in der selben Hautschicht befinden wie die Drüsen, werden sie ebenfalls zerstört.

REGINA MODL

GESUND UND SCHÖN

Für glatte Haut und einen makellosen Körper begeben sich immer mehr Menschen in die Hände von Spezialisten. Die plastisch-ästhetische Chirurgie verhilft zu immer feineren Ergebnissen.

Gesund und Schön online unter www.haz.de/gesund-und-schoen oder unter www.neuepresse.de/gesund-und-schoen

Mit schonenden Verfahren zu natürlichem Aussehen

In der plastisch-ästhetischen Chirurgie kommen modernste Wirkstoffe zum Einsatz.

» Seite 2

Mikrowellenenergie gegen lästigen Achselschweiß

Neue Behandlungsmethode führt nach nur einer Sitzung zum gewünschten Erfolg.

» Seite 3

OP-Technik rückt Besenreisern sanft zu Leibe

Selbst kleinste Äderchen lassen sich unkompliziert und dauerhaft entfernen.

» Seite 6

Tabuthema Achselschweiß

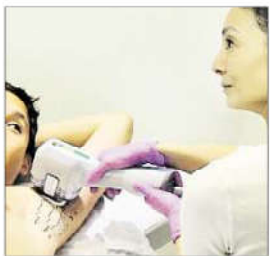
Neue Methode mit Mikrowellenenergie schafft mehr Lebensqualität für Betroffene

Sichtbarer Schweiß ist meist ein unangenehmer Begleiter. iStockphoto.com/ ChesiireCat

Schwitzen ist eine lebenswichtige Funktion des Körpers, er kühlt damit den Organismus für die lebenswichtigen Funktionen des Gehirns und der Organe. Es gibt allerdings Menschen, bei denen übermäßiges Schwitzen zum Problem wird. Sie schwitzen stark, was meist durch den unangenehmen Geruch auffällt und wegen Flecken unter den Achseln für jeden sichtbar wird.

Das hemmt viele Menschen. Sie schämen sich, obwohl sie keinen Einfluss auf das Schwitzen haben. Bei der Arbeit wird Abstand zu den Kollegen gehalten, aus Angst, sie könnten etwas riechen, und die Arme werden möglichst gar nicht gehoben. Auch privat werden meist bestimmte Farben gar nicht mehr getragen, da diese Schweißflecken nur noch mehr betonen würden. Die meisten Menschen leiden heimlich. „Nur jeder 20. Betroffene geht tatsächlich damit zum Arzt", sagt Dr. Nina Duckstein, Fachärztin für Plastisch-Ästhetische Chirurgie.

Als erste Maßnahme werden vielfältige Deos, Gels und Cremes ausprobiert. Bei den meisten Menschen reicht dies häufig aus, allerdings können auch Nebenwirkungen wie Hautreizungen oder Jucken auftreten. Wirken diese Mittel nicht, kommt ein breites Spektrum von mehr oder weniger hilfreichen Mittelchen wie Tees oder pflanzlichen Tabletten zum Einsatz.



Dr. Nina Duckstein bei der modernen Art der Schweißdrüsenverödung.

Beim Gang zum Arzt gibt es weitere medizinische Behandlungsmethoden. So kann er eine Behandlung mit Botulinumtoxin (Botox) durchführen. Dieses Protein hemmt die Übertragung der Schweißnervenreize auf die Schweißdrüse. Somit ist die Schweißdrüse komplett funktionslos für die Wirkdauer des Botox. Die Wirkung ist zuverlässig, muss allerdings alle sechs bis neun Monate erneuert werden. Wer eine dauerhafte Lösung sucht, kann sich die Schweißdrüsen operativ entfernen lassen. Diese Operation muss unter Vollnarkose durchgeführt werden und ist nicht risikofrei.

Bei der großen Anzahl an Lösungen ist also keine richtig zufriedenstellend. Deswegen wurde in den USA nun ein neues Verfahren entwickelt, das ebenso zuverlässige Ergebnisse wie die OP garantiert. Hierbei wird auf eine präzise Mikrowellen-Technologie zurückgegriffen, die genau in die entsprechende Gewebeschicht gelenkt wird. Dort werden die Schweißdrüsen dauerhaft zerstört. Eine Behandlung reicht meist aus. Für die einstündige Behandlungsdauer wird der Bereich lediglich lokal betäubt.

Die Wirkung wurde in diversen Studien nachgewiesen, sodass in den USA dieses Verfahren von der obersten Zulassungsbehörde für Medizinprodukte (FDA) noch vor der OP empfohlen wird. Auch erste deutsche Fachkliniken setzen dieses erfolgreiche Verfahren ein.

„Als Ärztin stehe ich neuen Verfahren durchaus skeptisch gegenüber. Daher habe ich neben der vielen Studien selbst lediglich eine Achsel behandeln lassen, um einen direkten Vergleich zu haben. Besonders beim Sport merke ich nun den extremen Unterschied und werde auch die andere Achsel behandeln lassen", betont Dr. Duckstein. Die Fachärztin hat aus Überzeugung die Mikrowellen-Technologie „miraDry" nach Hannover geholt, um Patienten damit bei youthconnection behandeln zu können.

Informationen

youthconnection

Ernst-August-Platz 10
30159 Hannover
Telefon: (0511) 45 01 31 70
www.youthconnection.de

ICH BRAUCHE KEIN DEO MEHR

LUCERNE CLINIC
EXCELLENCE
IN MEDICAL BEAUTY

Achselschweiss- und Geruchsdrüsen werden verödet – schmerzfrei und ohne Operation.

Achselschweiss ist lästig: Schweissflecken zeigen sich, dazu kommt der Geruch. Das Schwitzen und damit der Achselgeruch lassen sich jetzt durch einen einfachen Eingriff stoppen, und zwar dauerhaft. Wie, das sagt Dr. med. Jürg Häcki von der Lucerne Clinic im Interview.

Dr. Häcki, nie mehr schwitzen: Wie geht das? Die Lucerne Clinic verwendet als eine der ersten in der Schweiz eine neuartige Methode, die das Schwitzen unter den Armen durch einen kleinen Eingriff dauerhaft stoppt. Innerhalb etwa einer Stunde ist alles erledigt.

Wie funktioniert das? Die Schweiss- und Geruchsdrüsen werden verödet – und zwar ohne Operation. Als positiven Nebeneffekt verliert man auch noch 50 % der Achsel-Behaarung.

Sie haben sich selber diesem Verfahren unterzogen. Warum? Ich war nie ein starker Schwitzer. Ich musste jedoch jeden Morgen einen Deodorant verwenden, damit sich gegen Abend kein unangenehmer Achselgeruch bildet.

Wie ist das Resultat? Fantastisch, wirklich. Seit dem Eingriff vor ein paar Monaten habe ich nie mehr ein Deo benutzt. Am Abend rieche ich unter den Achseln gleich wie zum Beispiel am Oberarm.

Was ist dagegen einzuwenden, sich morgens etwas Deo anzuschmieren? Überhaupt nichts. Man kann nach dem Eingriff weiterhin ein Deo verwenden, das ist aber nicht mehr nötig. Das Schwitzen und der Geruch sind weg, das Deo auch. Auf all das verzichte ich sehr gern.

Ist das Verfahren schmerzhaft? Zumindest hört es sich so an? Während dem Eingriff habe ich überhaupt keine Schmerzen verspürt, sogar die Spritze zur Betäubung der Achseln hat nicht geschmerzt. Die folgenden zwei, drei Tage verspürt man etwas Schmerz. Es kommt praktisch nie vor, dass man deswegen Schmerzmittel nehmen muss oder nicht arbeiten kann. Auch ich habe ganz normal arbeiten können, und das ohne Schmerzmittel.

Das Verfahren, miraDry®, kommt aus den USA. Ist es auch sicher? Welche Komplikationen sind zu erwarten? Das Verfahren ist von der FDA in Amerika – der wohl strengsten Gesundheitsbehörde der Welt – zugelassen, es hat alle Sicherheitstest problemlos bestanden. Komplikationen sind bis heute keine beschrieben.

Kann es nicht zu einer Art Schweissstau unter den Achseln kommen? Nein, denn der Schweiss wird ja erst in der Haut selber produziert, durch die Schweissdrüsen eben. Sind sie verödet, wird kein Schweiss mehr produziert. Ein Schweissstau ist also nicht möglich.

Muss der Schweiss nicht irgendwo raus? Bei dieser Methode kann es nicht vorkommen, dass Sie anschliessend an einer anderen Stelle vermehrt schwitzen. Dieses kompensatorische Schwitzen kommt nur dann vor, wenn versucht wird, Achselschweiss durch Abtrennen der Nerven zu behandeln. Beim Veröden der Drüsen hingegen gibt es kein kompensatorisches Schwitzen.

Schwitzen sei gesund, sagt man. Ist eine Verödung der Schweissdrüsen damit ungesund? Wir schwitzen, um unsere Körpertemperatur zu regulieren. Der Schweiss unter den Achseln macht jedoch nur 2% des gesamten Schwitzen aus. Das heisst, dass wir unsere Temperatur weiterhin problemlos regulieren können.

Bieten Sie in Ihrer Lucerne Clinic auch andere Methoden gegen das Schwitzen an? Ja, einerseits Botulinumtoxin oder das Absaugen der Schweissdrüsen, Saugcurretage genannt. Doch miraDry® ist einfach zu vorteilhaft. Hinzu kommt, dass diese neue Methode garantiert dauerhaft ist und dadurch auch günstiger.

Können auch an anderen Körperstellen Schweissdrüsen verödet werden? Nein, dieses Verfahren ist nur gegen den Achselschweiss zugelassen.

Muss ich nach einer Behandlung mit miraDry® mein Verhalten ändern? Während der ersten Tage können leichte Schmerzen auftreten. Ein gewisses Schwellungsgefühl bleibt für ein paar Wochen. Sportliche Aktivitäten, die die Oberarme stark belasten, würde ich für eine Woche aussetzen. Danach kann man ohne Einschränkung wieder Sport machen.

Gibt es Fälle, in denen von dieser Behandlung abgeraten wird? Wir führen die Behandlung nicht durch, wenn eine Infektion der Haut vorliegt.

Ist miraDry® auch bei übermässigem, gar extremem Schwitzen erfolgreich? Absolut. Für viele, die unter sehr starkem Schwitzen leiden, also unter einer Hyperhidrosis, bedeutet dieser Eingriff ein neues Leben – man kann die Arme heben, ohne sich zu schämen.

Kann extremes Schwitzen auch andere Ursachen haben, die durch diese Behandlung nicht beseitigt werden? Nein, zum Glück nicht.

Hat diese Behandlung einen Einfluss auf andere Körperfunktionen? Nein, diese Behandlung hat keinen negativen Einfluss auf Ihren Körper oder Ihre Gesundheit.

Wird mich mein Partner weniger attraktiv finden – schlicht weil mein Körpergeruch nicht mehr da ist? Falls Ihr Partner Ihren Achselgeruch liebt, würde ich von der Behandlung abraten. Doch der individuelle Körpergeruch kommt nicht nur von den Achseln. Die Art, wie Sie riechen, bleibt somit erhalten.

Dr. med. Jürg Häcki führt seine «Lucerne Clinic» im Herzen von Luzern, in unmittelbarer Nähe des Bahnhofes. Ihm und seinen Kundinnen und Kunden geht es um Schönheit und Wohlbefinden: Neben ästhetischer Chirurgie und Spezialbehandlungen wie Microneedling gegen Falten und Kryolipolyse zur Reduktion von hartnäckigen Fettpolstern stehen auch Massagen, Lymphdrainagen und Medical Taping im Angebot, zum Beispiel eigens entwickelte Schwangerschafts-Massagen.

Dr. med. Jürg Häcki ist Facharzt FMH für Plastische, Rekonstruktive und Ästhetische Chirurgie und lebt mit seiner Familie in Luzern.

Lucerne Clinic
Seidenhofstrasse 9
CH-6003 Luzern

Tel. +41 41 511 80 80
info@lucerneclinic.ch
lucerneclinic.ch

Geschenke-Guide/Accessoires/Michael Bublé/Outdoor-Mode

GQ
DEUTSCHLAND

3,50 EURO

GENTLEMEN'S QUARTERLY

JANUAR
2017

REPORT

AUF BEWÄHRUNG: WAS PASSIERT 2017 MIT DEM EURO?

Auto

Dirty Driving
Schlammschlacht mit dem VW Tiguan

MODE

JARED LETO
DER STIL DES ALLROUND-GENIES

„Es gibt nur zwei Typen von Menschen: **Macher und Schwätzer**"
MICHAEL FASSBENDER

KHLOÉ KARDASHIAN
WIR VERNEIGEN UNS VOR DER REALITY-QUEEN

D3,50 €/A 3,50 €/CH 6,00 SFR
4 197641 203504 01

IMMER BESSER!

INTERVIEW
Schauspielgott MICHAEL FASSBENDER über Perfektion

Plus

SPECIAL
So tickt DER GENTLEMAN von morgen

DRAUSSEN KALT, DRINNEN LECKER FÜNF PRODUKTE, DIE GENIAL RIECHEN

1
VERFÜHRER
Nur romantische Abende vor dem Kamin sind noch besser. Aber als urbane Version bringt die Duftkerze eine ähnliche Wirkung.
→„Essenze Bougie", **Ermenegildo Zegna,** *85 €*

2
SAUBERMANN
Die Luxusdusche hinterlässt auf der Haut Aromen von roten Beeren und grünem Tee. Macht im Bad eine gute Figur.
→„La Crème Soyeuse", **Evidens de Beauté,** *80 €*

3
SCHUMMLER
Ein Textilduft, der an frisch gewaschene Wäsche erinnert. Einfach auf Sofa, Vorhänge oder Pullis sprühen.
→„Toile", **Byredo,** *45 €*

4
ABDECKER
Smarte Lösung bei miesem Wetter: Das schwerelose Haaröl macht die Frisur griffig und geschmeidig – und riecht männlich-herb nach Sandelholz.
→„Dark Oil", **Sebastian,** *26 €*

5
BURNER
Sehr altmodisch und die stilvollste Möglichkeit überhaupt, etwas anzuzünden: parfümierte Streichhölzer.
→„Byron", **Cire Trudon,** *15 €*

Nichts als Fakten #1: Duft und Medizin

•Forscher haben Geruchsrezeptoren überall im Körper nachgewiesen: „Riecht" die Lunge etwa Bananen und Aprikosen, entspannt sie sich – das soll bald Asthmatikern helfen. Sandelholzaroma kann dazu führen, dass Wunden schneller heilen, und die Prostata spricht positiv auf Veilchenduft an.

Constantin Herrmann

Behandlungen beim Arzt, neue Produkte, fragwürdige Trends – unser **Care-Experte** testet alles. Bis zur Selbstaufgabe und auch darüber hinaus.

Schweiß egal!

Achselflecken im Businesshemd und Schwitzefahne dank Winterpulli? Hab ich abgeschafft

JEDER MENSCH BESITZT bis zu drei Millionen Schweißdrüsen, die den Körper kühlen. Auch im Winter, unter dicken Pullis oder in überheizten Konferenzräumen. Das sieht man vielleicht und riecht es wahrscheinlich. Zumindest in meinem Fall. Das geht so weit, dass ich in vollen Räumen oder in einem Aufzug befürchte, dass alle um mich herum am liebsten verduften möchten. Kleiner Side-Gag der Evolution: Die für die Schweißfahne verantwortlichen Duftdrüsen legen richtig los, wenn man gestresst ist. Wer also Angst hat, zu stinken, schwitzt noch mehr. Oder in meinem Fall, schwitzte. Vergangenheitsform. Denn ich war bei Dr. Christoph Schick im Deutschen Hyperhidrosezentrum in München. Und der hat so etwas wie eine Mikrowelle to go: „miraDry" nennt sich das Verfahren, bei dem in einer guten Stunde die Schweißdrüsen in der Achsel gegrillt werden *(ca. 700 Euro pro Achsel)*. Erst wird das Areal mit Spritzen betäubt, das pikt kurz, aber sonst verläuft die Prozedur schmerzfrei. Dann setzt der Arzt ein pistolenartiges Handstück abschnittsweise an und schießt Thermowellen in das Gewebe. Dadurch entsteht ein Hitzeimpuls, der Schweiß- und Geruchsdrüsen dauerhaft vernichtet. Klingt martialisch, man spürt aber, wie erwähnt, nichts. Das Gewebe schwillt im Anschluss für ein paar Tage etwas an und wird druckempfindlich. Aber ich merke sofort: Alles bleibt trocken. Kein Schweiß, kein Geruch. Nie wieder. Mein Deodorant habe ich am selben Tag rituell in den Müll geworfen.

Wunderbare Achseln – schweißfrei, geruchsneutral und haarlos

S-thetic CLinic: miraDry-Behandlung stoppt lästiges Schwitzen unter den Achseln ohne OP

Frankfurt, den 29. Juni 2015: Dr. med. Afschin Fatemi, Facharzt für Dermatologie mit dem Schwerpunkt ästhetische Operationen sowie Ärztlicher Leiter der S-thetic Gruppe, kann in seiner S-thetic Clinic in Düsseldorf das Schwitzen unter den Achseln mit einem innovativen, nichtinvasiven Verfahren dauerhaft beenden: miraDry stoppt Achselschweiß, unangenehmen Geruch sowie Achselhaare.

Jetzt sind sie wieder vermehrt zu beobachten – die verdächtigen Flecken unterhalb der Achseln auf Hemd oder Bluse. Bei warmen Temperaturen beginnen wir zu schwitzen. Im Beruf kann er unangenehm sein, allgemein ist er meist lästig – der Achselschweiß.

Schwitzen ist natürlich

Um unsere Körpertemperatur zu regulieren, also unseren Körper vor Überhitzung zu schützen, produzieren die Schweißdrüsen Schweiß, der die Haut kühlt. Sauna, Sonne, Sport, Stress und Fieber bringen uns zum Schwitzen – das ist wichtig und völlig natürlich.

Eingeschränkte Kleiderwahl und die Angst zu „müffeln“

Doch Schwitzen ist nicht gleich Schwitzen. Es gibt Betroffene, die von regelrechten Schwitzattacken überfallen werden – egal bei welcher Temperatur oder in welcher Situation. Sie leiden unter der sogenannten Hyperhidrose, dem übermäßigen Schwitzen. Schuld sind überaktive Schweißdrüsen, die sehr viel und unkontrolliert Schweiß produzieren. Hyperhidrose kann sehr belastend sein: Die Furcht vor kritischen Blicken, spöttischen Kommentaren und unangenehmem Geruch wird zum ständigen Begleiter. Man beginnt die Kleiderwahl auf Schwarz und Weiß zu beschränken, da dort die Schweißflecken nicht so sichtbar sind, fühlt sich ständig unwohl und beginnt, sich aus Scham mehr und mehr sozial zu isolieren.
Beobachtet man übermäßige und unkontrollierbare Schwitzattacken bei sich, sollte man ärztlichen Rat suchen, um mögliche Ursachen zu klären. Leider kann nicht immer einwandfrei ergründet werden, warum die Schweißdrüsen überaktiv arbeiten, vor allem wenn man nur an einzelnen Körperstellen schwitzt (lokalisierte Hyperhidrose). Verschiedene Behandlungsansätze wie die Anwendung von Antitranspirantien oder die Injektion von Botulinum helfen meist nur bedingt sowie kurzfristig. Als letzter Ausweg erschien früher oft nur die operative Entfernung der Schweißdrüsen, die sogenannte Schweißdrüsenkürettage oder die radikale Schweißdrüsenexzision.

Eine neue, dauerhafte Lösung ohne OP bietet Dr. med. Fatemi in seiner S-thetic Clinic in Düsseldorf an: das miraDry-Verfahren.

miraDry: dauerhaft schweißfrei dank Mikrowellen

„miraDry ist eine neue Behandlung gegen die axilläre Hyperhidrose. Mit einer klinisch erprobten, nichtinvasiven Thermotherapie werden die Schweißdrüsen unter den Achseln zerstört, so dass übermäßiges

Schwitzen und unangenehmer Achselgeruch aufhören“, erklärt Dr. med. Afschin Fatemi, Facharzt für Dermatologie mit dem Schwerpunkt ästhetische Operationen sowie Ärztlicher Leiter der S-thetic Gruppe. Dr. med. Fatemi gilt als Experte im Bereich der Hyperhidrose-Therapie. Vor über zehn Jahren entwickelte er spezielle Kanülen für die Schweißdrüsenabsaugung, welche die Technik weltweit revolutionierte und populär machte. Nach intensiver Forschung verbesserte er seine Ergebnisse mit der von ihm entwickelten Schweißdrüsenlaserung, einem schonenden und minimal-invasiven Verfahren.

Das miraDry-Verfahren arbeitet mit präzise gesteuerter Mikrowellenenergie. Nachdem sie die Hautoberfläche durchdrungen haben, werden die Mikrowellen unter den Achseln in Wärme umgewandelt, welche die Schweißdrüsen „verödet“.

Ein hydrokeramisches Kühlsystem schützt die obere Hautschicht während der Behandlung und begrenzt gleichzeitig die Wärme auf den Bereich der Schweißdrüsen.

„Das miraDry-Verfahren führt zu einem dauerhaften Ergebnis – ganz ohne Operation, Schnitte oder Einschränkungen. Es entstehen keine Ausfallzeiten und man kann seinen gewohnten Alltag sofort nach der Behandlung wieder aufnehmen. Allerdings sollte auf Sport und Saunabesuche einige Tage lang verzichtet werden, um die Achseln zu schonen“, meint Dr. med. Fatemi.

Lebt wohl, Schweiß und Achselhaar

„Man sieht und spürt den Erfolg sofort: Die Haut unter den Achseln ist nach miraDry trocken. Die zerstörten Schweißdrüsen können keinen Schweiß mehr produzieren – und wachsen auch nicht mehr nach. Das führt zu einer dauerhaften Reduzierung des Schwitzens. Auch die Achselbehaarung wird spürbar weniger“, fasst Dr. med. Fatemi zusammen.

Weitere Vorteile des miraDry-Verfahrens sind:

• Sofortiger Effekt
• Dauerhaft und nachhaltig
• Keine OP
• Kein Schweißgeruch
• Weniger Achselhaare
• Kurze Behandlungsdauer
• Keine Ausfallzeiten

Starkes Schwitzen unter den Achseln muss dank dieser innovativen Hyperhidrose-Behandlung nicht länger sein – Betroffenen kann nun ohne Operation effektiv geholfen werden.

http://www.s-thetic.de/de/behandlungen/aesthetik-ohne-skalpell/hyperhidrose-behandlung/mira-dry

---

Unternehmensinformation / Kurzprofil:
Über die S-thetic Clinic

Die S-thetic Clinic Gruppe ist auf ästhetische Eingriffe spezialisiert. Unter der Leitung von Dr. med. Afschin Fatemi führt das Spezialisten-Ärzteteam plastisch-ästhetische Eingriffe wie Fettabsaugung, Facelifting, Brustchirurgie, Nasen- und Lidkorrekturen sowie Bauchdeckenstraffungen durch. Als europaweiter wie internationaler „Innovation Leader“ forscht und entwickelt Dr. med.Fatemi in der S-thetic Clinic weiter an sanften und ambulanten Verfahren. Behandlungen wie ThermaLifting® gegen Falten, Macrolane zur Brustvergrößerung, LipoSonix und SlimLipo™ zur Liposuktion sowie Hyperhidrose-Behandlung, BlueLight

und Laserverfahren zur Hautbehandlung etablierten sich dank der Vorreiter-Rolle. Der „S-thetic Circle“ ist ein jährlich stattfindender internationaler Fachkongress in Kooperation mit Universitäten und live-stattfindenden Operationen.
Die S-thetic Clinic Gruppe besitzt Standorte in Düsseldorf, Köln, Hamburg, München, Frankfurt am Main und Mannheim/Bad Dürkheim.

Biographische Eckpunkte zu Dr. med. Afschin Fatemi

Dr. med. Afschin Fatemi, Facharzt für Dermatologie und Phlebologie mit Schwerpunkt ästhetische Operationen, ist über seine vielfältigen Aktivitäten einer breiten Öffentlichkeit bekannt geworden: über seine Medienpräsenz, als Buchautor und als Referent bei renommierten nationalen und internationalen Fachkongressen. Seine Neuentwicklungen im Bereich von Operationsinstrumenten und -verfahren (Methoden der Liposuktion, Facelift, Lidplastik sowie Schweißdrüsenabsaugung) haben sich in der Branche schnell etabliert und seiner 2002 gegründeten S-thetic Clinic den Ruf eines „Innovation Leaders“ eingebracht. Dr. med. Fatemi ist u.a. Autor der Werke „Die gefragtesten Schönheitsoperationen“ und „Einmal J.Lo’s Po, bitte“, sowie Mitautor verschiedener Fachbücher. Zudem initiiert und verantwortet er den jährlich stattfindenden internationalen Fortbildungskongress „S-thetic Circle“.

S-thetic Clinic Düsseldorf
Kaiserswerther Markt 25
40489 Düsseldorf

Telefon: 0211 / 4369 340
Mail: info@s-thetic.de

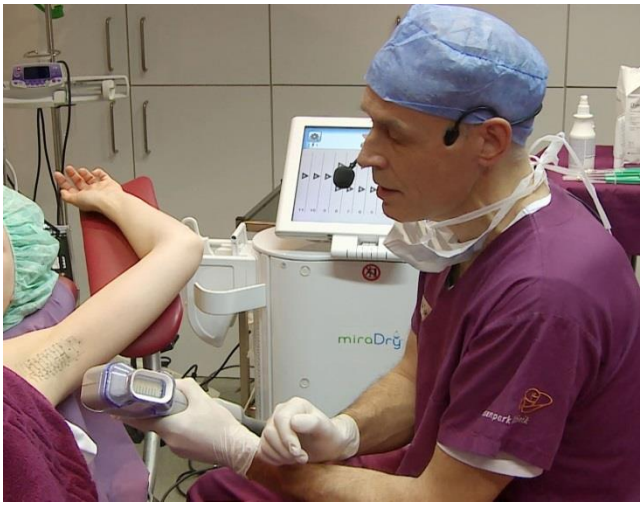
Web: www.s-thetic.de

MIRADRY – DIE DAUERHAFTE LÖSUNG BEI ÜBERMÄSSIGEM SCHWITZEN UND STARKEM SCHWEIßGERUCH

NEU IN DEUTSCHLAND UND EXKLUSIV IN DER HAUTMEDIZIN KELKHEIM

Kelkheim, Januar 2015 – Die Hautmedizin Kelkheim ist die erste und einzige Praxis in Deutschland, die das bahnbrechende Hyperhidrose-Verfahren aus den USA anbietet: das miraDry-Verfahren ist nicht-invasiv, liefert sofort Ergebnisse und erfordert keinen chirurgischen Eingriff. Die Schweißdrüsen werden mit gezielter elektromagnetischer Energie (Mikrowellen) bestrahlt und durch die entstehende Hitze dauerhaft zerstört. Gleichzeitig verschwindet auch der unangenehme Schweißgeruch, da die Geruchsdrüsen ebenfalls zerstört werden. Im Gegensatz zu den herkömmlichen Behandlungs-möglichkeiten bietet miraDry Hyperhidrose-Patienten erstmals eine nicht-operative und dauerhafte Lösung für ihr übermäßiges Schwitzen.

„Das Krankheitsbild des übermäßigen Schwitzens begegnet uns in unserer Praxis täglich. Um das Leid der Betroffenen zu lindern und dem Patientenwunsch nach einer sicheren und schnellen Behandlung mit dauerhaften Ergebnissen nachzukommen, haben wir uns für das nicht-operative und klinisch erprobte miraDry-Verfahren aus den USA entschieden. Schon kurz nach der Sitzung reduziert sich das Schwitzen spürbar und nach 2 Behandlungen wird die Schweißmenge dauerhaft auf ein Normalmaß gesenkt. Wir freuen uns, dass wir unseren Patienten mit miraDry ein großes Stück Lebensqualität zurückgeben können."



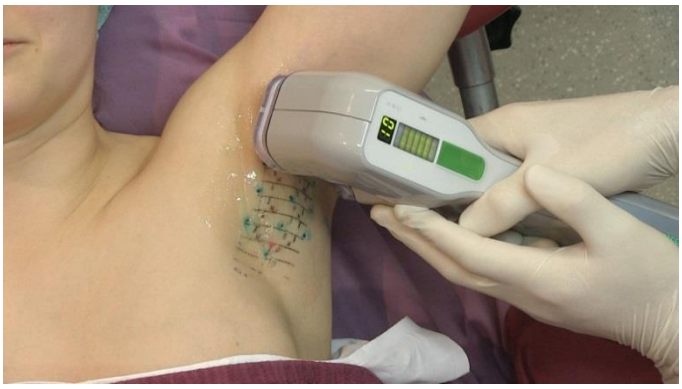
Dr. Jokisch während einer miraDry-Behandlung

Endlich dauerhaft schweißfrei dank Mikrowellen!

Auf das zu behandelnde Areal werden vorübergehend Markierungen angebracht, um die Behandlung zu leiten. Anschließend wird die Haut desinfiziert und mit einem lokalen Anästhetikum betäubt. Der Arzt setzt nun das Handstück abschnittsweise auf die markierten Bereiche. Dabei wird jedes Mal die Haut leicht angesaugt und so für die Energiezufuhr stabilisiert. Dann dringen die Mikrowellen zielgerichtet in das Gewebe ein und führen dort zu einer Thermolyse, d.h. es entsteht eine kurze aber intensive Hitze, die die Schweißdrüsen samt ihrer Versorgungsnerven ein für alle Mal zerstört. Gleichzeitig schützt ein

MIRADRY – DIE DAUERHAFTE LÖSUNG BEI ÜBERMÄSSIGEM SCHWITZEN UND STARKEM SCHWEIßGERUCH

kontinuierliches hydrokeramisches Kühlsystem die obere Hautschicht und begrenzt die Wärme auf den Bereich der Schweißdrüsen. Da sich einmal zerstörte Schweißdrüsen nicht wieder regenerieren, sind die Ergebnisse von miraDry bleibend. Nach der Behandlung werden die Markierungen entfernt und die Achseln mit Kühlpacks gekühlt. Der gesamte Arztbesuch nimmt im Allgemeinen 60 Minuten in Anspruch. Die eigentliche Behandlung dauert ca. 40 Minuten.



Dr. Jokisch führt das Handstück nach einem definierten Protokoll abschnittweise über das Hautareal.

Das miraDry-System kann leider nicht für die Behandlung von Hyperhidrose in anderen Körperbereichen, einschließlich Händen und Füßen, verwendet werden. Für Patienten mit Herzschrittmachern und anderen elektronischen Implantaten, die eine zusätzliche Sauerstoffversorgung benötigen oder die eine Unverträglichkeit gegen die Betäubungsmittel Lidocain und Epinephrin haben, ist das Verfahren nicht geeignet.

PD Dr. Christoph H. Schick, Leiter des Deutschen Hyperhidrosezentrums DHHZ, ist von miraDry überzeugt:

„Vor kurzem haben neuere Untersuchungen gezeigt, dass von übermäßigem Schwitzen Betroffene eine ähnlich starke Minderung ihrer Lebensqualität erleiden wie Tumorpatienten! Hyperhidrose ist also kein ästhetisches Problem, sondern eine sehr ernstzunehmende Erkrankung. Darum freue ich mich sehr, dass Patienten in Deutschland seit kurzem mit dem neuen miraDry-Verfahren aus den USA behandelt werden können. Die Schädigung der Schweißdrüsen durch Hitze ist ein hervorragendes Prinzip, weil dadurch das Schwitzen unmittelbar vermindert wird."

MIRADRY – DIE DAUERHAFTE LÖSUNG BEI ÜBERMÄSSIGEM SCHWITZEN UND STARKEM SCHWEIßGERUCH

Sofortige Ergebnisse

Meist spüren die Patienten schon kurz nach der Sitzung eine deutliche Reduzierung des Schweißes. Eine aktuelle Studie bestätigt, dass miraDry das Schwitzen bereits nach zwei Behandlungen um ca. 82%* reduziert. Da sich einmal zerstörte Schweißdrüsen nicht regenerieren, ist das Ergebnis effektiv und dauerhaft. Insgesamt sind zwei Behandlungen im Abstand von 3 Monaten nötig.

Positive Nebeneffekte

Kein Schweißgeruch mehr: Alle Patienten sind sehr erleichtert, dass nach der miraDry-Behandlung auch der unangenehme Schweißgeruch (Bromhidrose) verschwindet, weil die Geruchsdrüsen ebenfalls zerstört wurden.

Keine Achselbehaarung mehr: In der Hautschicht der Schweißdrüsen liegen auch die Wurzeln der Achselhaare. Daher reduziert sich bei vielen Patienten nach der Mikrowellen-Behandlung die Behaarung im Achselbereich deutlich.

Mögliche Nebenwirkungen wie vorübergehende Rötungen, blaue Flecken, Druckempfindlichkeit, Schwellungen oder ein leichtes Taubheitsgefühl in den Fingern klingen nach kurzer Zeit von selbst ab. Der Patient kann sofort nach dem Arztbesuch wieder seine Arbeit aufnehmen und nach einigen Tagen auch wieder Sport treiben.

miraDry – effizient, sicher & geprüft

miraDry ist ein neues, nicht-invasives und klinisch erprobtes Verfahren gegen übermäßiges Achselschwitzen (axilläre Hyperhidrose) und starken Schweißgeruch. Es basiert auf einer sicheren Mikrowellen-Technologie und ist die einzige Thermolyse-Methode, die eine FDA**-Zulassung und ein CE-Zeichen besitzt. miraDry wurde bereits über 30.000 Mal in den USA sowie im asiatisch-pazifischen Raum, in Kanada und in Mexiko erfolgreich durchgeführt. Experten schätzen, dass ca. 1-2% der Deutschen unter Hyperhidrose leiden – eine enorme Nachfrage! Miramar Labs Inc. gilt als Pionier auf dem Gebiet der Thermolyse-Behandlung von Hyperhidrose und brachte miraDry erst nach über 5 Jahren Forschung und Entwicklung auf den amerikanischen Markt. Zahlreiche Langzeit-Studien von führenden Dermatologen der USA belegen die Sicherheit und Effizienz von miraDry.

miraDry ist von der FDA zugelassen zur Behandlung der primären axillären Hyperhidrose bei Erwachsenen ab 18 Jahren.

MIRADRY – DIE DAUERHAFTE LÖSUNG BEI ÜBERMÄSSIGEM SCHWITZEN UND STARKEM SCHWEIßGERUCH

Über Miramar Labs, Inc.

Miramar Labs, Inc. ist ein 2006 von The Foundry gegründetes, privates Unternehmen mit Sitz in Kalifornien (USA). Die auf Medizintechnik spezialisierte Firma entwickelt Technologien zur Behandlung von dermatologischen Krankheiten, für die es einen hohen medizinischen Bedarf gibt. Nach langjähriger klinischer Forschung entwickelte Miramar Labs die miraWave™-Technologie. Dieses auf Mikrowellen basierende Verfahren wird bereits erfolgreich in zahlreichen medizinischen Bereichen eingesetzt. In der Dermatologie wird sie vor allem zur Behandlung des übermäßigen Schwitzens (axilläre Hyperhidrose) angewendet. Das miraDry-System ist die einzige Thermolyse-Methode, die eine FDA**-Zulassung für die USA und ein CE-Zeichen für den deutschen Markt besitzt.

Über die Hautmedizin Kelkheim

Dr. med. Matthias Bonczkowitz, Dr. med. Rainer Jokisch, Dr. med. Riklef Kleine, Dr. med. Tina Müller-Brenne, Dermatologin Anne Schieber

Ausgestattet mit der neuesten Lasertechnik, jahrelanger Erfahrung und dem Wissen um die Möglichkeiten und Grenzen der einzelnen Behandlungsmethoden, bietet die **Hautmedizin Kelkheim** qualitativ hochwertige Medizin, die weit über das Spektrum einer allgemeinen Hautarztpraxis hinausgeht. Die besonderen Schwerpunkte bilden die Tattooentfernung mit dem PicoSure, das Body-Contouring mit CoolSculpting, die Hyperhidrose-Behandlung mit miraDry, die Hautkrebsbehandlung und die Berufsdermatologie.

Neben den Leistungen der **klassischen Hautmedizin** (Diagnose und Behandlung von Hauterkrankungen: Hautkrebs, Neurodermitis, Schuppenflechte, Akne, etc. / Haar- und Nagelerkrankungen / Allergien / Berufsdermatologie) verfügt das Ärzteteam über umfangreiche Expertise im Bereich der **ästhetischen Dermatologie** (Augenlidstraffung / Liposuktion / Bauchdeckenstraffung / Body Contouring / Kombinationstherapien mit Fillern und Botox / minimal-invasive Behandlung von Krampfadern) und der **Laserbehandlungen** (Pigmentstörungen / Haarentfernung / Tattooentfernung / Faltenbehandlung / Hautverjüngung / u.v.m.).

miraDry ist von der FDA zugelassen zur Behandlung der primären axillären Hyperhidrose bei Erwachsenen ab 18 Jahren.

MIRADRY – DIE DAUERHAFTE LÖSUNG BEI ÜBERMÄSSIGEM SCHWITZEN UND STARKEM SCHWEIßGERUCH

Mehr Informationen unter www.hot-without-sweat.de oder www.hautmedizin-kelkheim.de

* H. Chin-Ho Hong, MD, Mark Lupin, MD et al.: Dermatologic Surgery, 2012; 38:728-735.
** Food and Drug Administration – Arzneimittelzulassungsbehörde der USA

KONTAKT

Hautmedizin Kelkheim
Dr. med. Bonczkowitz / Dr. med. Jokisch
Frankenallee 1
65779 Kelkheim am Taunus
Tel.: +49 (0)6195 6772-300
E-Mail: praxis@hautmedizin-kelkheim.de
Internet: www.hautmedizin-kelkheim.de

PRESSEKONTAKT

ART.media Public Relations
Juliane Thoß
Stromstraße 4
10555 Berlin
Tel.: +49 (0)30 740 744-745
E-Mail: presse@hautmedizin-kelkheim.de
Fotorechte@Hautmedizin Kelkheim.
Abdruck honorarfrei.

Bild der Frau **Gesund & fit**

Kristina Geschwill (24) litt jahrelang unter Hyperhidrose – und schämte sich

„Heute bringt mich nichts mehr ins Schwitzen“

Selbst bei Minusgraden hatte die Studentin nasse Achseln. Wie die Technik eines Küchengerätes das unangenehme Problem löste

Nach der Behandlung ging Kristina sofort einkaufen

Gäbe es in einem TV-Quiz eine Frage nach Deodorants, Kristina Geschwill könnte sie ohne zu zögern beantworten. „Ich habe alles ausprobiert, was der Deo-Markt hergibt, jede einzelne Marke“, schmunzelt die 24-jährige Studentin aus Mannheim rückblickend.

Geholfen hat ihr keine einzige. Der Grund: Kristina leidet an Hyperhidrose, einer vererbten Veranlagung zu übermäßiger, geruchloser Schweißbildung – in erster Linie in den Achselhöhlen. „Es begann in der Pubertät“, erinnert sich Kristina. „Meine Achselhöhlen wurden nass, ohne dass ich mich körperlich anstrengte. Wenn ich morgens im Winter auf den Schulbus wartete, fror und schwitzte ich gleichzeitig.“ Weil sich ständig große nasse Ränder unter den Armen bilden, trägt sie nur noch dunkle Shirts und Pullis. Bei einem besonders wichtigen Termin klebt sie sich sogar Damenbinden in die Bluse. „Das Schwitzen begleitete mich jahrelang“, sagt Kristina. Bis sie von einer Mitstudentin erfährt, dass ein amerikanisches Forschungsteam eine neue sanfte Methode entwickelt hat.

Dr. Rainer Jokisch
Hautarzt im Gesundheitszentrum Kelkheim

Mit Mikrowellen gegen Drüsentätigkeit

„In zwei Sitzungen innerhalb von drei bis sechs Monaten können die überstimulierten Schweißdrüsen mit einem Mikrowellen-Handstück dauerhaft entfernt werden. „Dabei betäuben wir zunächst die Achselhöhle“, erklärt Hautarzt Dr. med. Rainer Jokisch aus Kelkheim/Taunus. „Dann saugen wir mit dem Handstück des Geräts die Haut leicht an, schicken Mikrowellen ins Gewebe, die die Schweißdrüsen

Schon seit ihrer Pubertät waren Schweißflecken Kristinas ständige Begleiter. Durch den Eingriff endete für die junge Studentin diese belastende Situation

Zwei Mal lässt Kristina ihre Achseln mit Mikrowellen behandeln. Der schmerzfreie Eingriff dauert im Schnitt etwa 40 Minuten

Problem: Hyperhidrose

Krankengeschichte: Kein Deo half, Kristina litt unter dem Dauerschwitzen

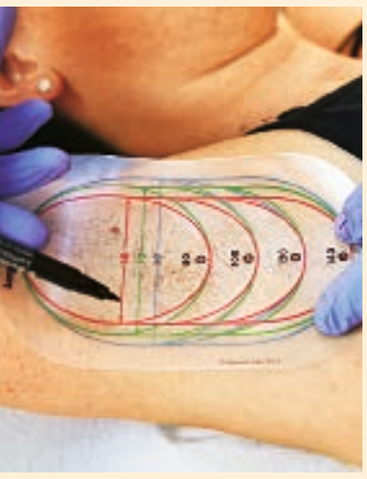
Lösung: Mikrowellen zerstören Schweißdrüsen

samt ihrer Versorgungsnerven ein für alle Mal zerstören." Auch Kristina lässt sich von Dr. Jokisch behandeln. „Bislang übliche Eingriffe wie regelmäßige Botox-Spritzen oder eine OP wie die Saugkürettage wollte ich vermeiden", begründet die Studentin ihre Entscheidung.

Jetzt fühlt Kristina sich wohl in ihrer Haut

„Eine Zeitlang ist die Haut unter den Achseln noch empfindlich und leicht geschwollen, doch schon Tage später spürt Kristina den Erfolg. „Ich habe jetzt keine peinlichen Schweißflecken mehr", freut sie sich. „Was ich nach der Behandlung als Erstes gemacht habe? Ich habe mir bunte Blusen gekauft."

STEFANIE KÖTTER



Die Markierungen grenzen den Behandlungsbereich ein

Für wen eignet sich das Anti-Schwitz-Verfahren?

Ein bis zwei Prozent der Deutschen, so schätzen Experten, leiden an Hyperhidrose, der krankhaften Überstimulation der Schweißdrüsen. Nur bei jedem Zehnten geht sie mit unangenehmer Geruchsbildung einher.

Kosten: 1500 Euro pro Sitzung, es werden zwei Behandlungen empfohlen. Die Kassen zahlen nicht.

INFO

Hautmedizin Kelkheim, www.hautmedizin-kelkheim.de, Tel. 06195/6772300

MELDUNGEN

Keine OP bei leichter Knie-Arthrose

Die Knie-Spiegelung (med.: Arthroskopie) zählt zu den häufigsten OPs in Deutschland. Dabei kann der Chirurg Schäden erkennen und direkt behandeln, etwa indem er Knorpelgewebe abträgt. Jetzt zeigt eine Auswertung mehrerer Studien, dass der Eingriff bei leichtem Gelenkverschleiß jedoch keinen Nutzen hat. Langfristig blieben die Schmerzen bei den Betroffenen gleich. Experten raten zu gelenkschonender Bewegung wie Schwimmen oder Radfahren. Dadurch wird mehr Gelenkflüssigkeit produziert und der Knorpel quasi innerlich geschmiert.

Protonenpumpenhemmer nicht teilen

Wer unter Sodbrennen oder Magengeschwüren leidet, schluckt oft Protonenpumpeninhibitoren (PPI). Sie reduzieren die Magensäureproduktion. Wichtig ist, die Medikamente im Ganzen einzunehmen. Sonst wird der schützende Überzug zerstört und die Mittel lösen sich schon im Magen auf. Ihre Wirkung entfalten sie aber nur, wenn sie erst im Dünndarm aufbrechen.

Sanfte Hilfe gegen Heuschnupfen

Für Allergiker beginnt jetzt eine schwere Zeit. Gerade haben sie die Pappel- und Birken-Zeit überstanden, beginnt im Mai die Hochsaison der Gräser. Und diesen kann man auch homöopathisch Paroli bieten statt ständig Antihistaminika zu schlucken. Studien beweisen die Wirksamkeit der Heilpflanze Galphimia glauca (z. B. in Heuschnupfenmittel DHU, rezeptfrei in der Apotheke). Sie reduziert nachweislich den Juckreiz, die Häufigkeit der Niesanfälle sowie das Augenbrennen.

Depressionen: Männer leiden anders

Fünf Prozent aller Männer erkranken jedes Jahr an einer Depression. Das Problem: Ihre Symptome unterscheiden sich von denen der Frauen. Während diese oft antriebslos sind, werden Männer häufiger aggressiv. Angehörige und Betroffene sollten im Zweifel ihren Hausarzt zu Rate ziehen.

Fotos: Richard Rosicka (5), Corbis (2)

Deutsche Version ab Seite 3

Avec miraDry®, dites stop à la transpiration!

Transpiration excessive? Auréoles de sueur qui vous gâchent la vie au quotidien? Si vous ne supportez plus de transpirer sous les aisselles, les spécialistes du centre DELC vous proposent une solution définitive et non invasive, le protocole miraDry® !

Dr méd. Adrian Krayenbuhl

La transpiration sous les aisselles, qu'elle soit excessive ou non, peut nous gâcher la vie! Perte de confiance en soi, auréoles inesthétiques, odeurs de sueur incontrôlables… miraDry® apporte à ce problème récurrent une solution simple, définitive, non invasive et à effet immédiat. Pour vous en parler, nous avons rencontré le Docteur Adrian Krähenbühl, fondateur du centre DELC (dermatologie, laser, esthétique et chirurgie) à Bienne, qui pratique ce protocole depuis plus d'un an avec d'excellents résultats.

Docteur Krähenbühl, parlez-nous du protocole miraDry®

miraDry® est un protocole développé par l'entreprise américaine Calista et approuvé par la très sévère FDA (Food and Drugs Administration). Il a pour but de réduire très significativement et durablement la transpiration axillaire (sous les aisselles) chez les personnes souffrant d'hyperhydrose (transpiration excessive) ou simplement gênées par la transpiration. Le protocole est réalisé à l'aide d'une machine qui génère un flux d'énergie électromagnétique ciblant très précisément les glandes sudoripares afin de les éliminer par échauffement. Le résultat est définitif car elles ne se régénèrent pas. Il est sans contre-indications et sans conséquences sur l'équilibre de l'organisme puisque 2% seulement des glandes sudoripares de notre corps se trouvent sous les aisselles.

Comment se déroule le protocole miraDry®?

Tout d'abord, nous définissons la partie de l'aisselle à traiter à l'aide d'une grille spécifique (appliquée sous forme de décalcomanie sur la peau). Cette grille dessine le tracé que suivra la technicienne pour effectuer le traitement. Elle recouvre la zone de pousse des poils, car les glandes sudoripares sont placées à fleur de peau, juste sous les bulbes pileux. Ensuite, le médecin pratique une anesthésie locale, puis la spécialiste place une tête amovible jetable à usage unique sur l'appareil et commence la procédure. Pendant le traitement la tête aspire légèrement la peau puis envoie le flux d'énergie tout en refroidissant la surface de l'épiderme afin qu'il soit préservé de la chaleur. Il faut compter environ deux heures pour un traitement complet. Les résultats sont immédiats et définitifs, la personne peut reprendre une vie normale tout de suite après le traitement, en évitant néanmoins les activités sportives pendant huit à dix jours.

Combien de séances conseillez-vous?

Une seule séance suffit pour réduire de 50 à 70% le niveau de transpiration, ce qui, en général, est tout à fait satisfaisant. Cependant, si la personne souffre d'hyperhydrose, on peut envisager une seconde séance après deux ou trois mois.

Combien coûte le traitement?

Le prix de la première séance est de CHF 2 900.- et celui de la seconde séance, si elle est nécessaire, est de CHF 1 500.-.

miraDry®, la solution non invasive pour éliminer la transpiration sous les aisselles la plus performante au monde vous attend dans votre centre DELC de Bienne!

DELC
Dermatologie Laser Chirurgie

DELC – Dermatologie Laser Chirurgie
Rue du Marché 17 – 2502 Bienne
Tél. 032 325 44 33 – www.delc.ch

MIT miraDry® SAGEN SIE STOP DEM ACHSELSCHWEISS!

EXZESSIVER ACHSELSCHWEISS? SCHWEISSRÄNDER, DIE IHREN ALLTAG BEEINTRÄCHTIGEN? WENN SIE DIESE UNANNEHMLICHKEITEN NICHT MEHR HINNEHMEN WOLLEN, BIETEN IHNEN DIE SPEZIALISTEN VON DELC BIEL EINE DEFINITIVE UND NICHTINVASIVE LÖSUNG AN: DIE miraDry® BEHANDLUNG!

Dr. med. Adrian Krähenbühl

Achselschweiss, ob exzessiv oder nicht, kann einem das Leben vermiesen! Verlust an Selbstvertrauen, unschöne Schweissränder, unkontrollierbarer Schweissgeruch. miraDry® ist für diese immer wiederkehrenden Probleme eine einfache, definitive und nichtinvasive Lösung mit Sofortwirkung. Um Sie darüber zu informieren, haben wir Herrn Dr. Adrian Krähenbühl zum Interview getroffen. Er ist der Gründer des Centers DELC (Dermatologie, Laser, Chirurgie) in Biel, in welchem diese Behandlung seit mehr als einem Jahr mit überzeugenden Resultaten durchgeführt wird.

Herr Dr. Krähenbühl, erklären Sie uns bitte die miraDry® Behandlung

miraDry® wurde von der US-Unternehmung Miramar Labs entwickelt. Es ist das einzige von der sehr strengen FDA (Food and Drugs Administration) zugelassene Verfahren, das eine dauerhafte Schweissreduzierung auf nichtinvasive Weise bei Personen ermöglicht, die unter einer Hyperhidrose (übermässige Schweissabsonderung) leiden, oder die sich ganz einfach durch den Achselschweiss gehemmt fühlen. Die Behandlung wird mithilfe eines Gerätes durchgeführt, das mit präzise kontrollierter elektromagnetischer Energie in Form von Mikrowellen die Schweissdrüsen unter Hitzeeinwirkung beseitigt. Das Resultat ist definitiv, denn diese Drüsen regenerieren sich nicht. Die Entfernung der axillären Schweissdrüsen beeinträchtigt übrigens das Gleichgewicht des Organismus in keinster Weise, da diese lediglich 2% der rund vier Millionen Schweissdrüsen im Körper ausmachen.

Wie läuft die miraDry® Behandlung ab?

Zuerst definieren wir die Lage der Schweissdrüsen bei jeder Achsel. Anschliessend wird das miraDry® Handstück an die genau bezeichneten Zonen gehalten, die Haut leicht angesaugt und die präzise kontrollierte elektromagnetische Energie in die Schweissdrüsen geleitet. Gleichzeitig schützt ein Kühlsystem die Oberfläche der Haut vor Verbrennung. Dank Lokalanästhesie ist die rund zwei Stunden dauernde Behandlung schmerzlos. Das Resultat überzeugt durch Sofortwirkung und ist dauerhaft. Mit Ausnahme von sportlichen Aktivitäten, die erst nach acht bis zehn Tagen wieder aufgenommen werden sollten, kann die Person direkt nach der Behandlung wieder ihrem normalen Alltag nachgehen.

Wie viele Sitzungen empfehlen Sie?

Eine einzige Sitzung genügt, um 50% bis 70% des Achselschweisses zu reduzieren, was meistens zufriedenstellend ist. Leidet die Person unter einer übermässigen Schweissabsonderung, kann eine zweite Behandlung nach zwei bis drei Monaten durchgeführt werden.

Wie viel kostet die Behandlung?

Der Preis der ersten Behandlung beträgt CHF 2900.-, die zweite Behandlung (sofern nötig) kostet CHF 1500.-.

miraDry®, die weltweit wirkungsvollste und nichtinvasive Lösung für die Reduzierung des Achselschweisses erwartet Sie in Ihrem Center DELC in Biel!

DELC
Dermatologie Laser Chirurgie

DELC – Dermatologie Laser Chirurgie
Marktgasse 17 – 2502 Biel-Bienne
Tel. 032 325 44 33 – www.delc.ch