A multi-center clinical evaluation of the performance of fractional radiofrequency technology for improvement of skin texture

Introduction & Objectives

The visible reduction in the appearance of the acne scars, skin texture irregularities and or rhytides.

42 centers in North America and one hospital in Israel, participated in an IRB approved, multi-center study using a fractional radio frequency device to treat skin textural irregularities.

Up to 15 subjects per center received 3 RF Scan treatments with a one and two month post treatment follow up was performed.

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Materials & Methods

- RF Applicator with160 total pins in a rectangular pattern. 150x20x700 micron footprint with a 30^0 angle.
- 4 pins are active while 156 pins reciprocating until all 160 pins complete the scanner delivery of RF energy.
- Enrolled both genders, ages 21-60 and all Fitzpatrick types
- Patients pre treated with a mild topical anesthetic
- Face received one pass of energy pulses for one treamtent every 2 weeks for a total of 3 tx over 6 weeks.
- One - two days post treatment some reported events were limited to mild inflammation and erythema. All resolved without sequelae.

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Results

Over 75% of patients have observed a visible improvement in their skin and more than 77% said the treatments were very tolerable.

Significant improvement has been observed in pigmentation abnormalities but further study is required to establish the device's efficacy for melasma, solar lentigo or lentigo senilis.

Biopsies reveal that the depth of the wound can be as deep as 500 microns and the recovery of the wound is less than 5 days, in most cases, with altered collagen visible at 200 microns.

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Conclusions

Scanner delivered RF technology can be used with a high degree of confidence to improve the textural appearance of the skin with little downtime and helps to avoid complications, which can be associated with more aggressive or ablative laser treatments.

Treatments have proven safe for all skin types.

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Before and After

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A Pilot Study for the Safety and Efficacy of Using the Venus Viva Nano-Fractional Device for the Treatment of Wrinkles and Rhytides

ABSTRACT

Fine wrinkles and deep facial wrinkles, referred to as elastosis, are common skin conditions. For many individuals, especially women, facial wrinkles cause significant concern or psychological distress. This pilot study describes the use of nano-fractional radiofrequency to effectively reduce the occurrence of facial wrinkles and elastosis in 10 subjects who underwent a series of three treatments during a 4-week interval. Moderate improvements were observed for >90% of the subjects and no serious adverse events were reported.

INTRODUCTION

Skin laxity, facial texture irregularities such as post acne scars, and facial wrinkles, clinically referred to as rhytides, are common skin conditions in both men and women. The appearance of these types of facial irregularities can result in distress for people of all ages, causing them to turn to cosmetic treatments such as surgical procedures (e.g., face lifts) as well as non-surgical procedures including chemical or laser peels, non-ablative laser resurfacing, or dermabrasion [1]. These procedures are usually associated with prolonged recovery times as well as arduous side effects. To circumvent these issues, the use of non-invasive, nonsurgical approaches that do not require downtime are becoming the preferred method of choice for patients seeking cosmetic improvements. An innovative technique that was introduced to reduce facial wrinkles and rhytides is known as radiofrequency (RF).

One of the earliest procedures entailed using mono-polar RF [2], although bipolar and multi-polar RF devices have also been developed. The premise behind RF technology is dermal heating, which initiates the denaturation of collagen and the stimulation of neocollagenesis through the induction of inflammation that leads to the production of fibroblasts at the heated area and the subsequent development of new collagen [3, 4]. RF energy produces an oscillating electrical current that can penetrate the dermis and hypodermal tissues without disturbing the epidermal-dermal barrier. The generation of the heat energy is the result of the natural resistance that dermal tissue has to the movement of ions with an electromagnetic field. Accordingly, the oscillating electrical current causes collisions between charged ions that are transformed into heat energy [3, 5]. The production of heat energy through RF typically results in ablation, coagulation, and skin resurfacing.

Mono-polar RF devices were used initially for facial treatments, and although the results appeared to be promising, this approach was associated with serious pain as well as the high incidence of adverse events including second-degree burns that are caused by the deeply penetrating heat production of the single electrode [6]. Bipolar and multi-polar RF devices allow the heat energy to be distributed more evenly with less depth-penetration, thereby resulting in less pain and improved safety profiles [7, 8] but concerns remained regarding the ability to precisely control the degree of ablation and coagulation that is required depending on a patient's skin type. Moreover, a randomized, blinded, split-face study comparing the use of mono-polar and bipolar RF devices for the treatment of skin laxity and wrinkles indicated that there was no difference in pain, side effects, or efficacy between mono-polar and bipolar devices [9]. Therefore, RF techniques that improve the ability to control the ablation and

coagulation of the skin can result in treatment consistency that will provide more flexibility to treat a wider variety of skin conditions.

The objective of this study was therefore to evaluate the safety and efficacy of using a nano-fractional RF device to reduce facial wrinkles, rhytides, and elastosis. Nano-fractional RF technology offers more precise depth penetration and consistent selection dermal heating as well as controlled coagulation and ablation ability in comparison to other RF devices. The technology is delivered through 160 pins per tip with 62mj per pin and a smaller footprint per pin (150x20 Microns), which results in micro wounds, efficient skin resurfacing, and minimal downtime.

MATERIALS AND METHODS

Ten subjects (9 females, 1 male) between the ages of 34 and 67 (mean age=42.30 years, SD=10.023) with facial wrinkles and rhytides participated in this pilot study. The inclusion criteria included having 3 to 9 degrees of elastosis on the Fitzpatrick Wrinkle and Elastosis Scale as well as providing written consent. Exclusion criteria were: implanted pacemakers, arrhythmias, or any other known severe heart disorder, implantable metal devices (excluding metal dental devices), medication that affects the skin or hormones, malignant skin cancer in the treatment area, a history of keloid formations or hypertrophic scarring, pregnant or lactating subjects, autoimmune disorders, diabetes, clotting disorders, epilepsy or severe migraines, permanent makeup, tattoos, or body piercings in the treatment area, extreme general weakness, subjects with psychiatric disorders being treated with psychiatric medications, and skin therapy in the past 6 months.

Each subject had a screening assessment, a pretreatment photograph, three treatment visits over a 4-week interval with photographs of the treated areas, and two post-treatment visits (1 month and 3 months post-treatment). Each subject received three RF scan treatments with the use of the 160-pin tip (per area of 8x20 mm). The treatment area was cleaned thoroughly with soap and water; then dried prior to the treatment. The treatment parameters such as the pick power (180 to 280 Volts-V) and the duration of pulses (5 to 25 milliseconds-ms) was determined based on subject skin type and the area of treatment. Biopsies were also performed at varying times after treatment and the tissue was stained with hematoxylin and eosin (H&E) for histological evaluation of the depth of ablation and coagulation.

Before each treatment, every subject was photographed in a standardized way. Subjects were assessed for discomfort during each treatment. Immediately after each treatment, the treated area was assessed for skin responses including hemorrhage, burn, erythema, edema, hyperpigmentation or hypopigmentation, pain, scarring, or infection. In addition, subjects were asked to rate the perceived pain level during the treatment through the use of a visual analog scale (VAS). The Global Aesthetic Improvement (GAI) Scale was used to assess treatment efficacy: 4-Improved significantly; 3-Improved moderately; 2-No difference; 1-Worsedned slightly; 0-Worsened significantly. All of the patient observations were based on comparisons to the baseline and the scale criteria were as follows: 4- marked visual improvement in texture, fine lines, and wrinkles after treatment; 3- visual improvement was noted after treatment, but not dramatic in relation to texture, fine lines, and wrinkles; 2- treated area was the same as the baseline; 1- texture, wrinkles, and fine lines were slightly more apparent than at baseline; 0- dramatic visible increase in texture, fine lines, and wrinkles were apparent after treatment.

RESULTS

All 10 subjects enrolled in the study completed the treatment, including the 1-month and 3-month follow-up visits. Clinical and histological improvements of the treated facial areas were observed for all of the parameters that were evaluated, which included: laxity grade, wrinkles, acne scars, pore appearance, skin elasticity, and pigmentation. At the post-treatment follow-ups, a GAI score of 3 was recorded for >90% of the subjects, indicating that moderate visual improvement in the facial areas that were treated was observed, but dramatic differences in wrinkles and elastosis were not.

The treatments resulted in RF thermal zones within the papillary and reticular dermis. There were no serious complications or adverse events such as burning, scarring, hemorrhage, or infection during the treatments or at post-treatment follow-ups. In the moderate RF energy group (pick power: ≥245 V, pulses: 5 to 30 ms), transient swelling, erythema, and ecchymosis were observed. In the low RF energy group (pick power: 180 V, pulses: 5 to 25 ms), itching, erythema, and skin pins marks that remained for up to 72 hours were reported. All events resolved without sequelae.

DISCUSSION AND CONLCUSION

Skin laxity and deep facial wrinkles are typical signs of skin aging, while dyschromia, elastosis, fine wrinkles, telangiectasia and keratoses are usually attributed to photo-aging. Post acne scars are especially problematic for individuals who suffer from life-long acne. Each of these types of skin conditions is common among both men and women of all ages. The demand for non-invasive facial treatment approaches has increased dramatically as it affords patients with advantages such as marked cosmetic improvements, minimal risks, and rapid recovery periods, but in order to achieve such results safely and consistently it is important that factors such as the degree of ablation and coagulation of the skin can be controlled through the use of the RF device. The present study demonstrates that a nano-fractional RF device is a minimally invasive treatment approach that offers efficient standardization. Furthermore, the current findings indicate that the Venus Viva system resulted in sufficient ablation and coagulation that initiated skin resurfacing in the treated areas. These results also provide implications for marked changes in texture, fine lines, and wrinkles in addition to visual improvement with treatment periods that are longer than 4 weeks.

All 10 of the subjects that participated in this pilot study reported a fair level of comfort during the treatments and no serious adverse events or complications were recorded throughout the duration of the study. Minimal side effects that developed as a result of the treatment resolved without sequelae. Furthermore, subjects with various skin types were treated with varying degrees of RF output energy (maximum of 280 V) and pulse times (max. of 25 ms) and no serious adverse events were observed or reported. These results support the safety of nano-fractional RF scan treatments.

In addition, the GAI scale as well as the subject improvement questionnaire ratings showed that the majority of the patients experienced moderate improvements in all of the parameters that were measured, indicating that the RF treatments resulted in efficient ablation and skin resurfacing. Although some of the subjects reported that they were unsure regarding whether improvements had occurred, none of the subjects reported being dissatisfied with the RF scan treatment results. Therefore, the clinical and histological improvements that were measured for the facial areas that were treated support the efficacy of nano-fractional RF treatment at

reducing the appearance of facial wrinkles, rhytides, and elastosis. Due to the positive clinical outcomes of nano-fractional RF scan devices as well as the minimal risks and side effects; this approach is becoming the gold standard treatment method for patients with skin laxity, deep facial wrinkles, photo-aging, and post acne scars.

LIMITATIONS

Although the results of nano-fractional RF scan treatments are promising, the long-term sustainability of reduced facial wrinkles and elastosis is currently unknown. Therefore, further investigation is required. Furthermore, the formation of areas of encrustation (< 0.5 mm) for 24-72 hours post-treatment must be discussed with patients prior to RF treatment. This is an essential part of skin resurfacing, but may be viewed as cosmetically disadvantageous for some patients as the use of make-up to conceal such formations must be avoided for at least 24 hours after each treatment. In addition, patients may experience noticeable or moderate improvement after RF treatment, but to date, the complete elimination of skin wrinkles and elastosis has not been achieved through this method.

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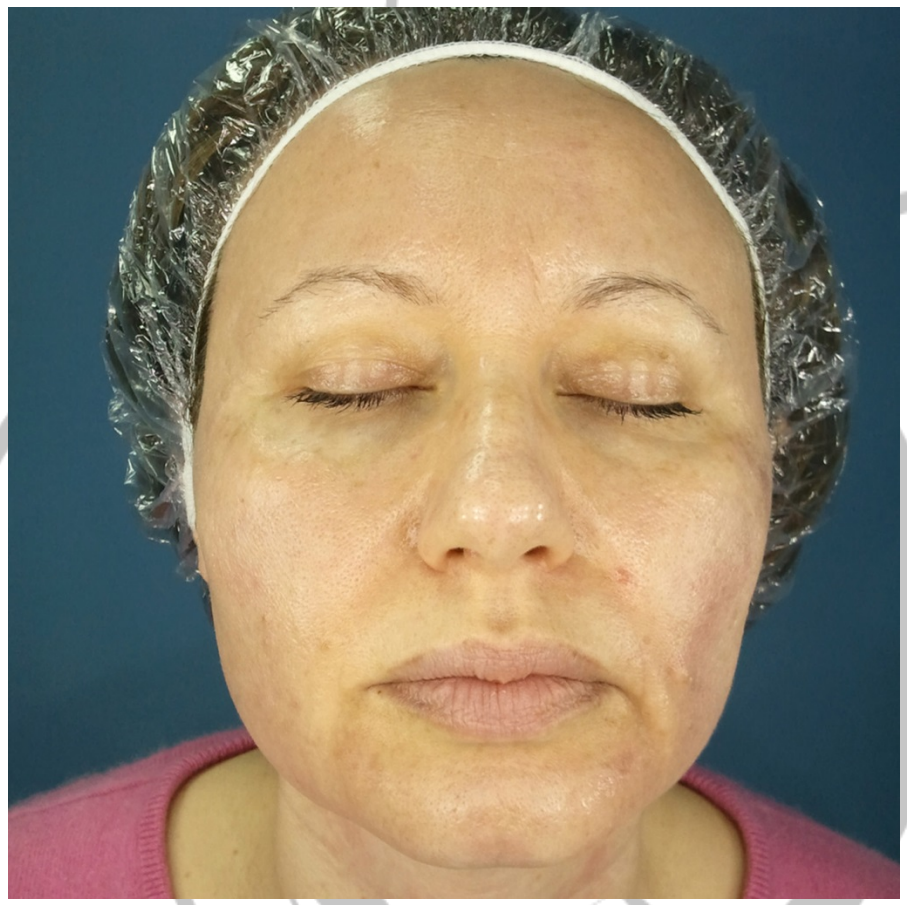

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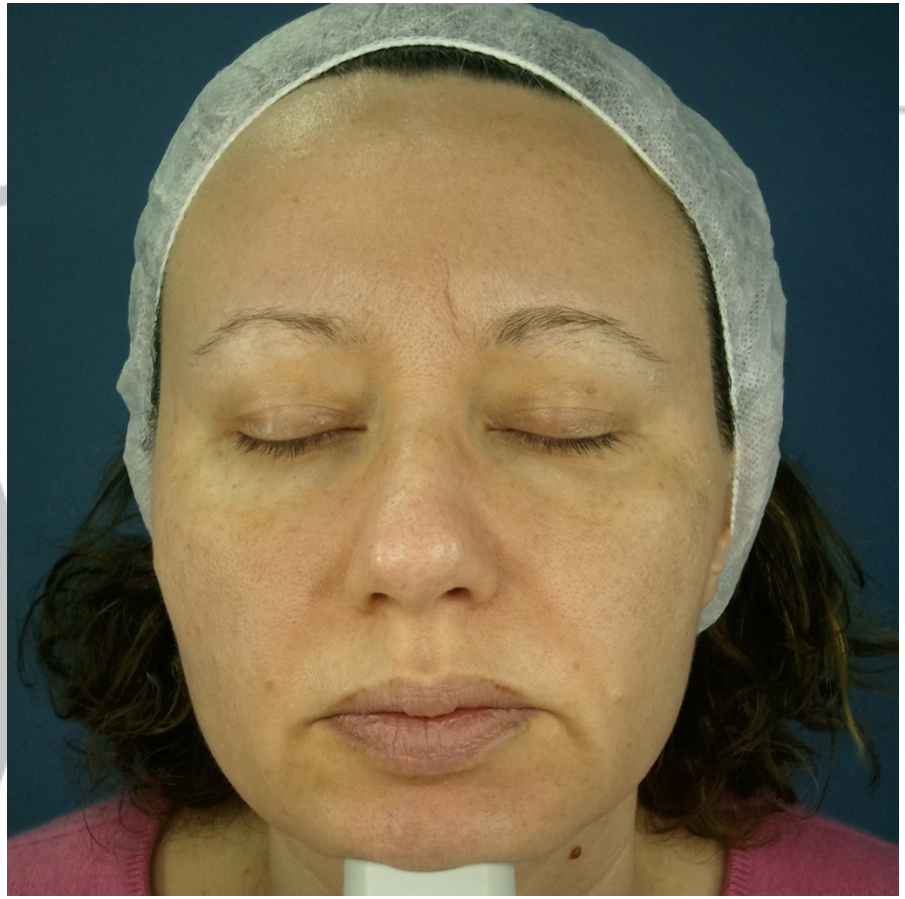

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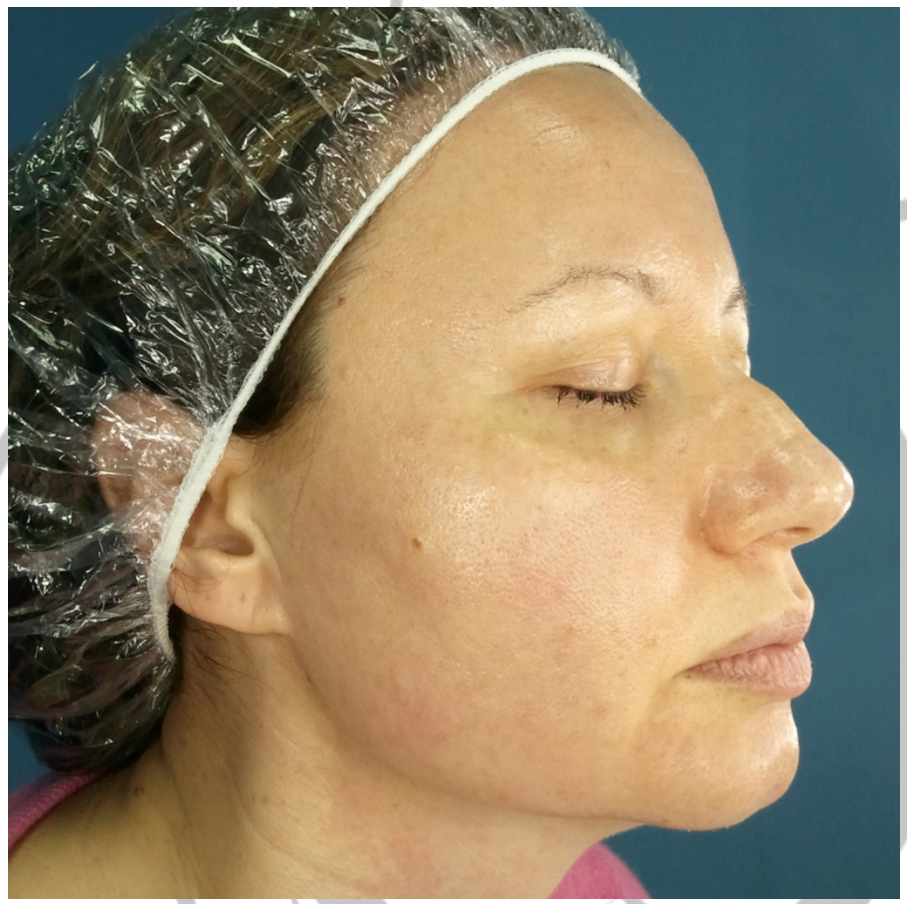

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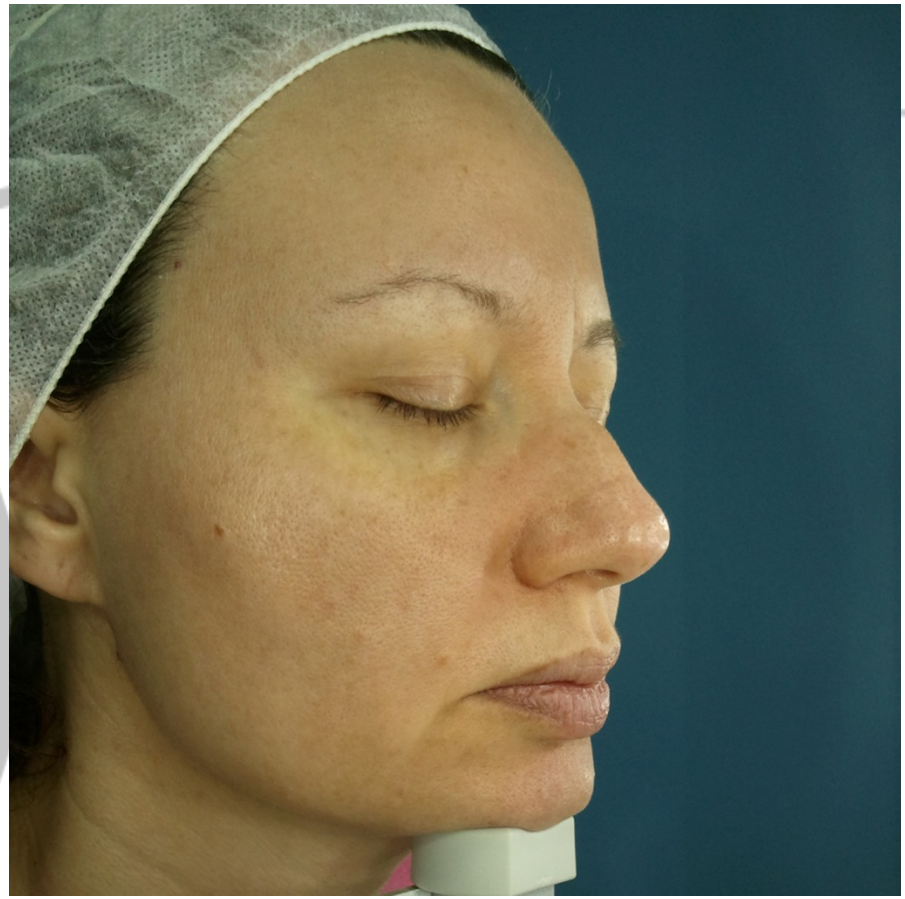

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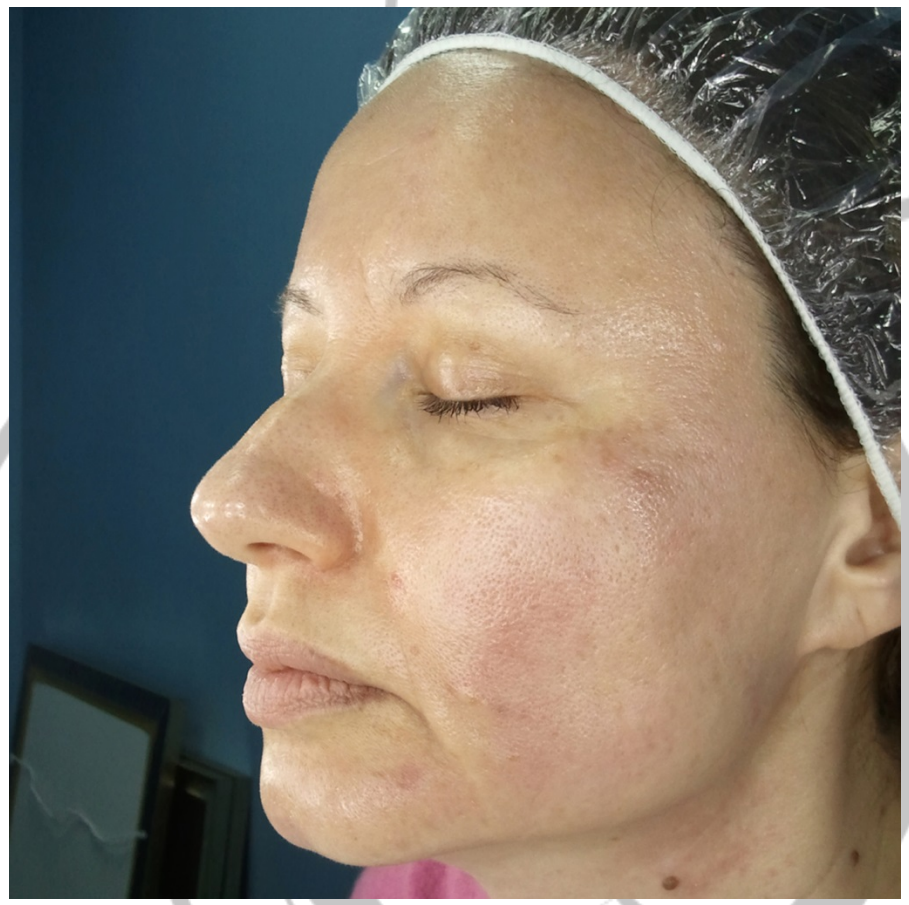

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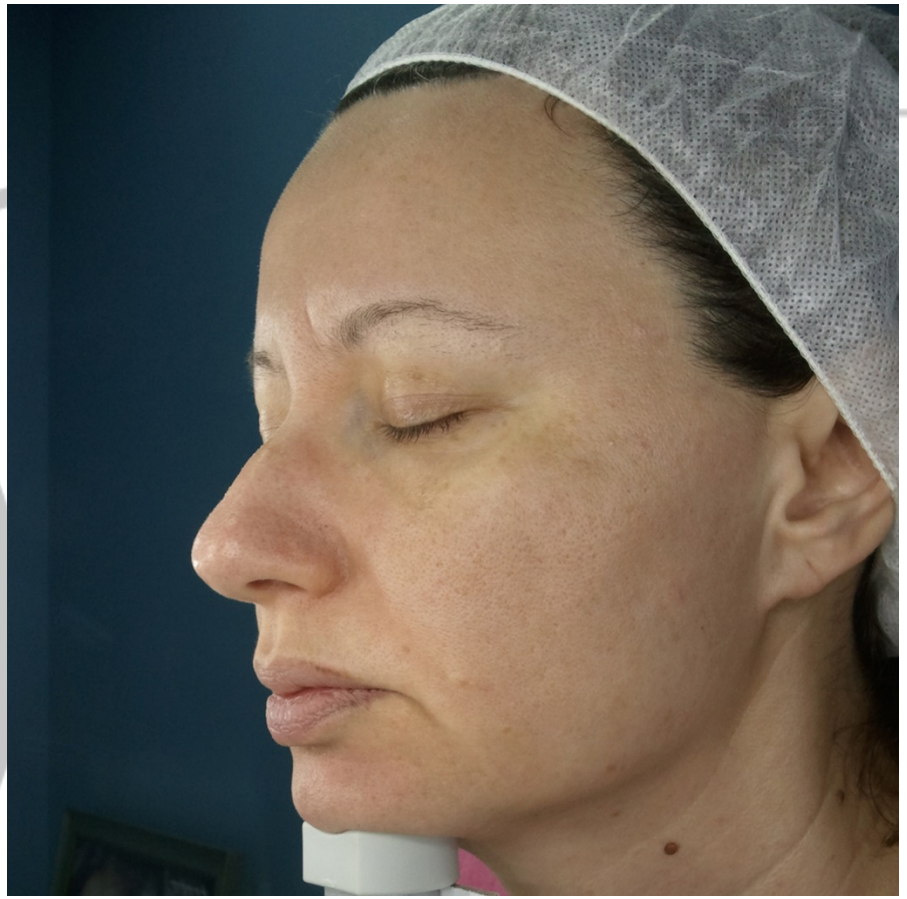

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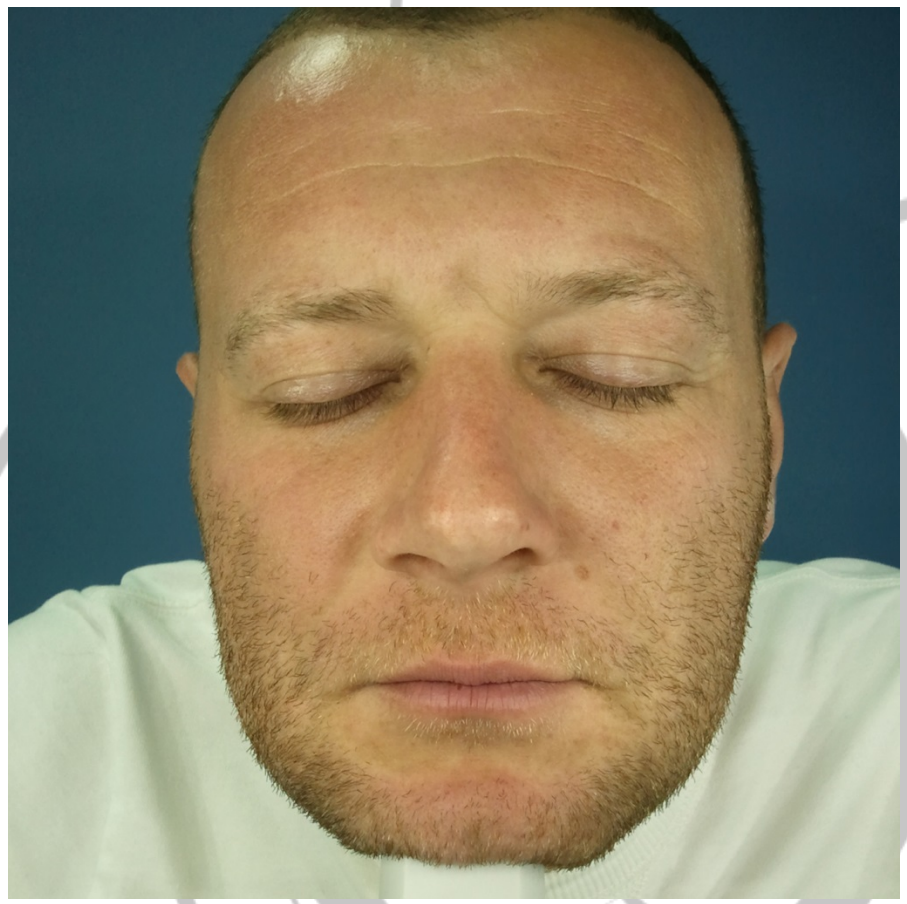

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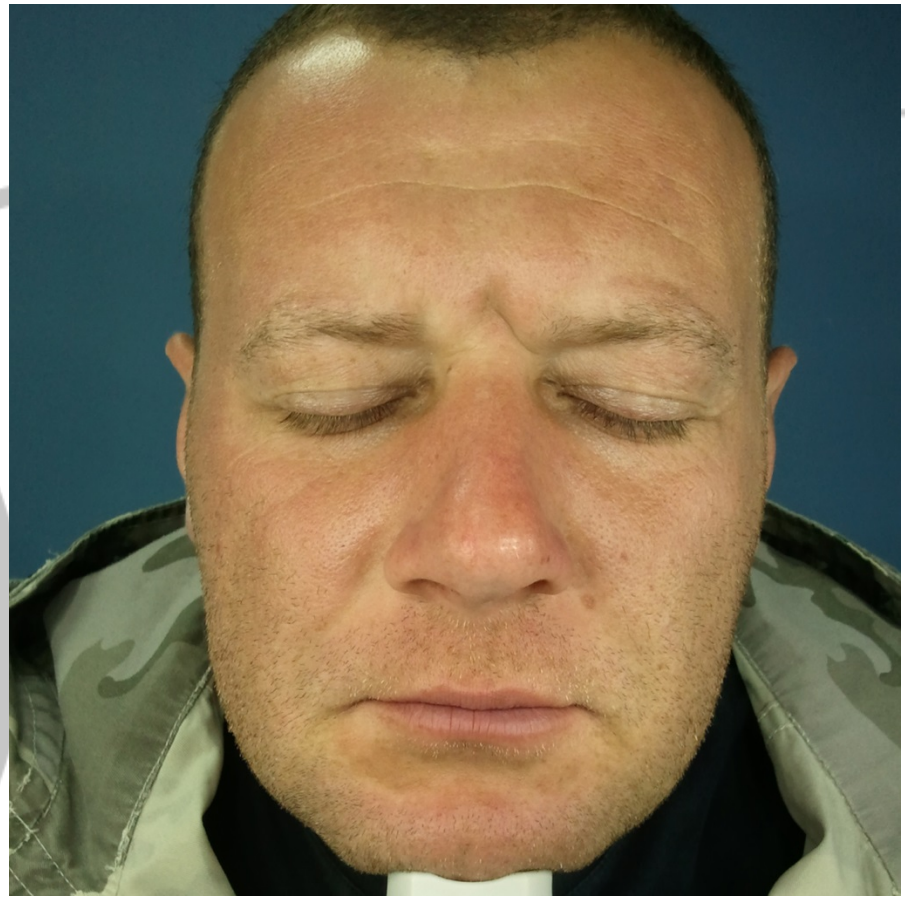

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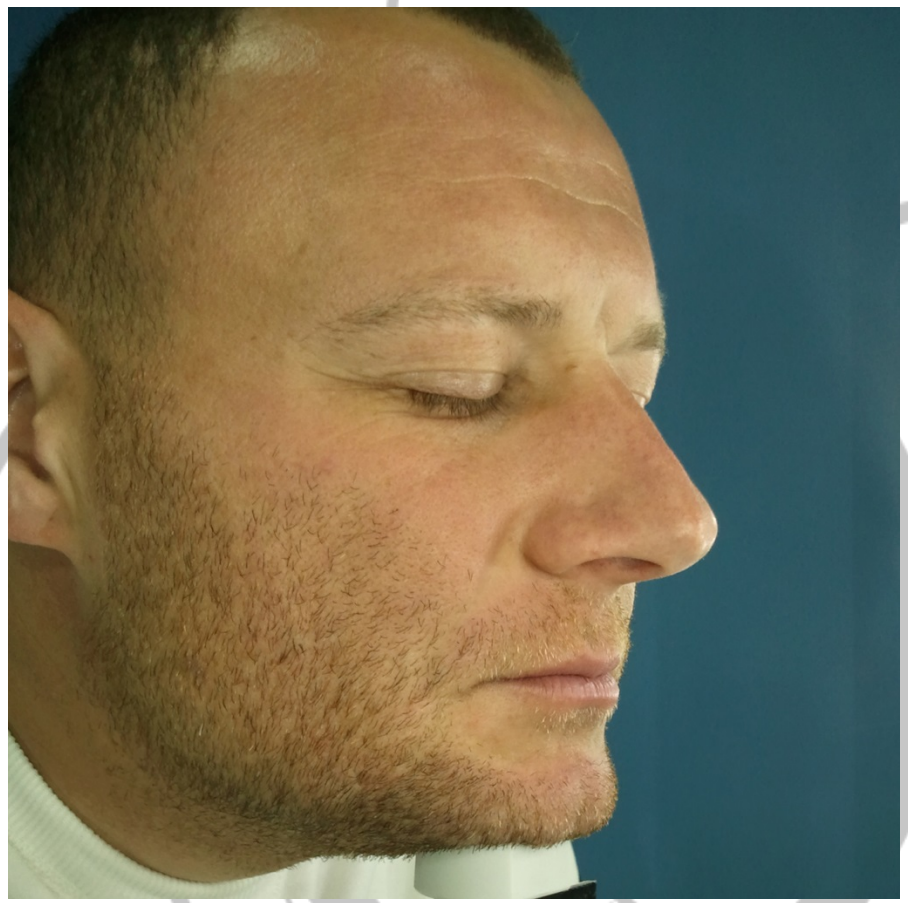

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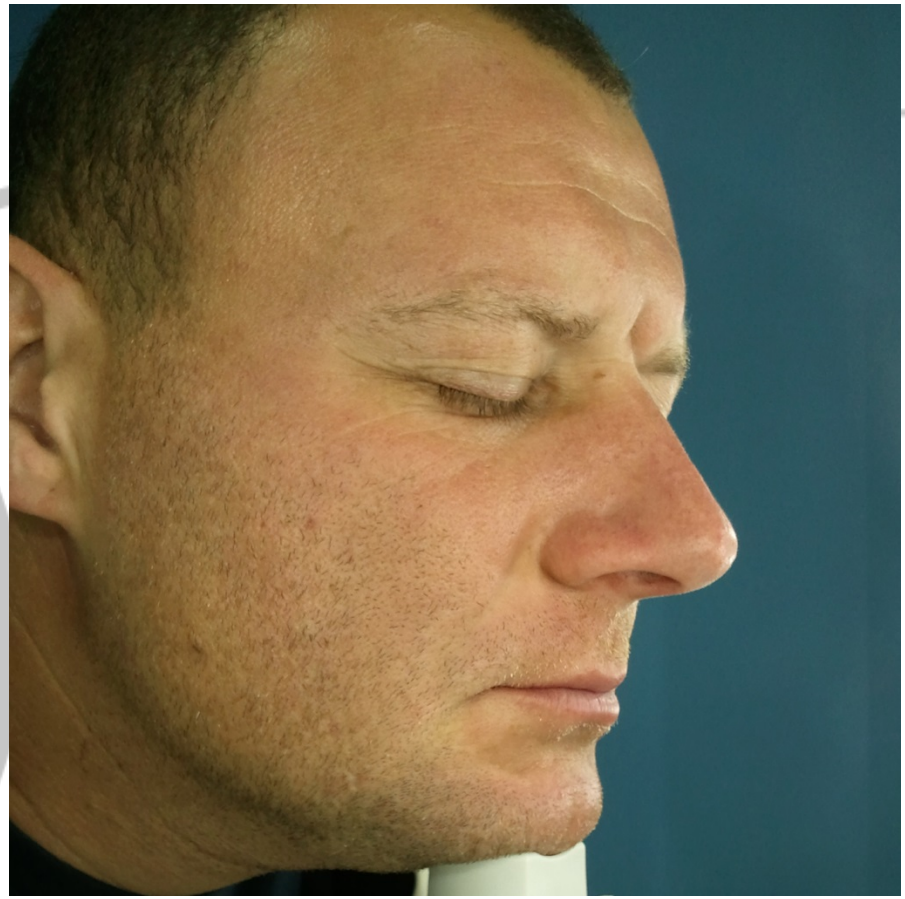

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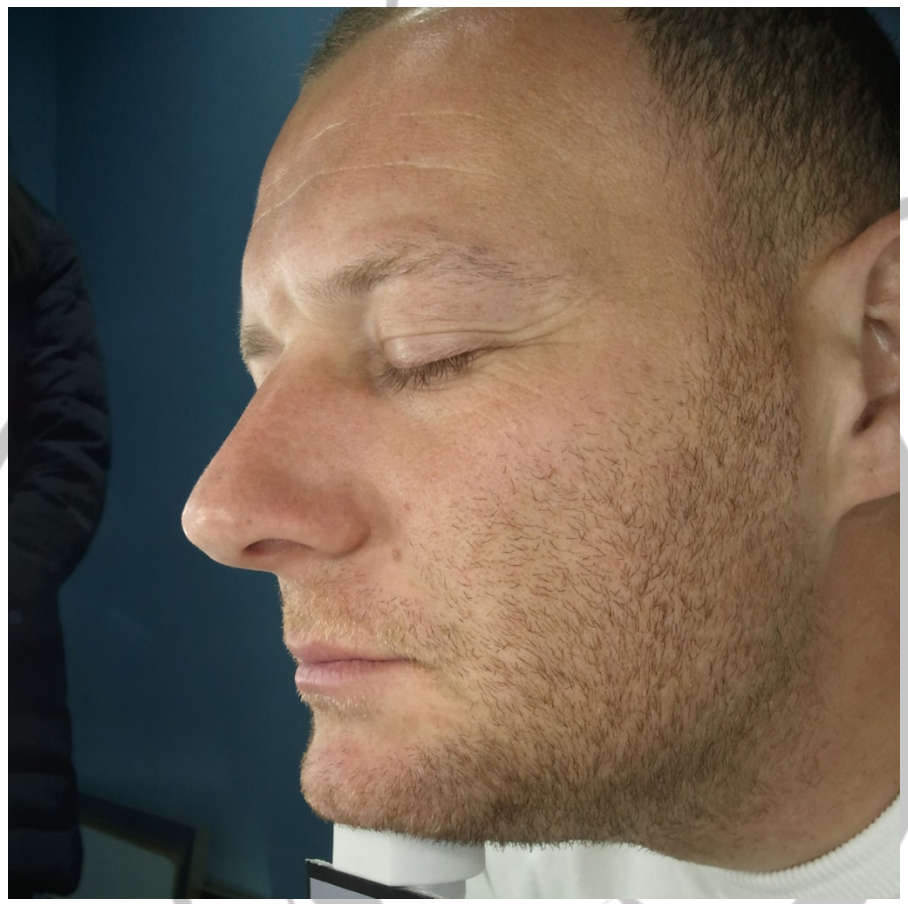

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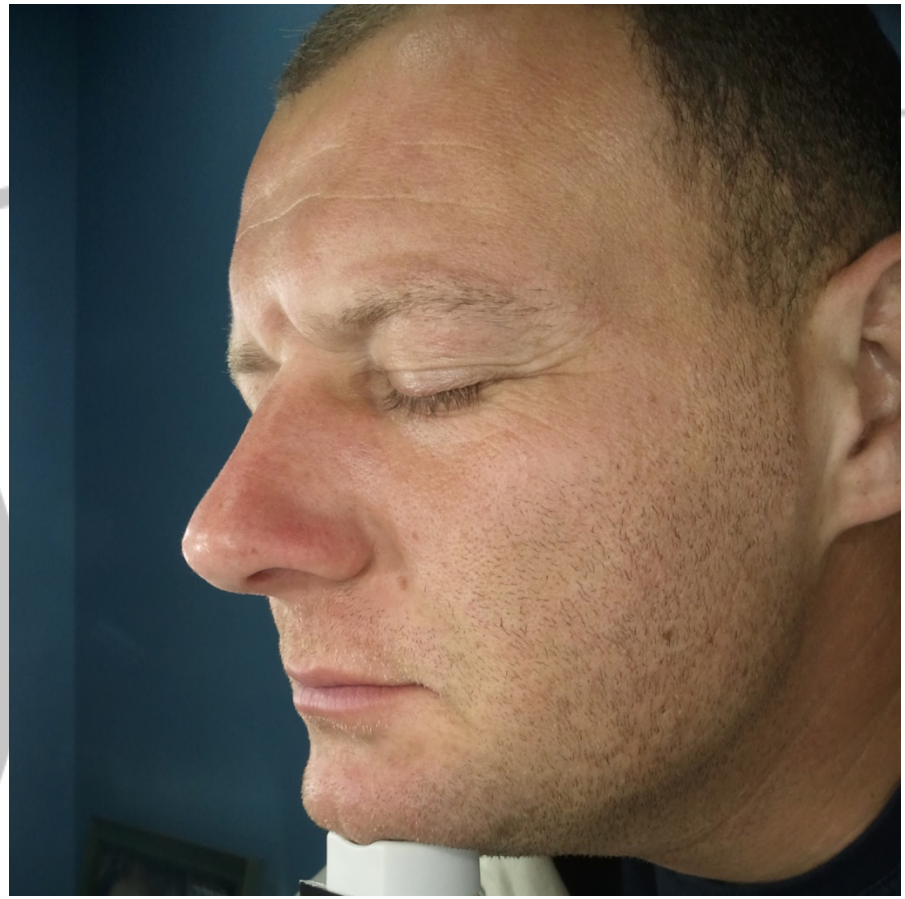

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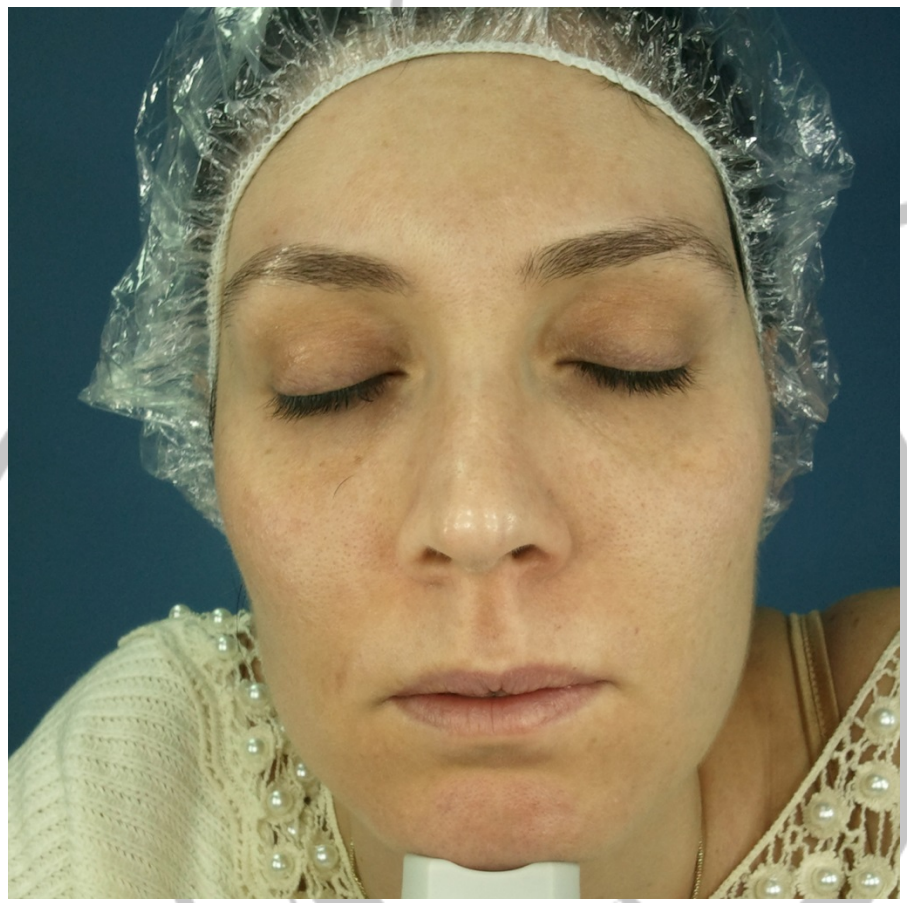

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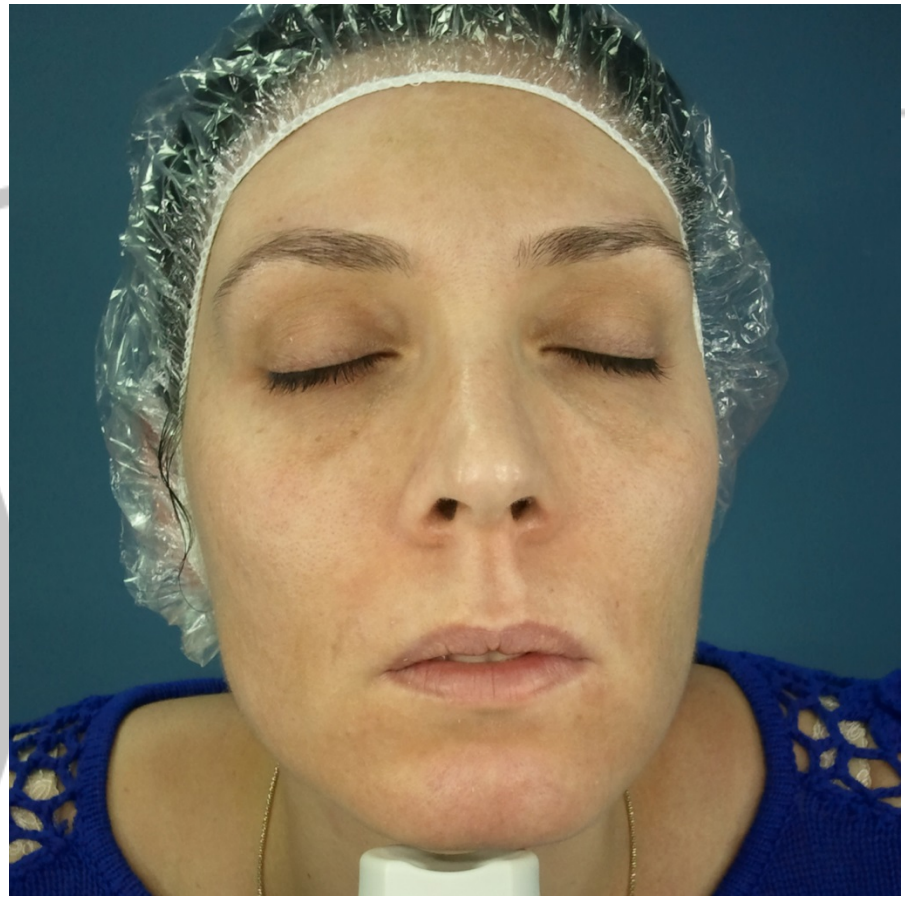

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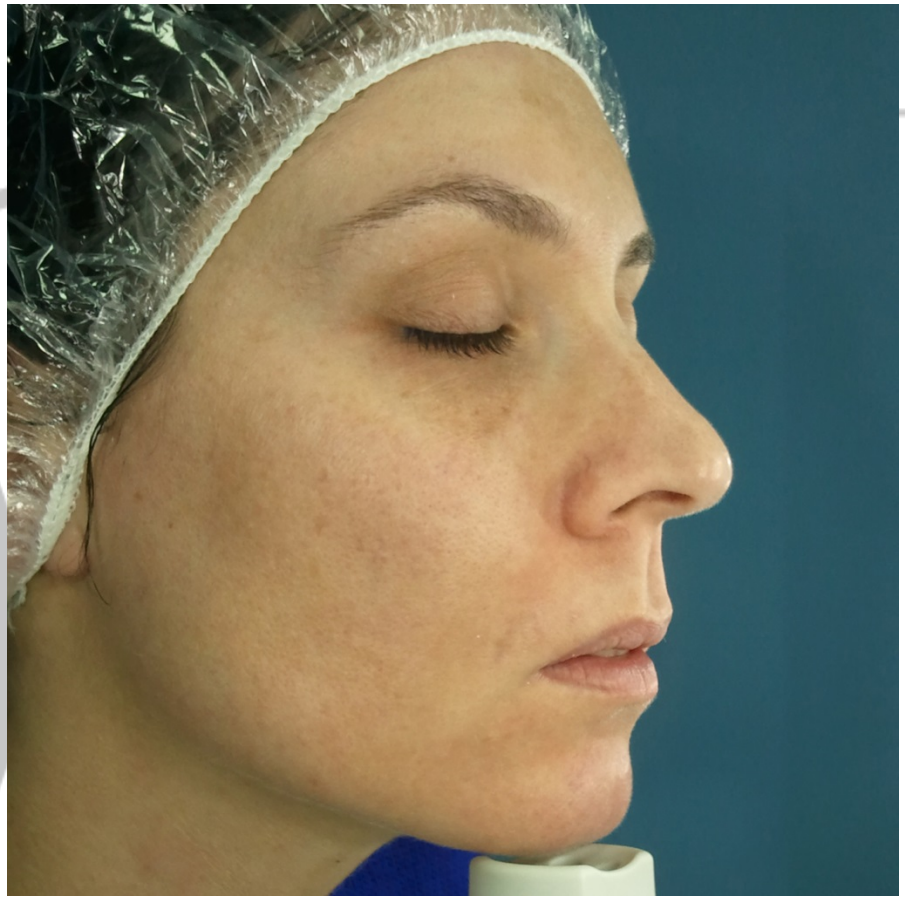

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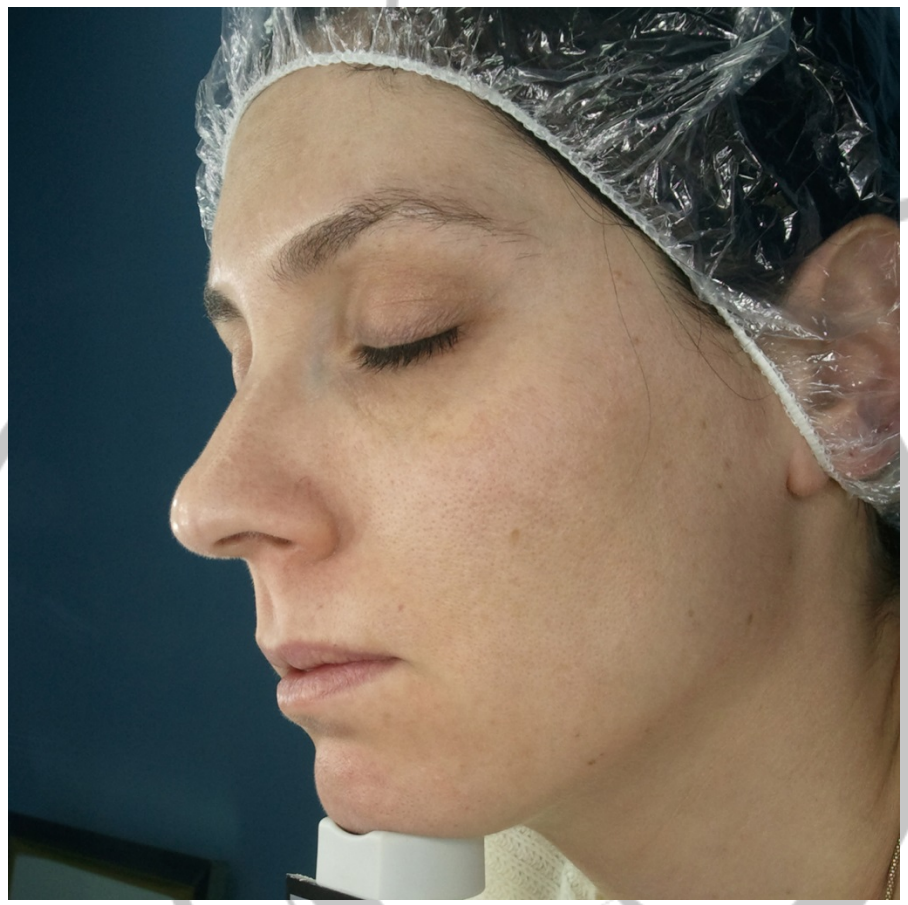

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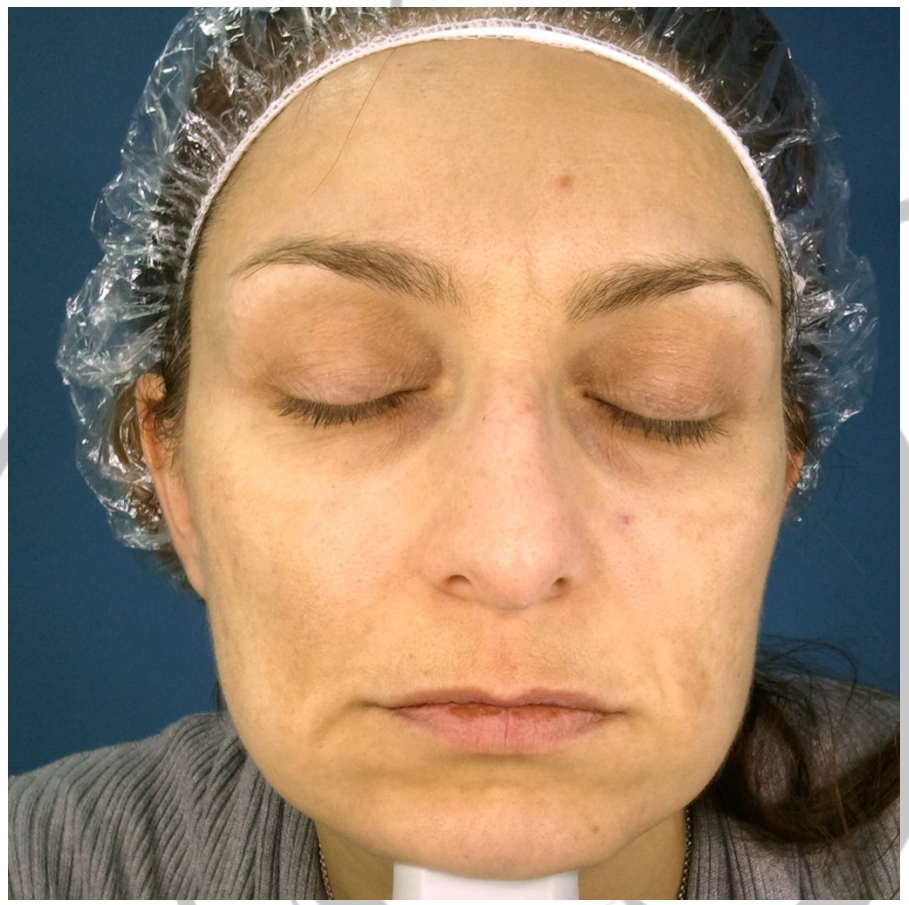

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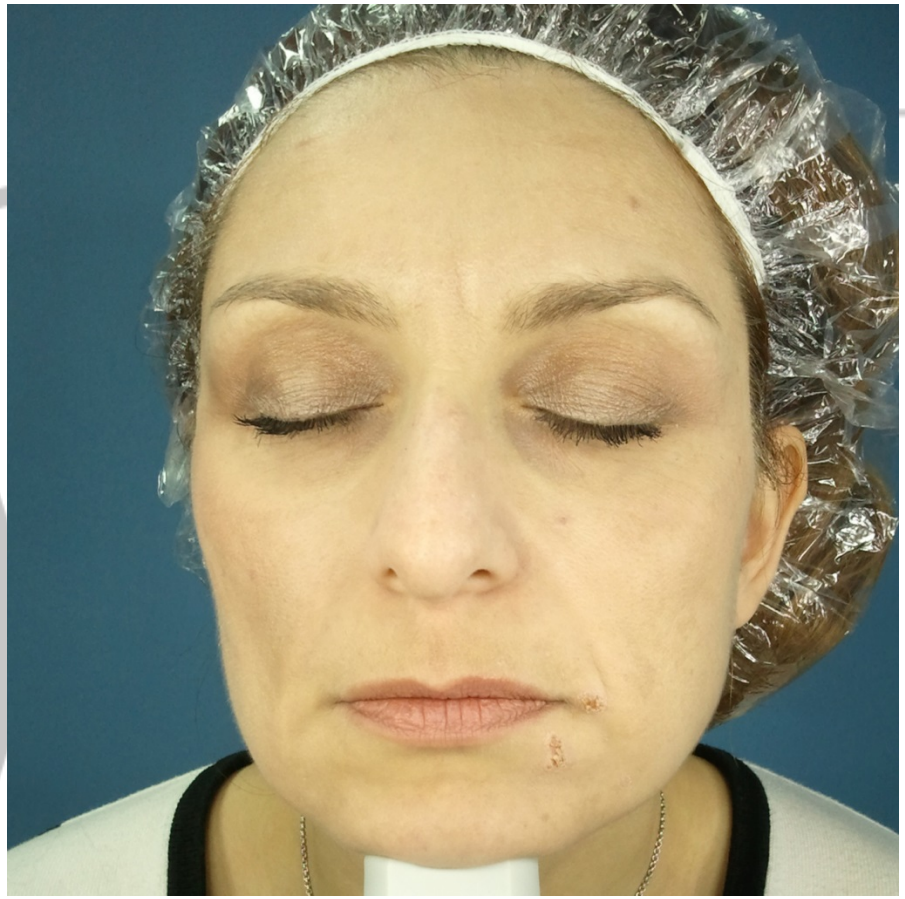

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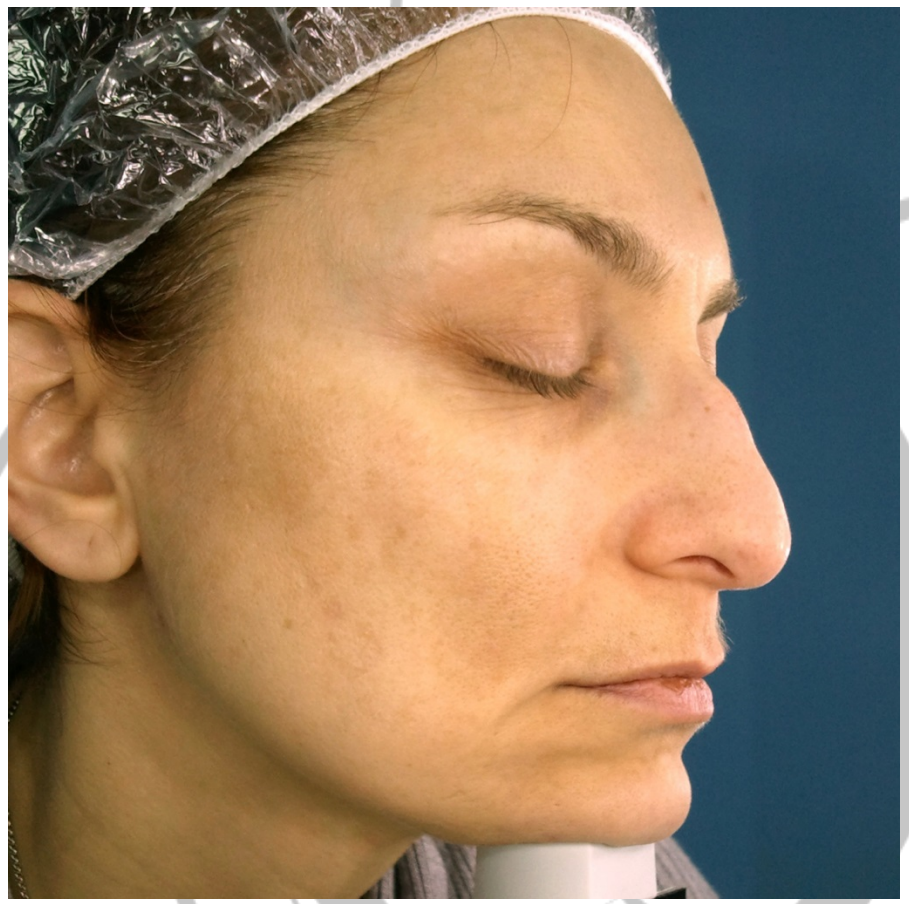

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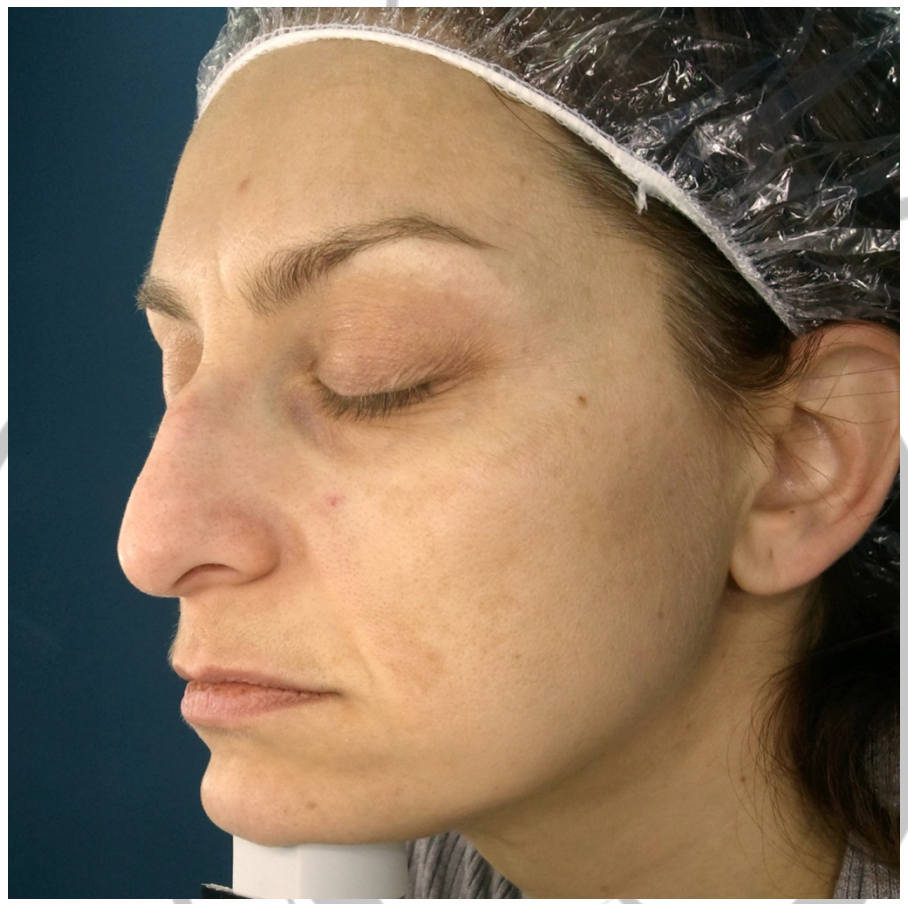

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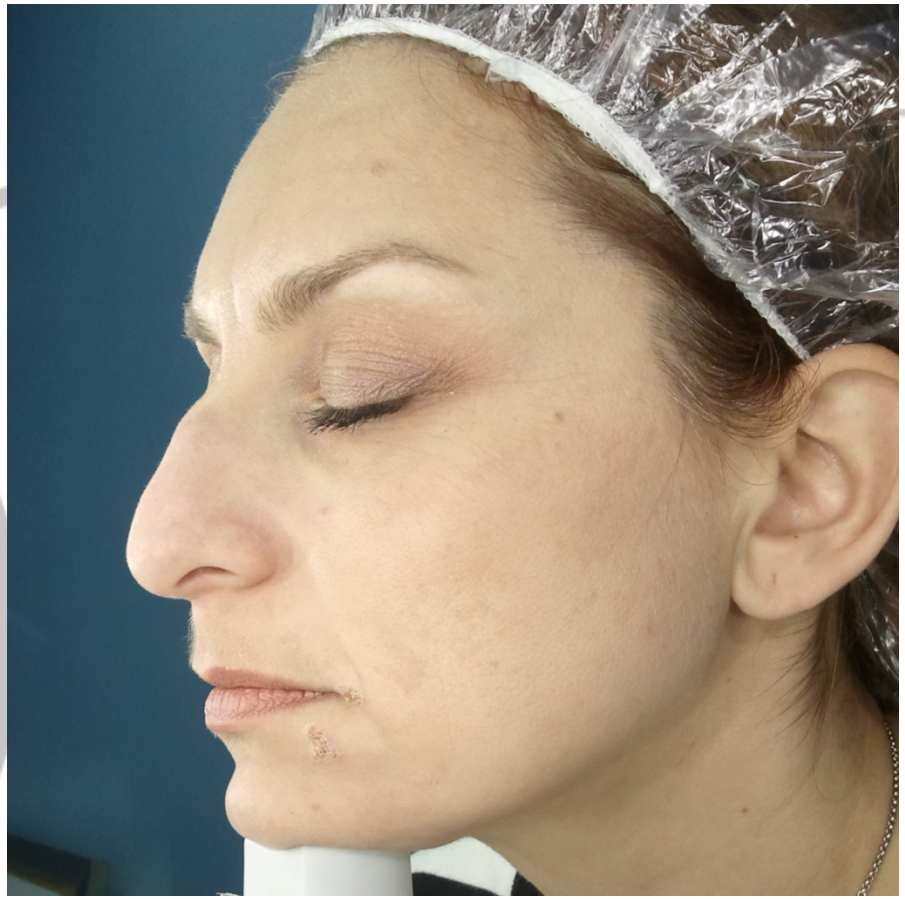

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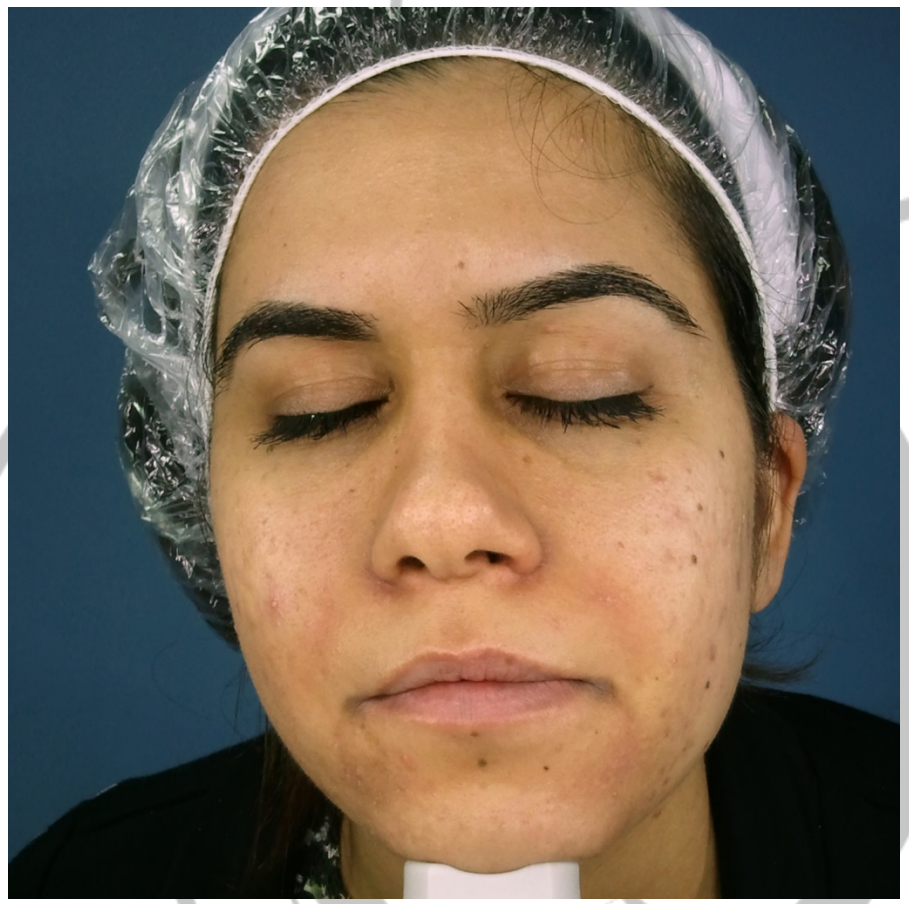

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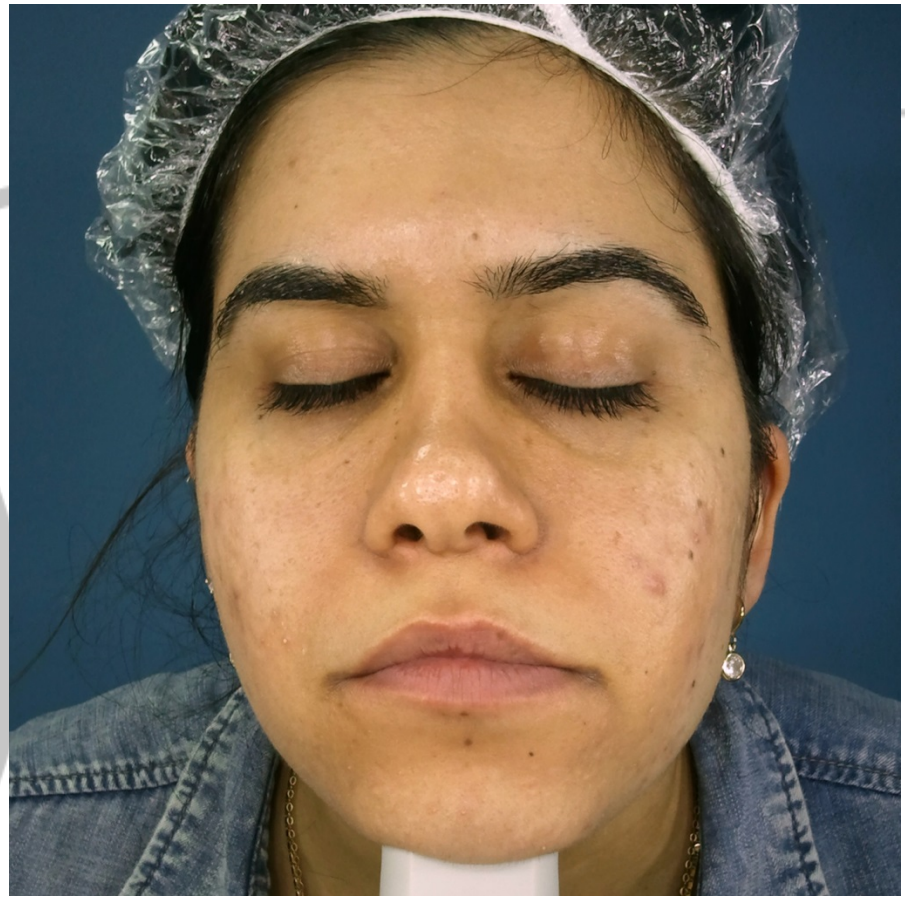

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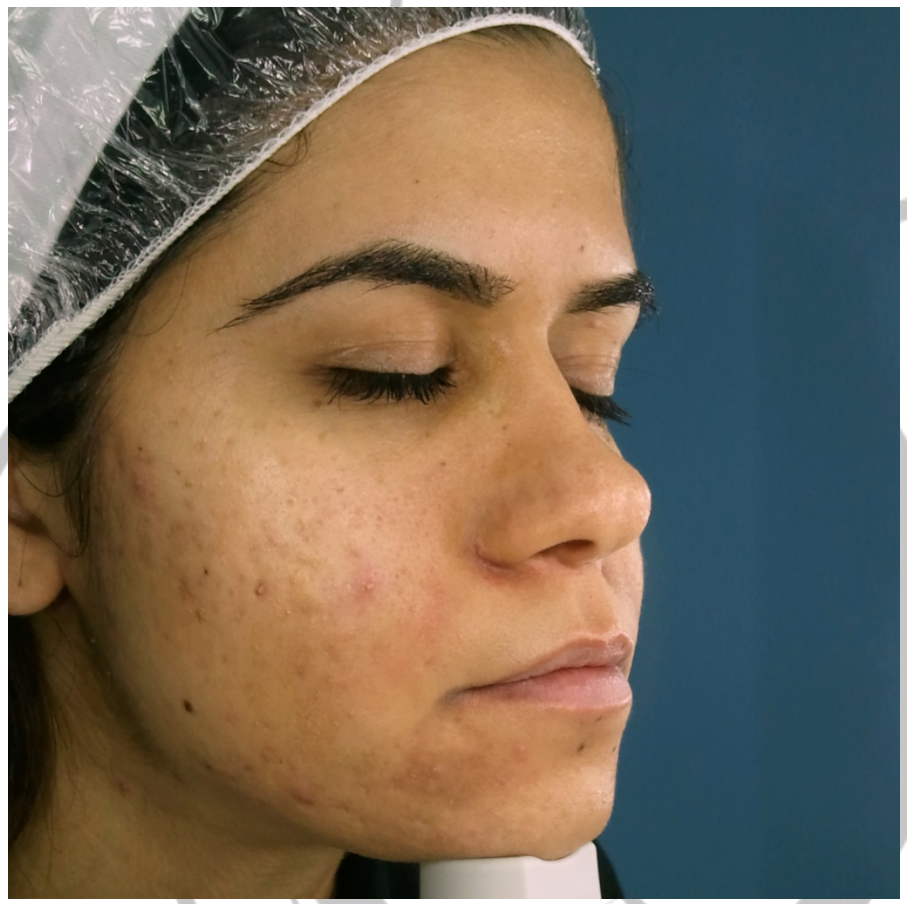

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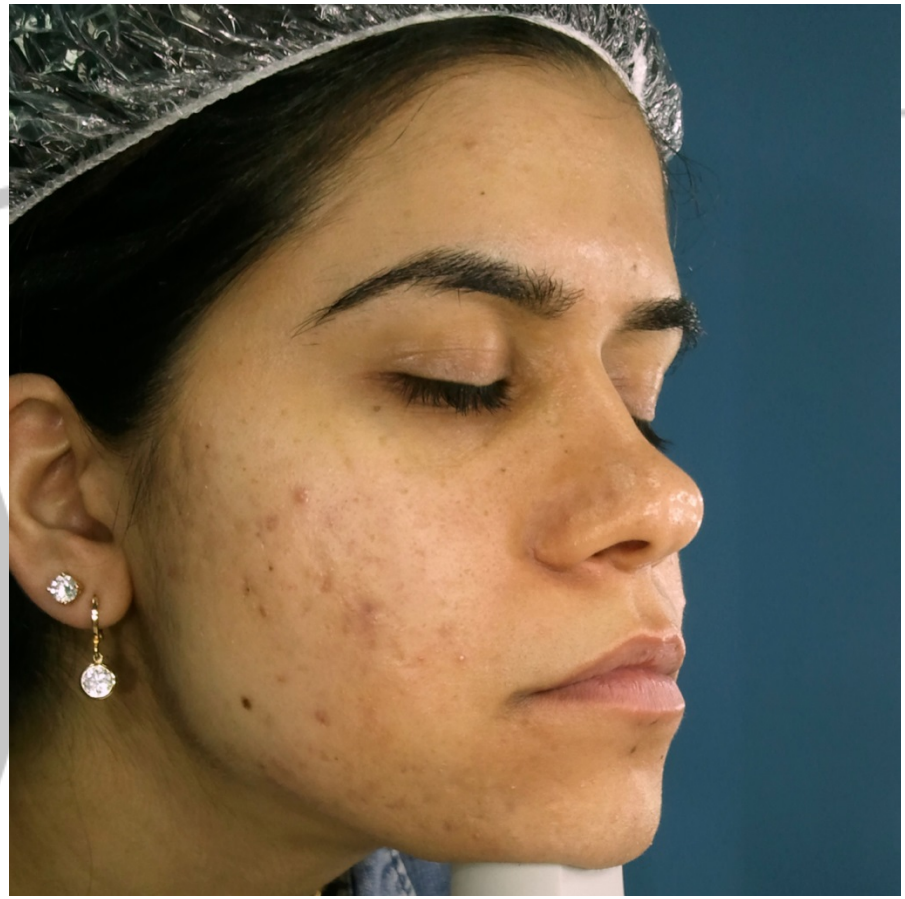

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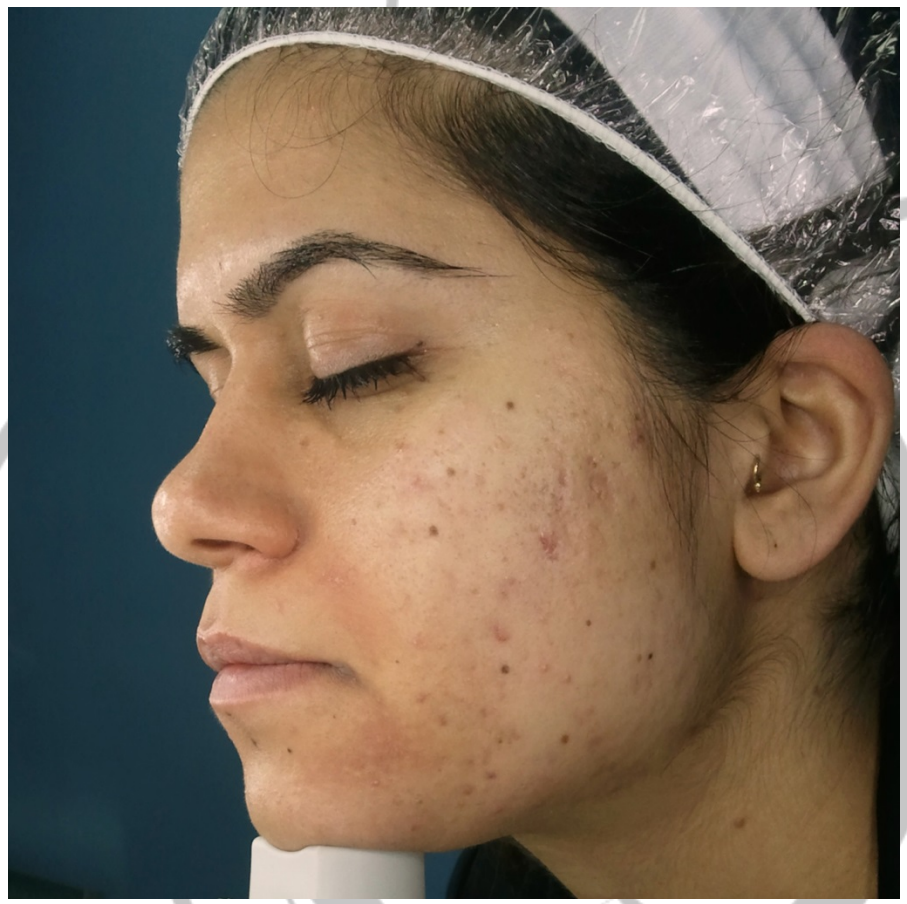

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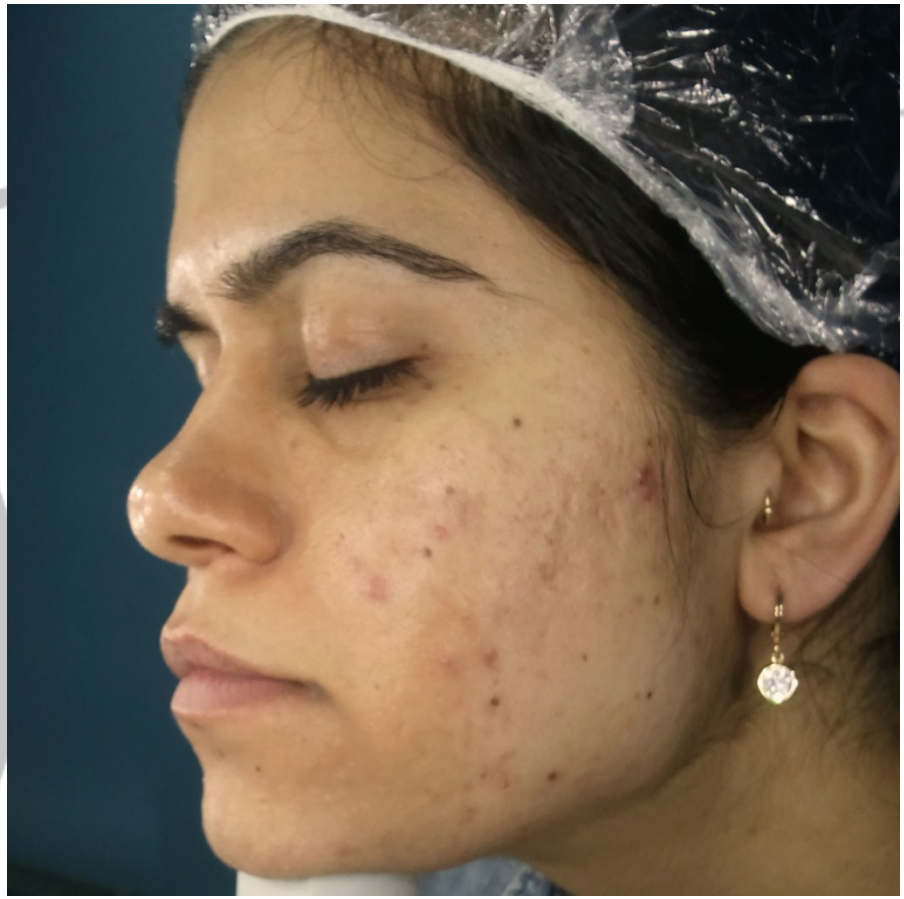

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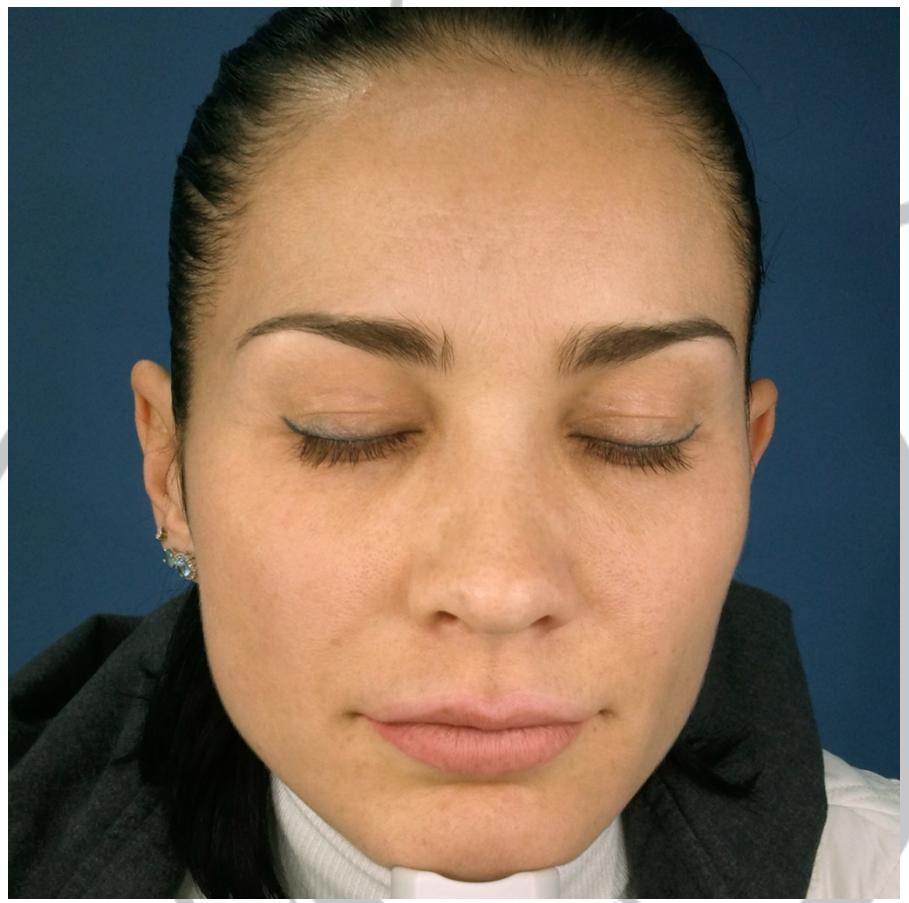

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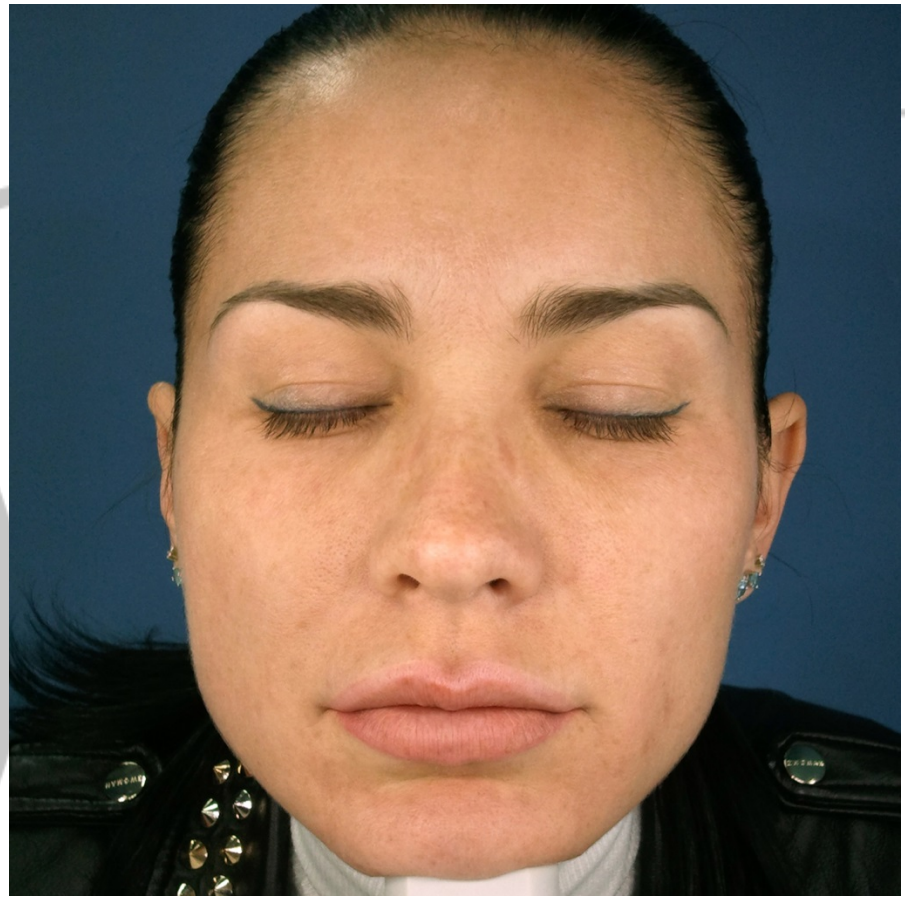

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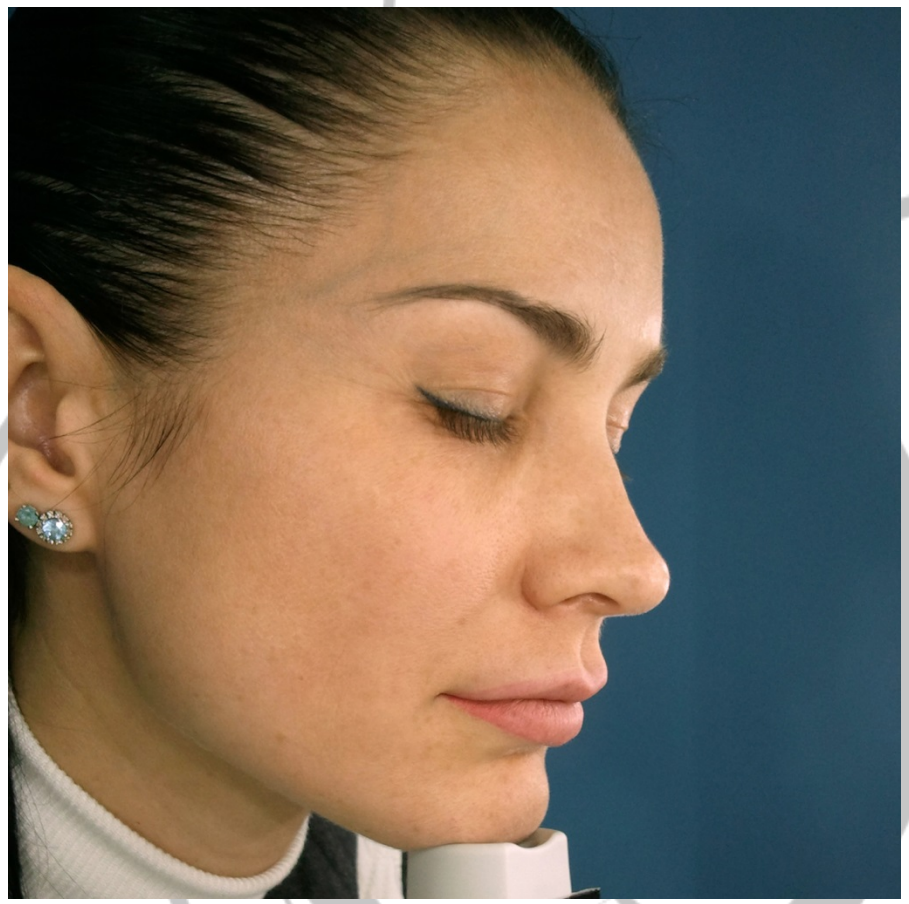

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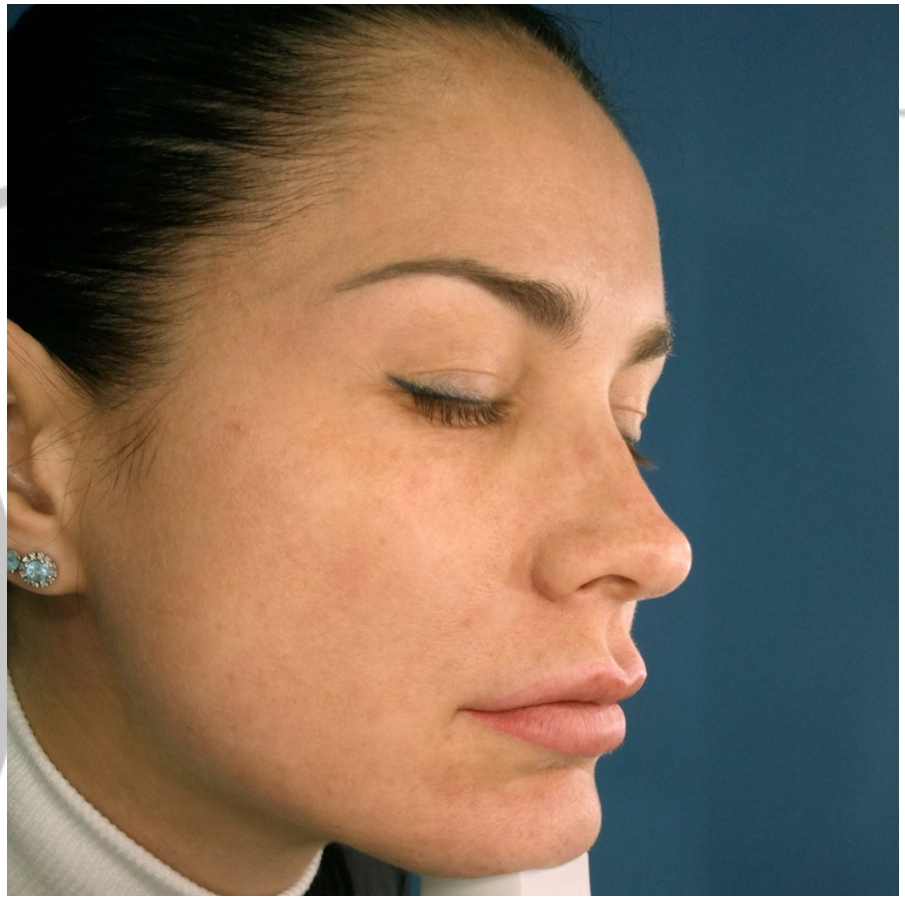

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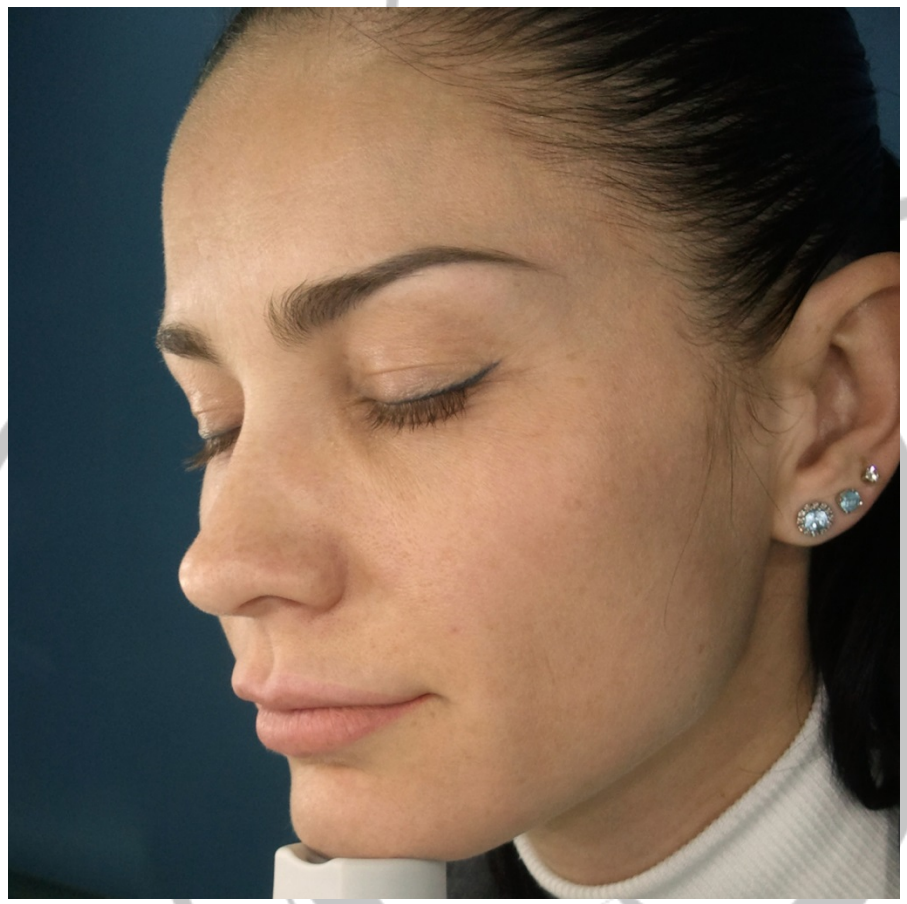

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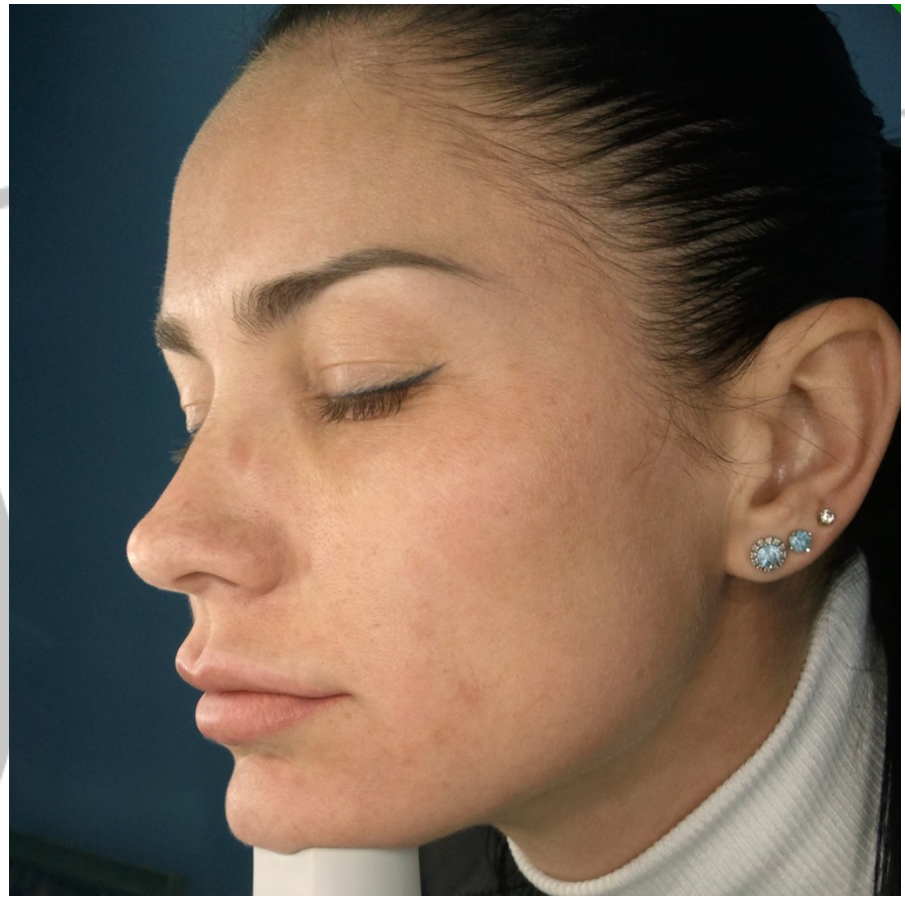

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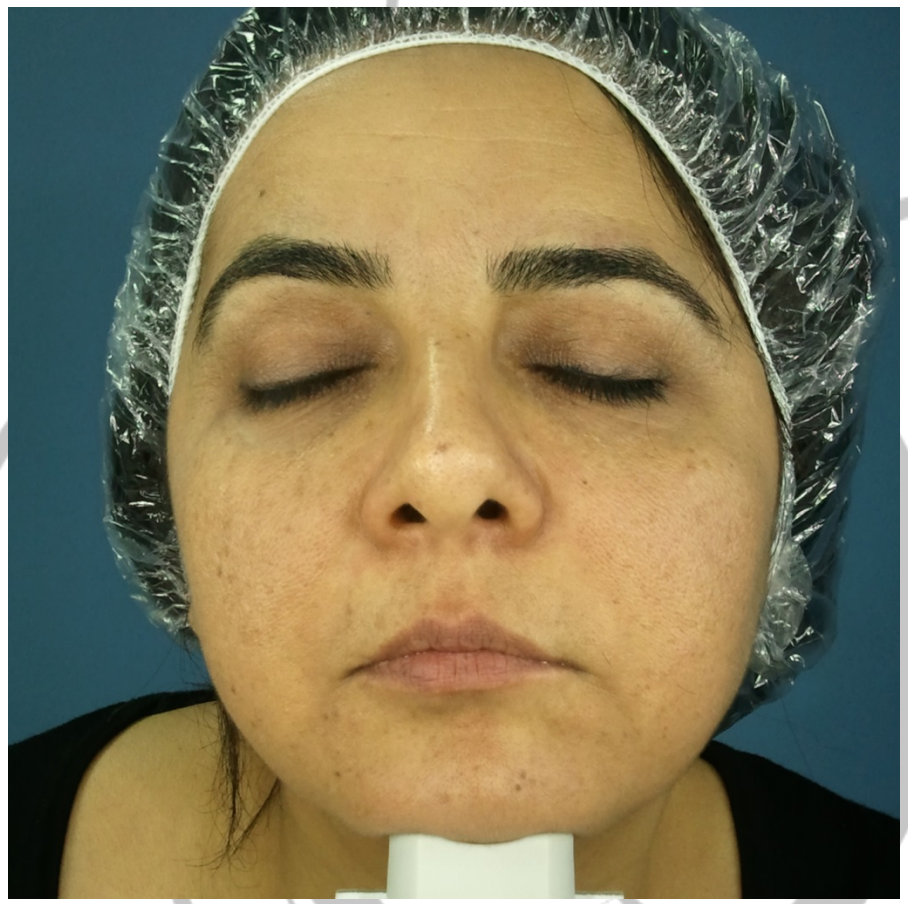

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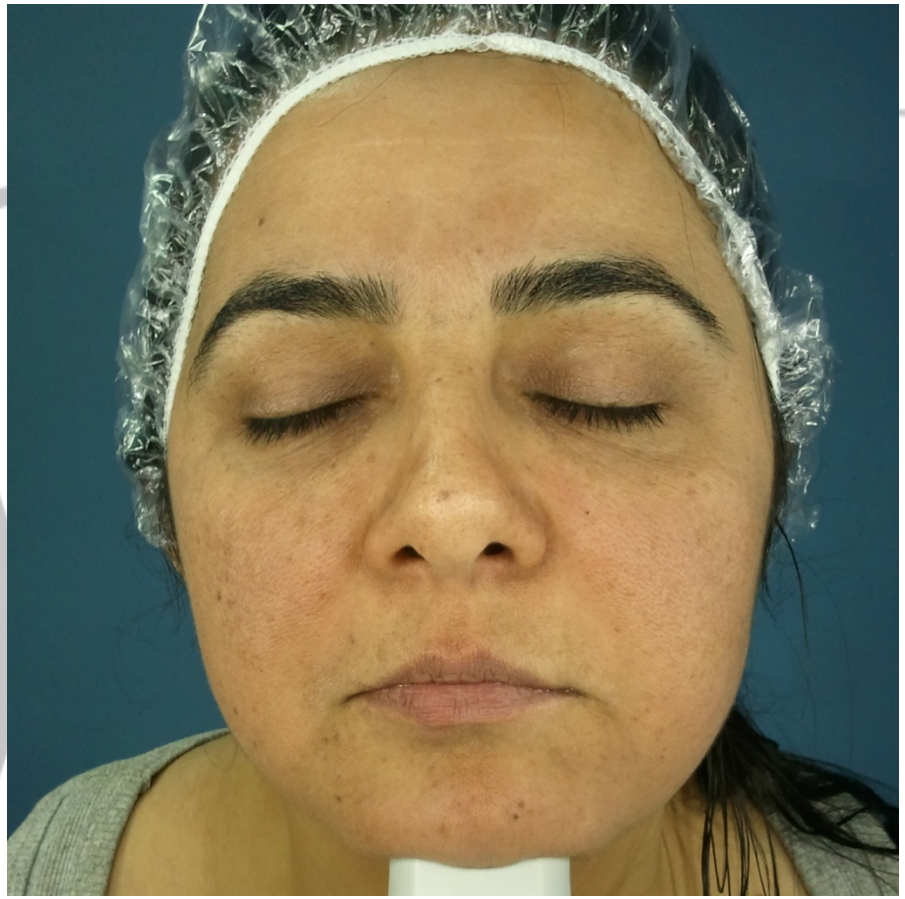

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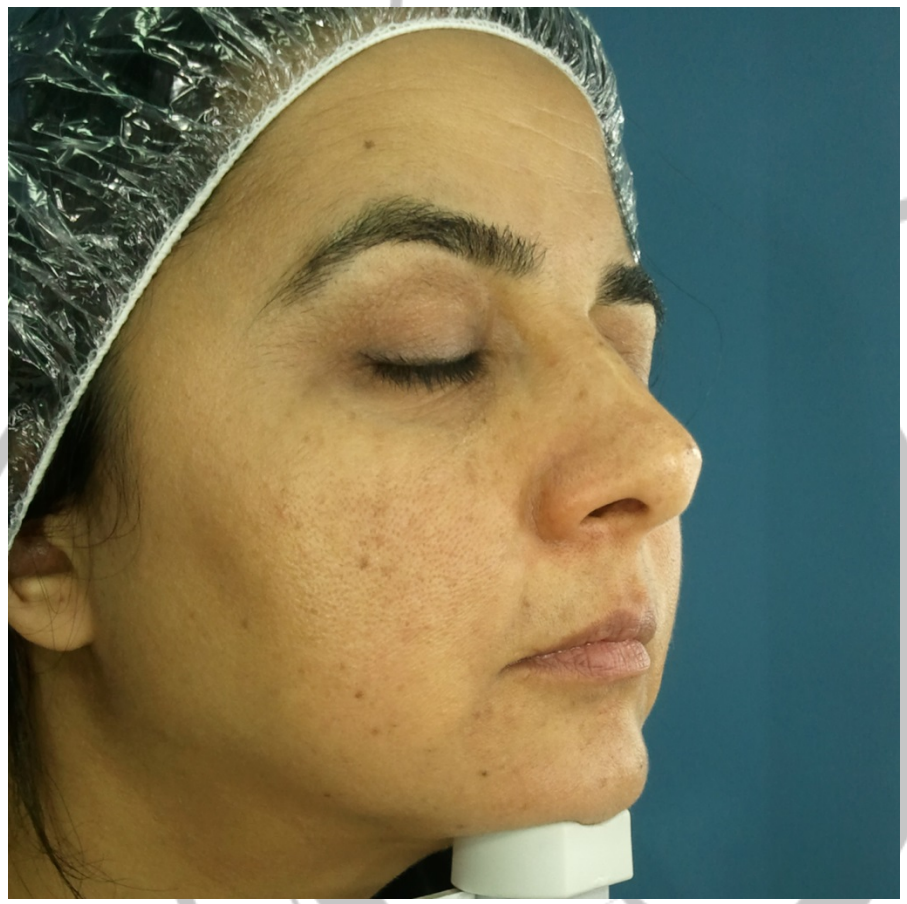

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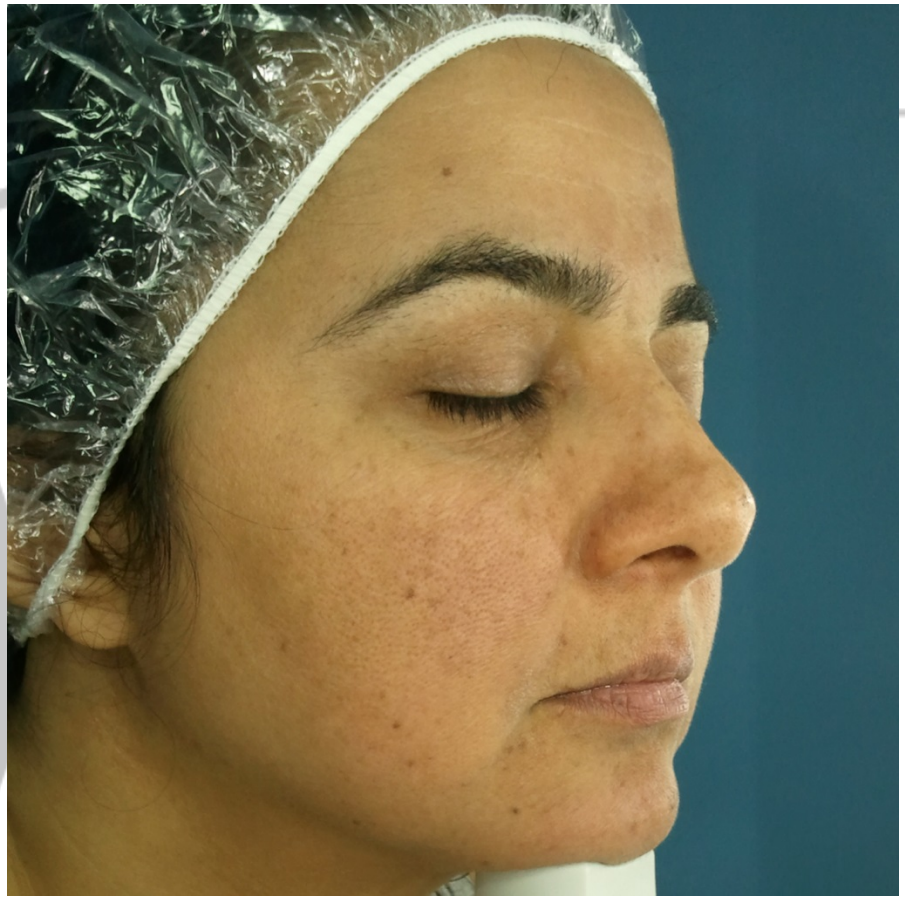

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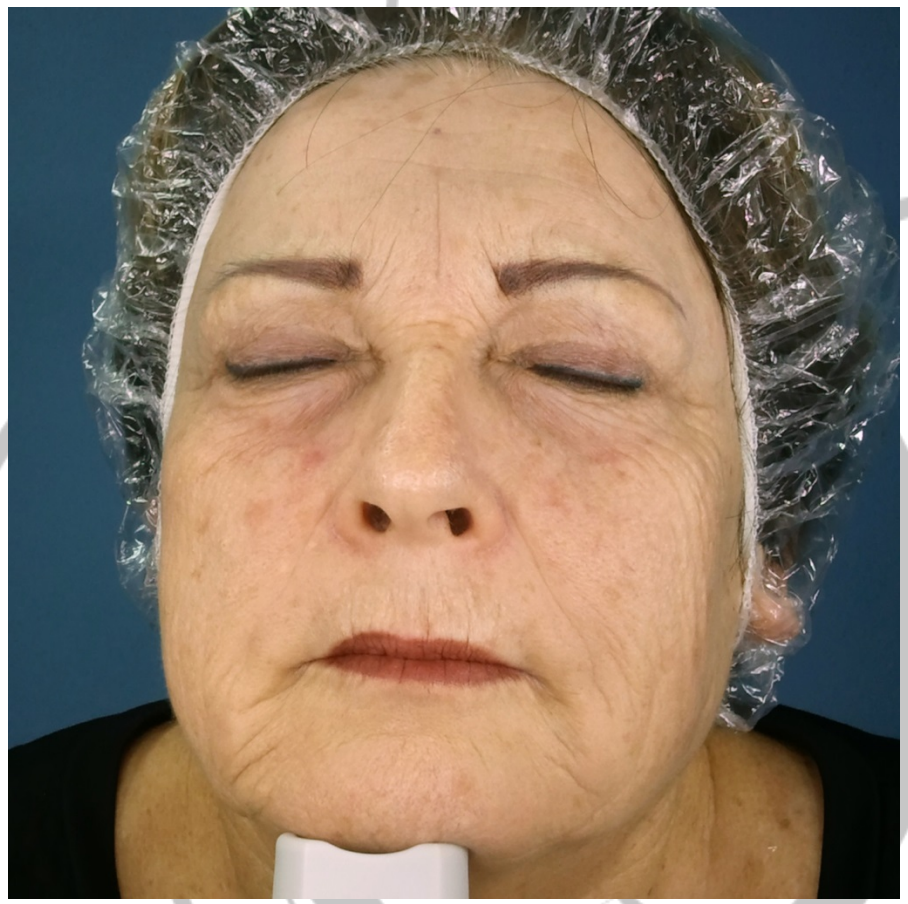

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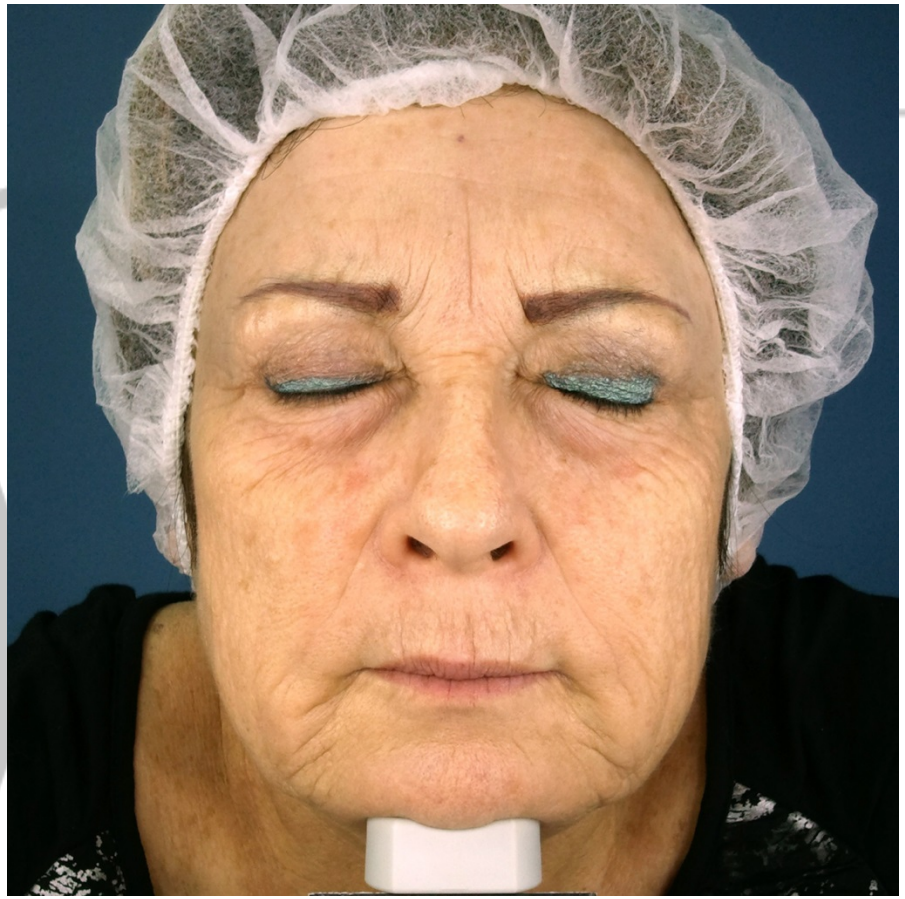

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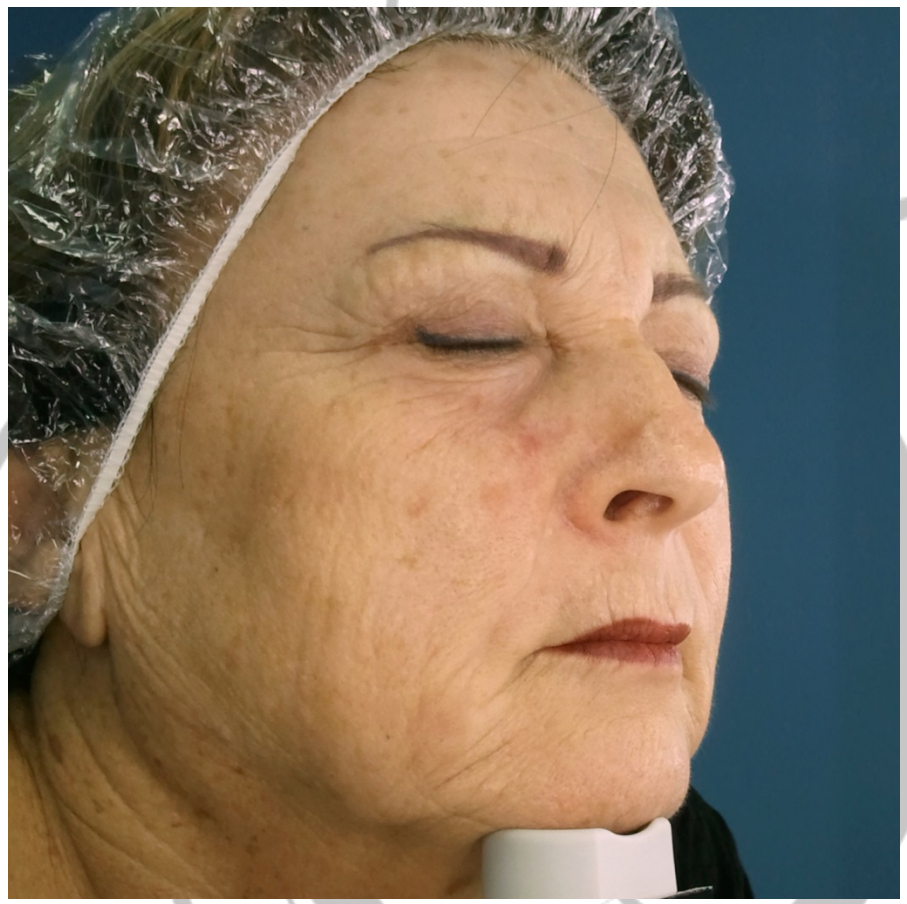

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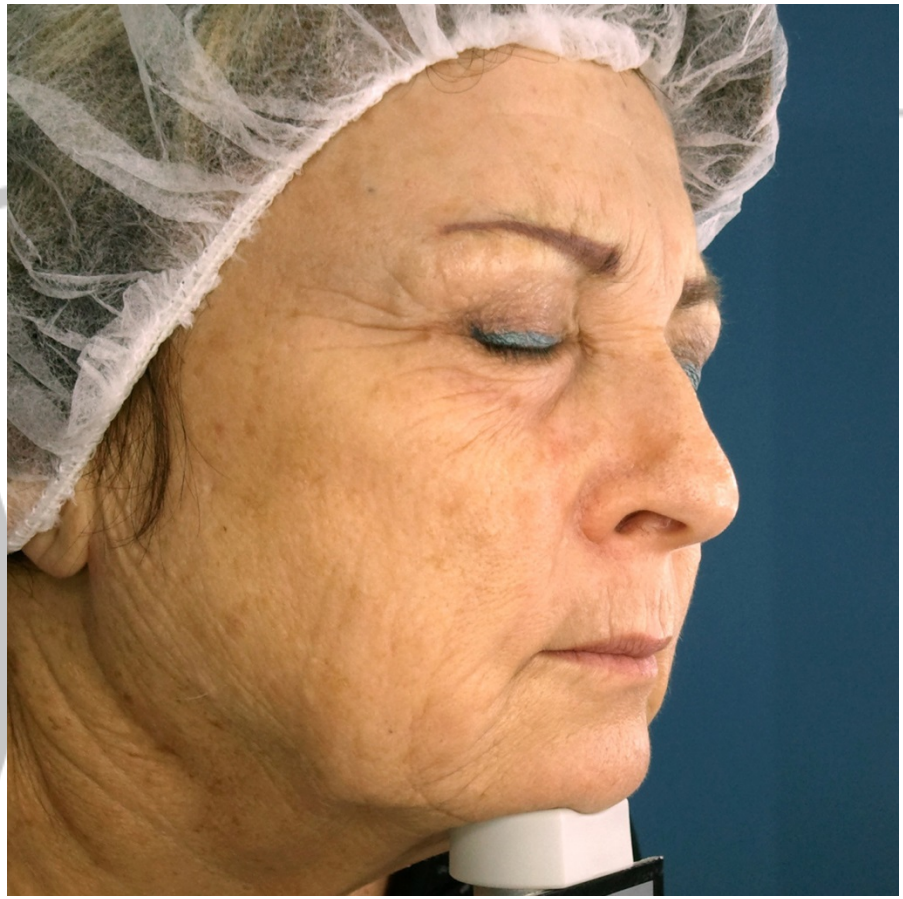

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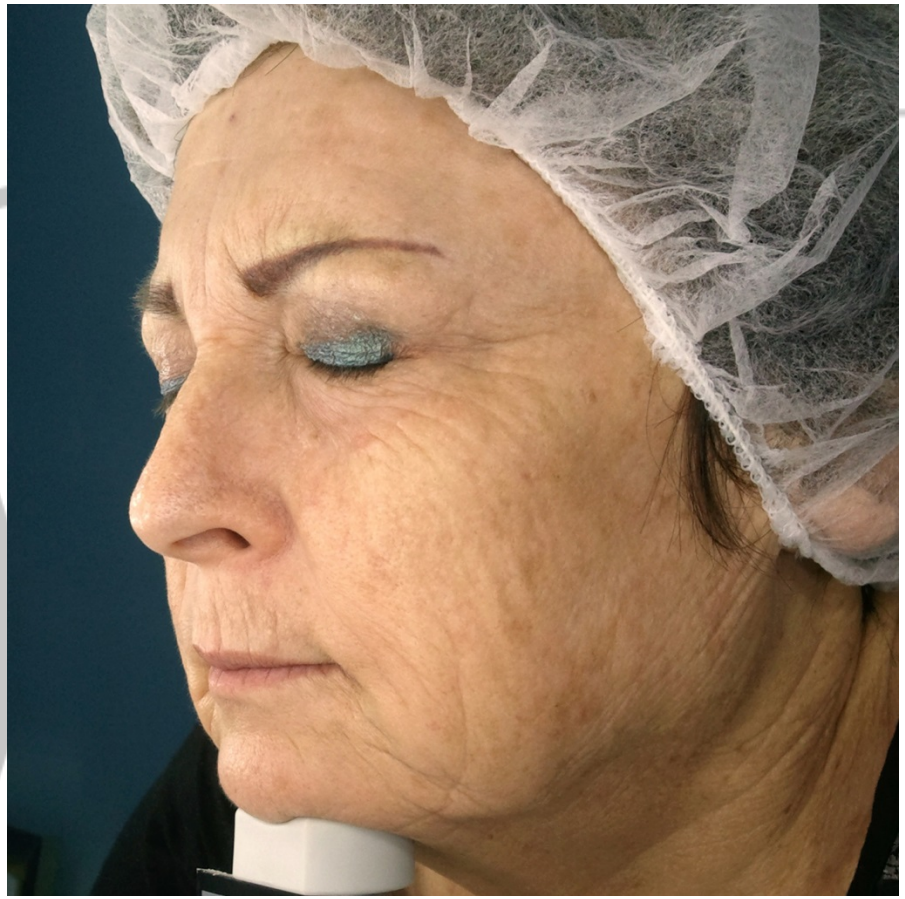

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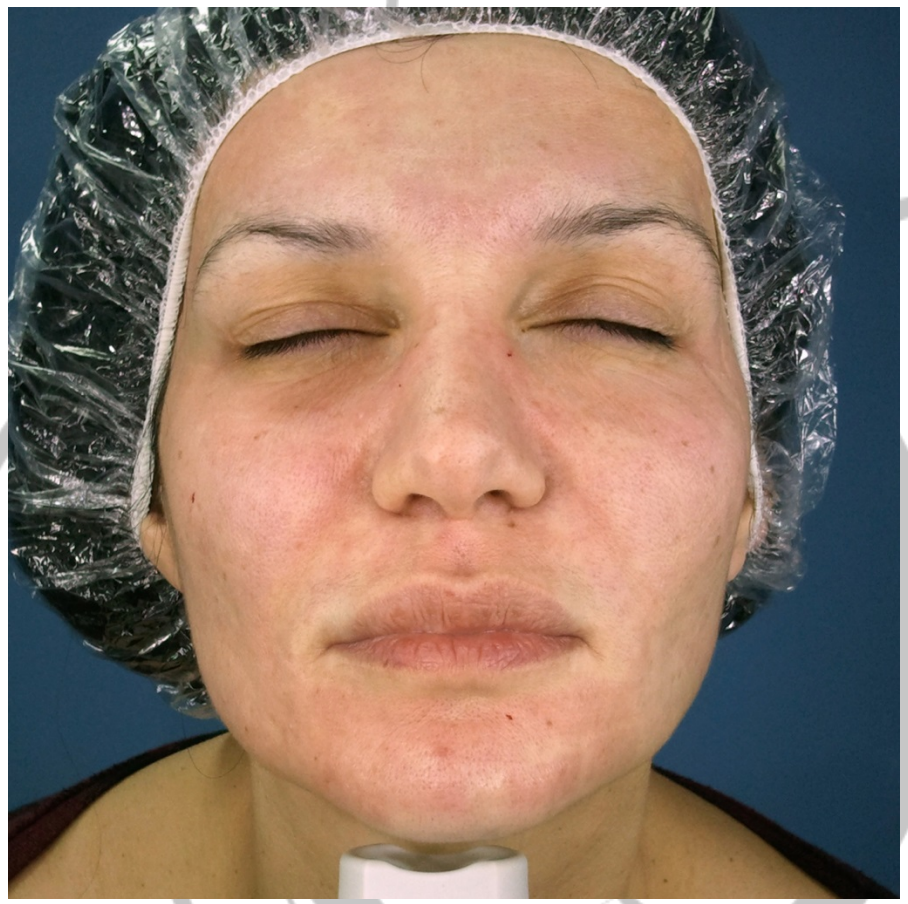

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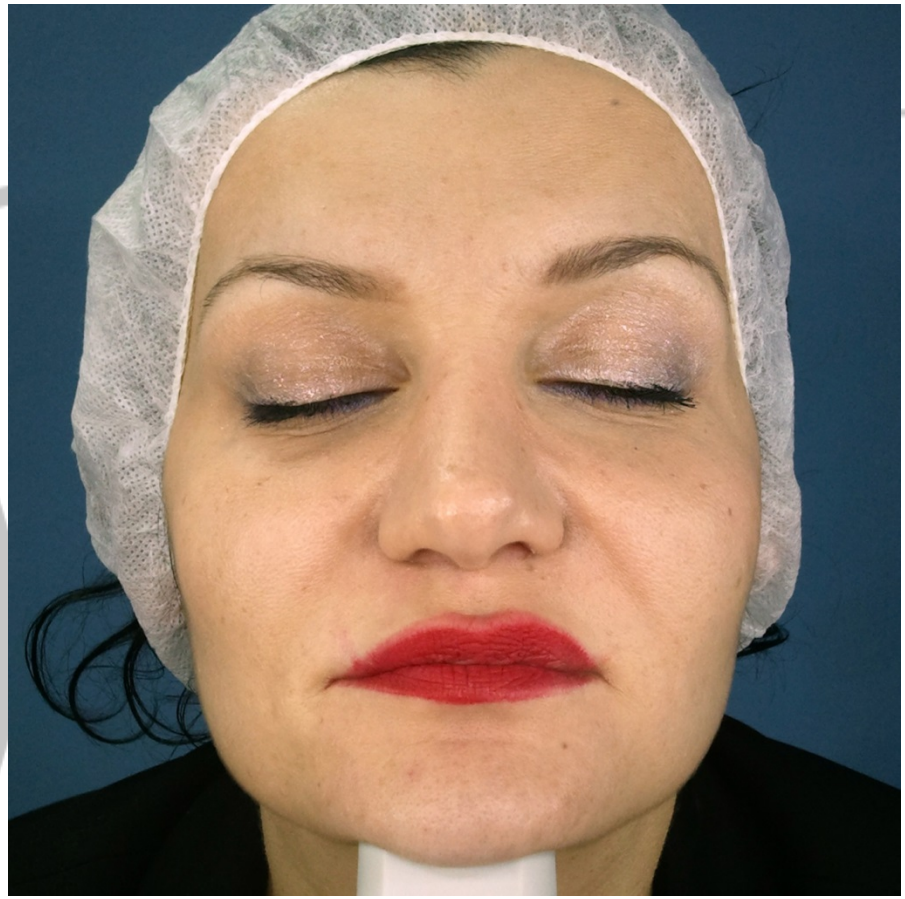

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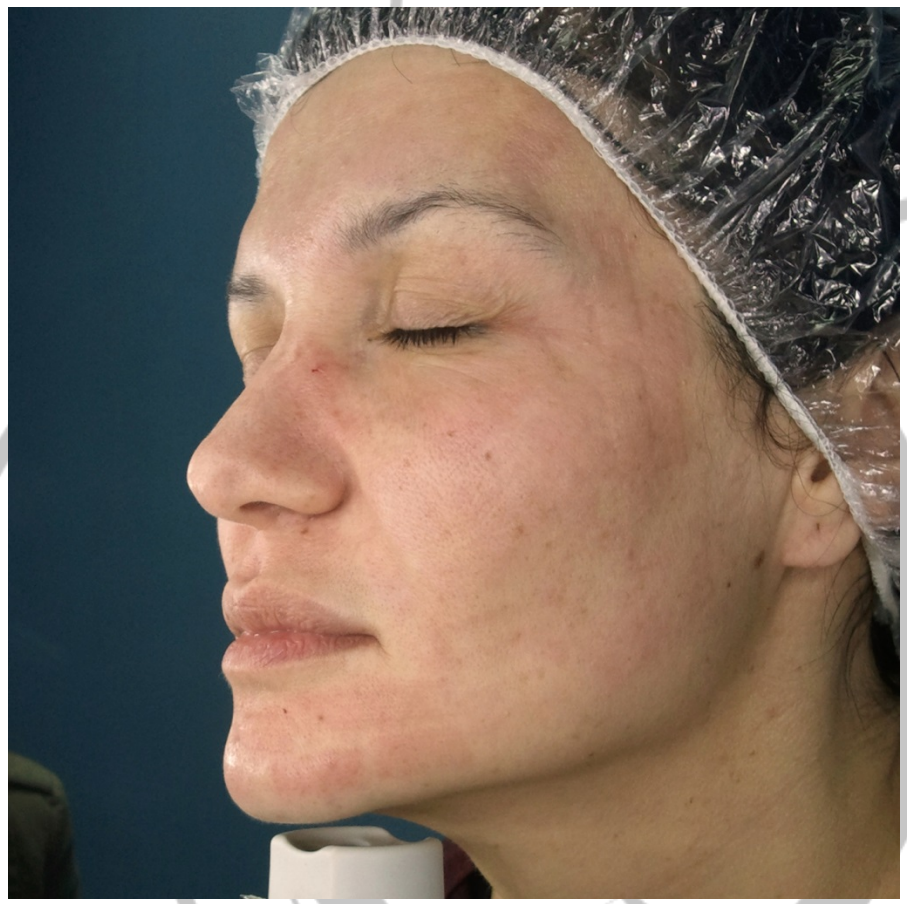

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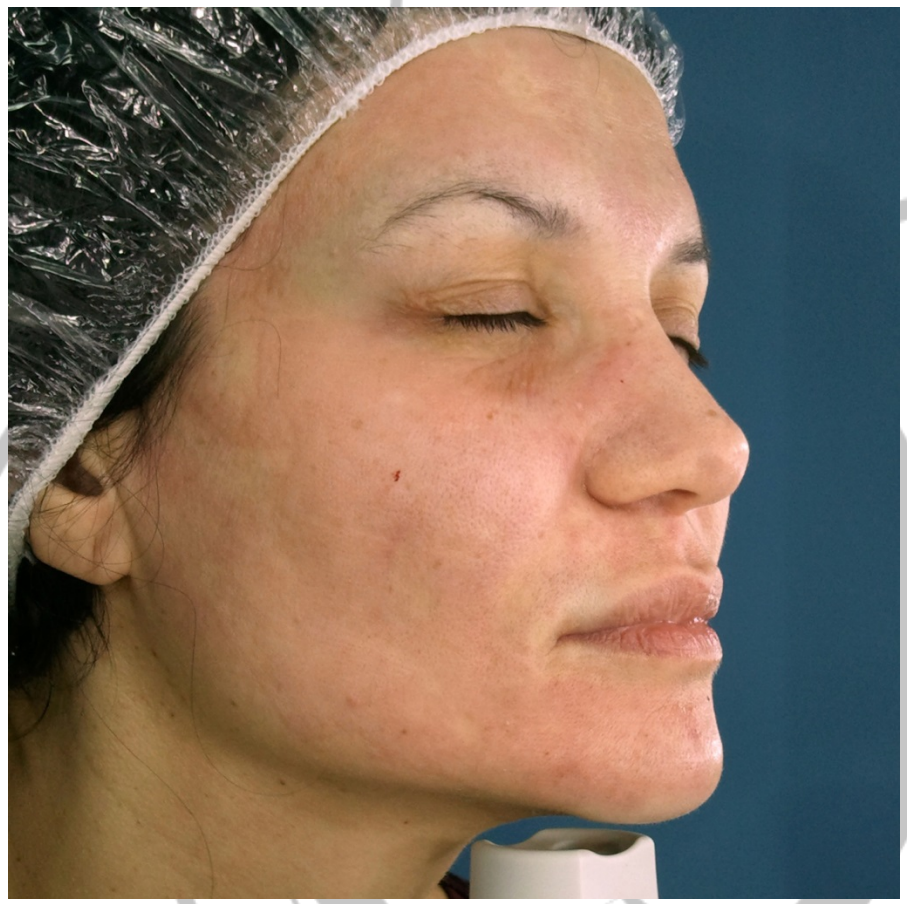

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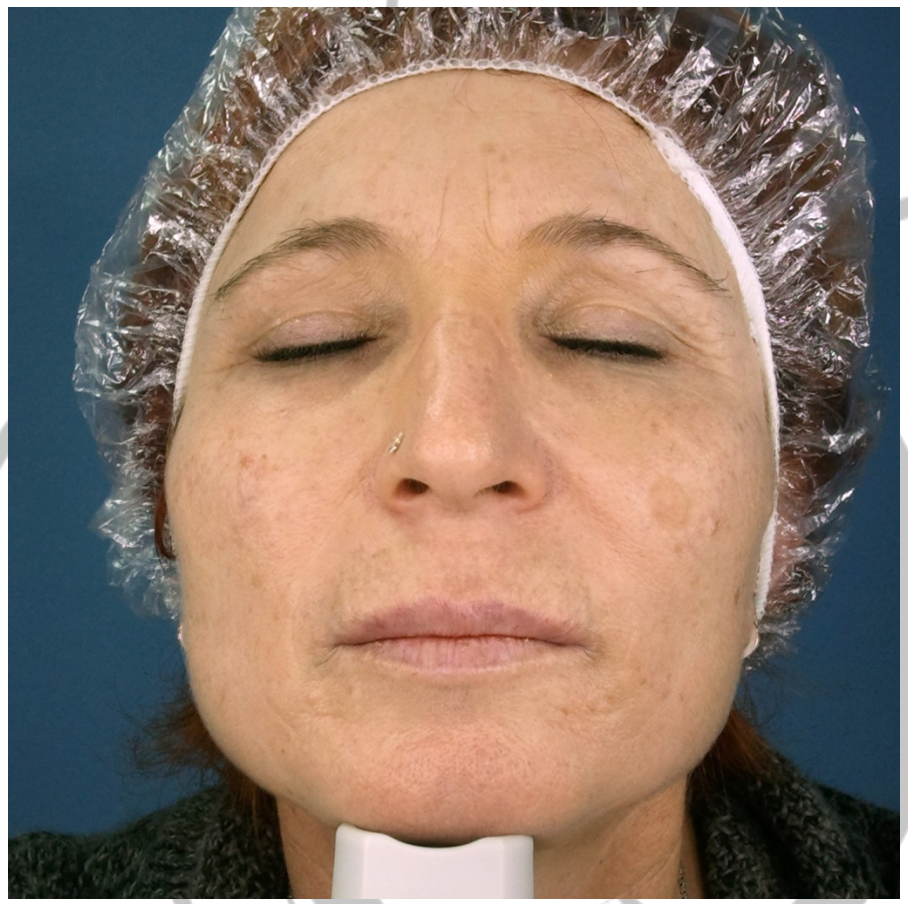

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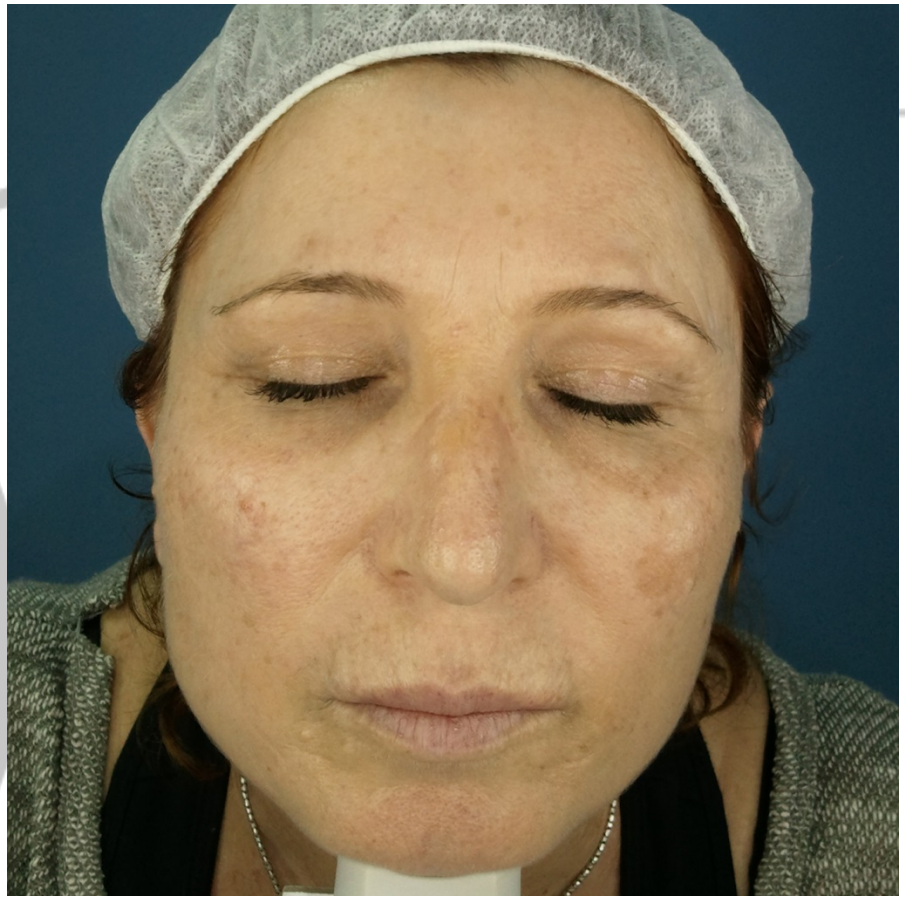

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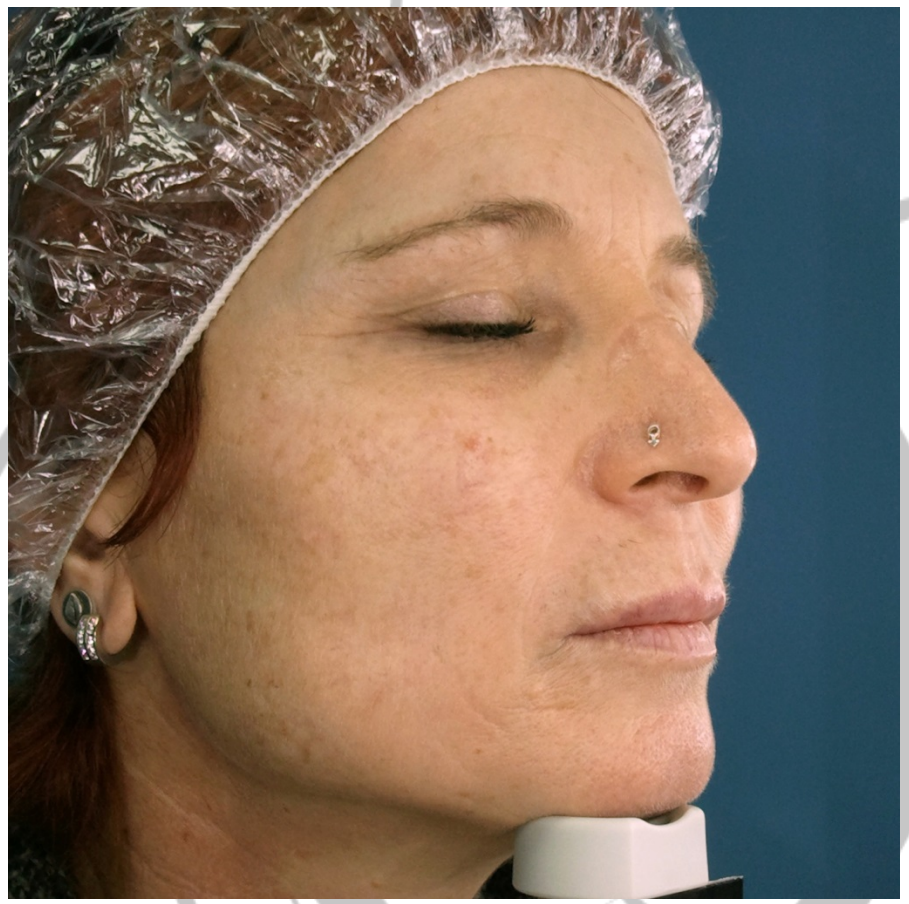

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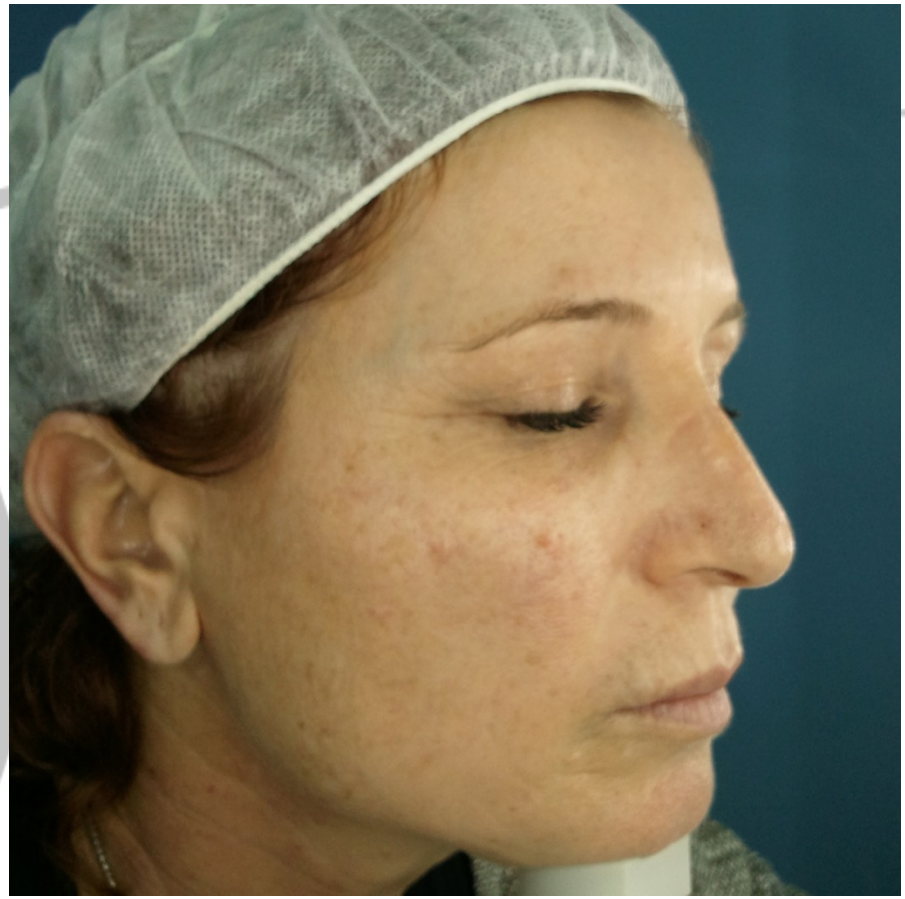

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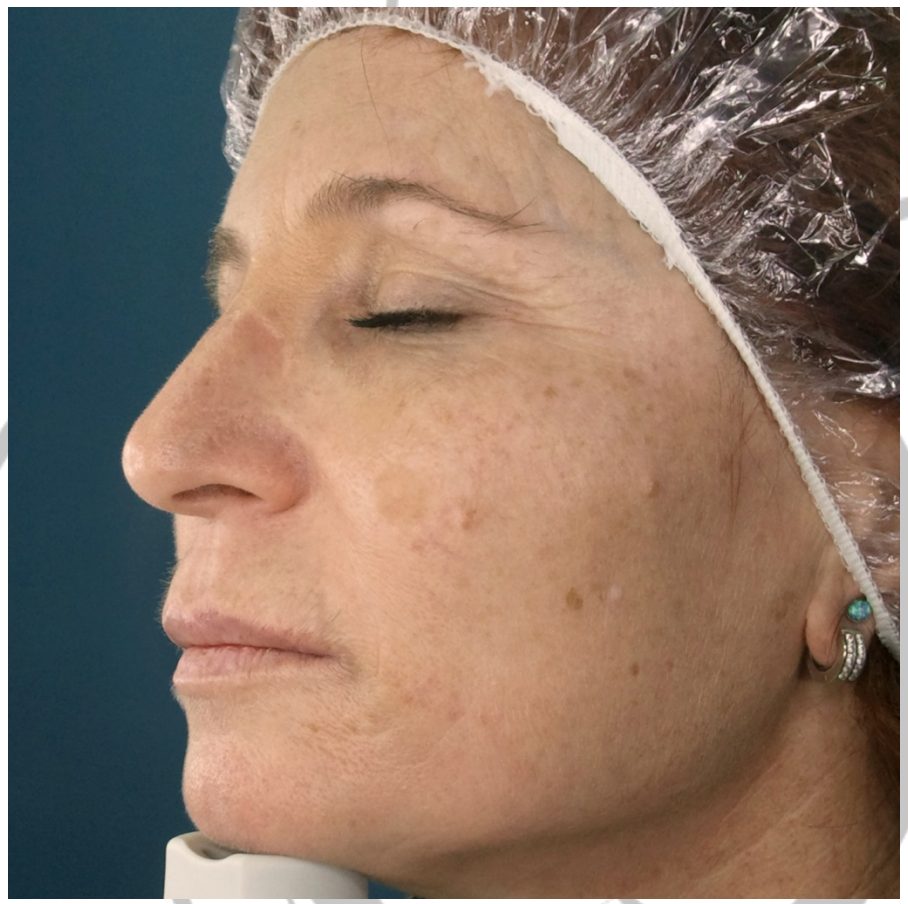

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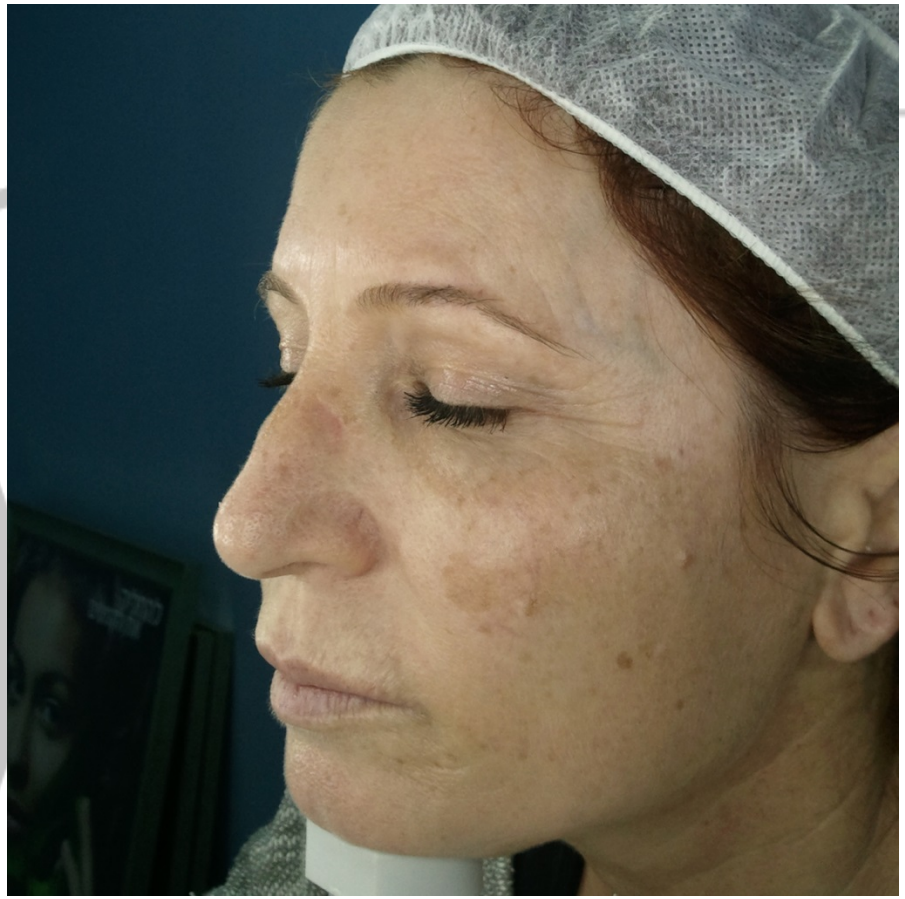

VENUSCONCEPT
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The Use of Nano-Fractional Radiofrequency Treatments (Venus Viva) on the Appearance of Acne Scars

Purpose:

Acne scarring is psychologically distressing and cosmetically difficult to treat.[1,2] The difficulty lies in the variation in the types of acne scars and the irregular pigmentation that often accompanies them.[3] Common treatments for acne scars such as surgery, subcision, deep peels, and ablative lasers can be painful and result in scarring and irregular pigmentation. Fractional radiofrequency treatments (FRF) are innovative technologies that transmit a current into the skin that generates micro-thermal wounds and deep dermal heating, both of which stimulate the body to heal and produce collagen. In turn, an improvement in skin texture, scarring, wrinkles and pigmentation is seen.[4] Additionally, since FRF produces less thermal damage than other devices such as lasers, fewer side effects are seen and darker skin types can be treated with little risks.[5]

Design:

The purpose of this study was to assess the efficacy and safety of a novel nano-fractional RF device for the treatment of acne scars. Five patients were treated at settings of 230-250V and 10-20 msec with 1-2 passes to the full face and multiple passes over the acne scars. Topical anesthetic (20% benzocaine, 6% lidocaine, 4% tetracaine) was applied for 45 minutes prior to each procedure to limit procedural pain. Post-treatment all patients were given 10 mg of loratadine and ice packs were applied for 10 minutes.

Results summary:

Improvement was noted for all types of acne scarring, with greatest improvement with boxcar and rolling scars. Mild side effects such as redness and swelling were seen in all patients immediately post procedure and effects resolved within 1-3 days without sequelae. No other complications were seen and all patients showed clinical improvement.

Conclusion:

Nano-fractional RF therapy is an innovative and safe modality for the treatment of acne scarring and is appropriate for those desiring treatments with minimal downtime or those with darker skin types who cannot undergo other more invasive options.

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Clinical Experience with a Novel NanoFractional Radiofrequency Based Aesthetic Device Used for the Improvement of Scars

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Background

Regardless of the etiology, scars have always been notoriously challenging to treat with truly effective therapeutic options few and far between. Depending on the location of the scar and the individual patient, scars can be a source of considerable physical as well as psychological distress and can be the cause of significant anxiety and depression in the affected patient. This can often lead to a loss of self-esteem and a stigmatization of the patient frequently resulting in a diminished quality of life (1,2). Beyond the psychological impact, scars can also be associated with severe itching, tenderness, pain, sleep disturbances, and can cause the disruption of daily activities, begging the need for more effective treatment solutions for this common aesthetic indication.

Scar formation is part of the natural physiologic healing process following an injury to the skin where typically, collagen fibers will cross-link and form a pronounced alignment in a single direction instead of having a random basket weave formation as seen in normal, non-scarred dermal tissue. The appropriate treatment of scar tissue depends on several different factors including the depth and size of the scar, its location, as well as the age, gender, ethnicity and genetics of the individual patient. Several different types of scars and scar morphologies exist including keloidal scars, contracture scars, hypertrophic scars, and acne scars. Acne scars can be categorized into atrophic, hypertrophic or keloidal type scarring. Often dominated by the presence of fibrous tissue and fibrotic bands running throughout the dermis in the histopathology, atrophic acne scars are further subdivided into ice pick scars, rolling scars, and boxcar scars, which are defined as having less than a 2 mm diameter defect at the skin's surface, a greater than 4-5 mm diameter defect at the skin's surface, and a 1-4 mm diameter defect at the skin's surface, and a 0.1-0.5 mm depth, respectively.

The choice of scar treatment is often guided by the type, age, and location of the scar lesion. Over the years, several different treatment modalities have been used and tried alone and in combination for the improvement of scars. These include surgery, punch biopsy/excision, intralesional corticosteroid injections, subcision, cryotherapy, silicone sheeting, filler injections, electrodessication, as well as the use of various scar minimizing creams and gels. Resurfacing techniques have also been tried including chemical peeling, dermabrasion and microdermabrasion (1-3). Continued research however has led to the development and implementation of novel energy-based technologies that are used to resurface the target skin region leading to a smoother more homogenous appearance of the skin. Both ablative and nonablative laser technologies have been successfully employed for scar therapy however, these modalities are often limited by their side effects including post-inflammatory hyperpigmentation (PIH) as well as prolonged healing times, particularly true for ablative lasers. Largely viewed as a paradigm shift in skin rejuvenation therapy, the dawn of fractional technology has been shown to be very effective in this regard, achieving excellent cosmetic outcomes while keeping potential adverse events and downtime to a minimum (4-16), particularly when compared to non-fractional energy-based modalities. Bridging the gap between ablative and nonablative modalities, fractional technology creates predetermined symmetric columns of microthermal zones (MTZ) surrounded by healthy unaffected tissue, resulting in much quicker healing times.

An ideal treatment can be characterized as safe and effective with minimal to no discomfort perceived by the patient as well as little to no downtime. One leading technology that has been shown to fulfill these criteria is fractional radiofrequency (RF)-

based devices, which have a proven efficacy and safety for the treatment of numerous aesthetic thorns including rhytids, skin laxity, skin texture and smoothening as well as the aesthetic improvement of scars with very little downtime. Fractional RF technology has been proven to effectively and efficiently deliver heat energy deep into the targeted dermis, resulting in fibroblast stimulation, dermal remodeling, neocollagenesis, and elastogenesis, while only causing very minimal disruption of the epidermis, leading to excellent treatment outcomes with minimal downtime. In this paper, we present our clinical experiences using a novel Nanofractional™ radiofrequency-based aesthetic device for the treatment and improvement of scars.

Materials and Methods

Device Description

Venus Viva™ (Venus Concept, Toronto, Canada) is a fully customizable, noninvasive treatment solution for many of the demanded indications commonly seen in the aesthetic practice today. Having received an official nod from Health Canada and FDA clearance for facial remodeling and resurfacing, the Venus Viva device (*Figure 1*) is engineered to successfully address a myriad of common aesthetic indications that fall under the umbrella of skin rejuvenation including skin laxity, wrinkles, fine lines, rhytids, skin texture, acne and traumatic scars, dyschromia, rosacea, striae distensae, and enlarged pores.

Figure 1. Venus Viva device

Proven to be safe for all Fitzpatrick Skin Types, the Venus Viva system employs NanoFractional™ RF and innovative proprietary SmartScan™ technology that enable precision control over the heated zone density and unique pattern generation during treatment, resulting in homogenous treatments and reproducible clinical outcomes. These two technologies are delivered to the targeted skin via the Viva™ applicator, ideal for the treatment of larger surface areas. The ergonomic applicator houses 160 pins/tip with 62 mJ/pin, and a smaller pin footprint (150x20 microns), treatment with which results in minimal downtime due to the micro wound created. Energy is delivered to each micro-pin individually maximizing patient comfort and ensuring that the tissue is treated uniformly. The patented tip technology with a depth of penetration of up to 500 microns allows for varying energy densities during treatment, which enables both manually controlled ablation of the epidermis and coagulation of the targeted dermis resulting in a precision resurfacing of the skin.

Methods

Patients presenting with Fitzpatrick Skin Types ranging from II-III and various types of scar lesions located in different anatomic regions underwent multiple treatments with the Venus Viva aesthetic device for the purpose of improving the appearance of their scars. In our patient cohort, any type of scar was considered for Venus Viva therapy including surgical and post-traumatic scars, and both fresh erythematous colored scars as well as older, longer standing, hypopigmented and/or atrophic scars. The patients included in this observation were followed up at each subsequent treatment session, and pre- and post-treatment clinical photographs were taken at baseline and at each follow up visit, and were made available for comparison at the end of the treatment period. Treatment safety was assessed by the frequency and severity of adverse events reported throughout the duration of the treatment period. All of the patients provided written informed consent prior to the initiation of therapy, and noted their satisfaction from the treatment procedure at the predetermined follow up visits.

Just prior to performing the Venus Viva scar treatment, any moisturizer cream and make-up was

thoroughly removed from the target skin, followed by a meticulous disinfection of the area using 70% alcohol and then degreasing with a mixture of acetone 20% in water. The typical parameters used during the scar treatment procedure were between 250 to 270 V, and between 6 to 10 msec pulse duration. According to our protocol, the thicker the individual patient's skin and individual scar, the longer the pulse duration and higher fluence was used. For each of the scars addressed, a maximum of 3 passes were performed perpendicular to the surface of the skin, with a slight angle in between each pass to avoid pulse stacking. After the completion of each treatment, a calming moisturizing cream was amply applied to the treated skin region, such as Cicalfate Baume B5 (La Roche Posay).

Results

Over 50 female and male Caucasian patients ranging in age from 20 to 75 years and Fitzpatrick Skin Types from II to III received treatment with the Venus Viva aesthetic device for the improvement in the appearance of their scars. The treated scars lesions were of mild to moderate severity, and included post-surgical and post-traumatic scars as well as post-acne scarring located on different anatomic areas such as the face, forehead, lower eyelid, cheek, nose, chin, upper lip, chest, shoulder, breasts, abdomen, forearm, hand, and knee. Our patients underwent anywhere from 2 to 8 treatments with the device depending on the individual clinical presentation as well as the location of the scars addressed, until a satisfactory outcome could be achieved. It was found that regardless of the scar type, age of the scar, as well as anatomic location, Venus Viva treatments could significantly improve the scar tissue in all of our patients. Results showed that all of the scars achieved a marked improvement in their appearance, some as soon as post two treatments sessions with the device (*Figures 2a and 2b*). Post surgical scars also showed significant improvement in color, texture, and overall appearance (*Figures 3a and 3b,* and *Figures 4a and 4b*). Only a mild but transient erythema was observed in the targeted skin immediately following each treatment session, and none of the patients experienced any adverse events. All of the patients reported a high tolerability from treatment, and the vast majority of patients were content with the improvements achieved in the appearance of their scars.

Figure 2a. Baseline image depicting a scar on the upper lip 6 months post Mohs surgery

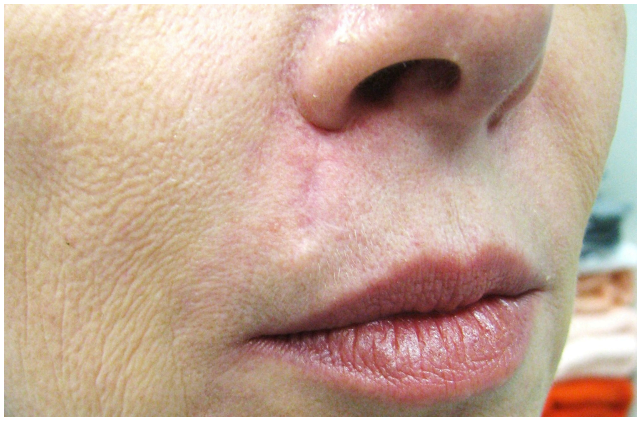


Figure 2b. Image taken post 2 treatment sessions with the Venus Viva device

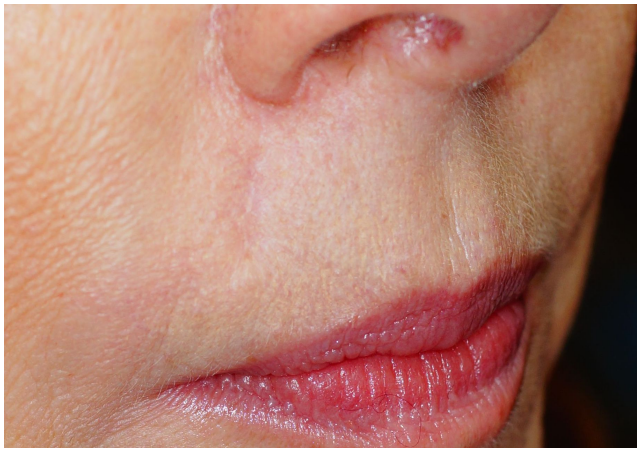


Figure 3a. Post Mohs surgery scar on dorsum of the nose

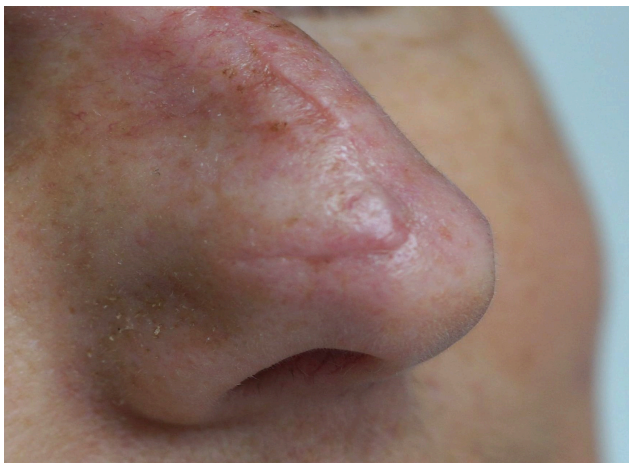


Figure 3b. Post 4 treatments with the Venus Viva device

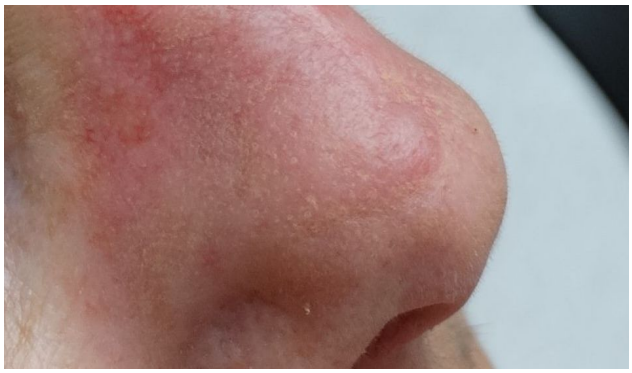


Figure 4a. Baseline image of multiple surgical scars over the abdomen

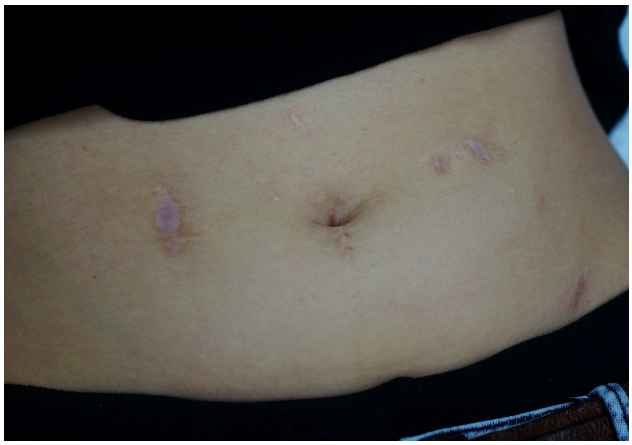
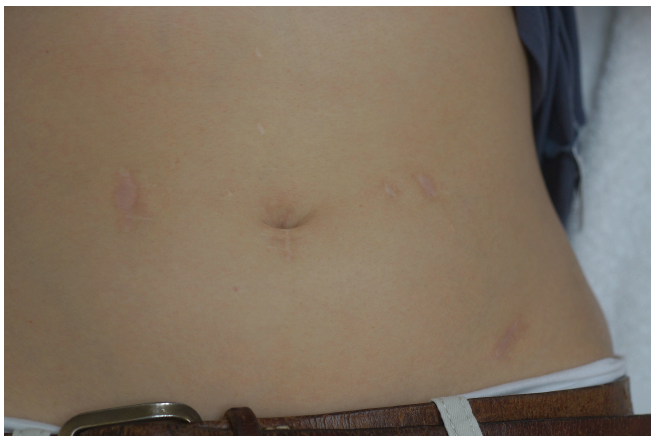


Figure 4b. Post 5 treatment sessions with the Venus Viva device



Discussion

In this observation that included over 50 patients with various types of scarring in different anatomic regions, we used the Venus Viva system, a novel Nanofractional radiofrequency device for the treatment and cosmetic improvement of scar lesions. All of the treated scars in our patients demonstrated significant improvement in their appearance, as witnessed in the comparative before and after images. After only a few treatments, the texture and color of the scar tissue appeared more homogenous in respect to the adjacent healthy looking non-scarred skin. The treated scars also appeared more flush to the skin, further enhancing the cosmetic result. None of the patients experienced any adverse events and patients were very satisfied with the treatment and outcomes achieved.

Several different treatment modalities and techniques are currently being used for the improvement in the appearance of scar lesions ranging from various surgical techniques and energy-based aesthetic devices to a myriad of topical therapies. Energy-based aesthetic systems in particular used for the cosmetic improvement of scars are more popular than ever in aesthetic medicine today due to the significant impact they can have on scar tissue. Fractional radiofrequency-based devices have proven to be particularly successful for this indication due to their favorable aesthetic outcomes coupled with an excellent side effect profile (1,4-7,11,14).

The impact of radiofrequency technology in the skin is based on dermal heating and the subsequent therapeutic fallout of the induced tissue inflammation. During treatment, the radiofrequency energy will heat the targeted skin and initiate an inflammatory response, leading to a denaturation of collagen and the stimulation of fibroblasts to generate new collagen and elastic fiber formation. Fractionated bipolar radiofrequency technology effectively delivers thermal energy deep in to the dermis, resulting in significant dermal remodeling, neocollagenesis, and elastogenesis, while only causing very minimal disruption of the epidermis. The exemplary NanoFractional radiofrequency technology found on the Venus Viva device proved its great utility in the cosmetic treatment of scars of different etiologies, as witnessed in this patient cohort. This novel mode of RF energy delivery and subsequent tissue inflammation and repair cascade has been demonstrated time and again to achieve excellent skin rejuvenation outcomes for a myriad of cosmetic indications including wrinkles and rhytids, dyspigmentation, striae distensae, rosacea, as well as scars. As similarly found in previous studies using fractional bipolar radiofrequency for scar treatment, the positive results achieved in this small cohort of patients further supports the use of NanoFractional radiofrequency technology for the treatment and improvement in mild to moderate scar lesions of varying etiologies.

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A Comparison Study of Venus Viva™ Fractional Radiofrequency Treatment for Acne Scars

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Abstract

Historically, dermatological conditions, such as acne scarring, have been treated with surgery or full ablation of tissue. Following the emergence of the first fractional thermolysis devices in 2004, treatments for various skin conditions no longer require surgery or full ablation. These new treatment devices now utilize techniques that deliver thermal energy, derived from fractional radiofrequency (RF) energy, in a highly targeted manner through multiple micro-needles. These micro-needles are referred to as pins. When used to treat dermatological conditions, such as acne scars, this technique reduces the degree of damage to the epidermis; thereby speeding the recovery time following treatment and reducing the number of side effects. Currently, there are a wide variety of treatment techniques to choose from utilizing RF technology, making if challenging for patients to decide on the ideal method for them. The goal of this comparison study was to evaluate patient satisfaction and effectiveness of the Venus Viva™ device when compared to another popular fractional RF treatment method for skin resurfacing. Participants included 8 healthy adult volunteers who reported varying degrees of acne scarring. Participants received 2 sessions of treatment using the Venus Viva™ on the left side of the face and a competing skin resurfacing treatment on the right. Results indicated that 7 of the 8 participants preferred treatment with the Venus Viva™ device due to its recovery time, fewer and less severe side effects, and overall effectiveness of the treatment.

Introduction

Traditionally, dermatological conditions, such as acne scarring, were treated with surgery or full ablation of tissue. The premise behind this is that most skin conditions are the result of the disorganization of collagen proteins and atrophy of the epidermis [1]. This can be seen in an overall flattening of the dermal-epidermal junction, loss of rete processes, reduced number of fibroblasts, and a reduction in overall collagen levels. Thus, ablating the tissue was considered the only way to remove the atrophied tissue and encourage the growth of new, healthy skin tissue. Given that these traditional techniques destroyed epidermis and induced dermal injury, they are associated with a number of negative side effects. Some examples of these traditional treatment techniques include dermabrasion, chemical peels, erbium-doped yttrium aluminum garnet (Er:YAG) lasers, and char-free pulsed carbon dioxide (CO_2) [2-3].

More recently, however, there has been a growing interest in the development of minimally invasive or even non-invasive techniques for skin rejuvenation that allows for little to no down time during recovery, as compared to the traditional surgical methods. In 2004, the first fractional thermolysis devices entered the market [4]. Unlike techniques that use light-based resurfacing techniques, these treatment techniques now offered skin resurfacing using radiofrequency (RF) energy [5, 6]. More specifically, these techniques use RF to generate thermal energy using an oscillating electrical current, which causes charged molecule and ions to collide against one another generating heat energy. This thermal energy is generated with a targeted location in the skin, which then leads to dermal injury. Given that these RF techniques generate thermal energy within the skin, they minimize the area of damaged tissue and thereby reduce the potential risk for infection, scarring, and hyperpigmentation [7, 8].

In terms of acne scarring in particular, the traditional gold standard method of treating this condition was a CO_2 laser system [9]. Essentially, a continuous delivery of damaging lasers was delivered, which damaged all of the epidermis, along with a portion of the dermis. The recovery time following this treatment tended to last at least one week or more and side effects include pain, persistent erythema, edema, infection, post-inflammatory hyperpigmentation, and hypopigmentation [10]. Given these adverse side effects and long recovery time, this treatment technique quickly dropped out of favor. Patients suffering from acne scarring sought out more light-based treatments, with only minimal effects on the damaged collagen and elastin.

However, once the development of fractional RF techniques emerged, the field exploded in its application of this non-ablative treatment technique [11]. This technique was quite preferred over traditional, full ablation, methods, due to the reduction in adverse side effects and more rapid recovery times. Moreover, techniques using RF technology were found to be much more effective in treating acne scarring than light-based laser, making it the ideal treatment of choice [9]. As the clinical uses for the technique expanded, so did the availability of treatment devices. Today, there are a wide variety of devices available on the market. This can make it difficult for individuals to choose which treatment might be right for them. As such, the goal of this study was to compare patient satisfaction and effectiveness of the Venus Viva™ device compared to another popular fractional RF treatment method for skin resurfacing.

Materials and Methods

Study participants included 8 healthy volunteers reporting varying degrees of acne scarring and texturing irregularity. Participants were over the age of 18 years and were enrolled in the study after meeting all inclusion and exclusion criteria. Individuals who were pregnant or nursing, had an implanted pacemaker or defibrillator, or exhibited symptoms of an acute systemic or local infection, such as herpes simplex, were excluded from participating in the study. Participants provided informed consent prior to receiving the skin treatments. Study participants completed two treatment sessions using RF technology.

On the left side of the face, participants were treated with the Venus Viva™ device, whose exclusive design operates using both SmartScan™ and non-ablative, Nano-Fractional RF™ technology to deliver skin-resurfacing treatment. This non-ablative Nano-Fractional RF™ technology offers a more targeted density control of the delivery of heat energy, which means that RF energy is delivered to the heated zone individually through 160 pins per tip, with 62mj per pin and a small footprint per pin (150x20 microns). Two passes were used 4.55j/cm2). The unique pin design allows for more control over the ablation/coagulation ratio, thereby reducing patient discomfort during the procedure and resulting in minimal downtime following the procedure for recovery. The Venus Viva™ device also used patented SmartScan™ tip technology, which offers 800 pulses, penetration depths totalling up to 500 microns, and multiple options for pattern selection. SmartScan delivers the energy to the tissue in a controlled algorithm, allowing 4 pins at a time to be active while the other 156 pins are receiving the energy. This unique sequencing reduces discomfort and the occurrence of unwanted side effects such as PIH (post inflammatory hyperpigmentation) commonly associated with traditional RF fractional methods of delivery.

On the right side of the face, participants were treated with a a traditional system using fractional radio frequency technology. The traditional RF technique relies on the use of fractionated bi-polar RF to deliver heat energy to the targeted area. This allow for a high degree of dermal impact, while also minimizing the degree of epidermal disruption. The device used in this study utilized similar joules to the Venus Viva™, delivering 62mj per pin and 2 passes were used (3.28j/cm2).

In order to evaluate treatment safety, areas that had received treatment were assessed visually for adverse side effects, including edema, erythema, localized infections, thermal burns, or other changes in skin pigmentation, immediately following treatment. The areas receiving treatment were photographed in a standardized way, using high-resolution macrophotography, in order to assess treatment effects. Study participants were also asked to provide self-reports of treatment preference following treatment and were assessed at 30, 60, and 90 days following their final treatment session. Fig 1, Fig 2

Results

There were no unexpected adverse side effects from the treatment reported or detected during the study. A portion of the study participants reported mild to moderate skin erythema and edema at the treatment site, though these symptoms tended to resolve within several days of receiving the treatment. During the healing phase after receiving skin-resurfacing treatment using RF technology, individuals typically will experience tiny pinpoint epidermal crusts at each micro-ablated spot. These crusts generally exfoliate naturally within several days following the treatment. This exfoliation then leads to epidermal resurfacing. No study participants reported experiencing more severe side effects following treatment, such as burns, skin irritation, or scarring.

Results from self-reports indicated that 7 of the 8 study participants favored skin-resurfacing treatment using the Venus Viva™. These individuals reported that they preferred this method, over the traditional RF delivery method, for several reasons, including healing time, degree of scabbing following the treatment, and also the final result from treatment. It should be noted that the final participant failed to see any notable results from treatment.

Discussion

The use of RF technology has revolutionized the field of skin resurfacing for the treatment of acne scarring and the advancement of this technology has lead to an increase in the availability in a number of different treatments using RF technology. Many of the non-ablative techniques even offer the benefits of minimal downtime and very low risk for side effects following treatment sessions. Deciding on the right skin-resurfacing technique for the treatment of acne scars can be challenging.

The goal of this study was to complete a side-by-side comparison of two skin resurfacing techniques, which utilize RF technology. Results from this study provide additional support of the use of the Venus Viva™ device for treating varying degrees of acne scarring in otherwise healthy adults. Findings from self-reports indicated that study participants preferred this device owing to its shorter healing time following the treatment and mild degree of scabbing. Participants also noted that they preferred the Venus Viva™ for its overall results in treating their acne scarring. Given these findings, the Venus Viva™ device may be regarded as the ideal treatment modality for providing skin rejuvenation to patients suffering from symptoms of acne scarring.

Limitations

The current study is not without limitations, which can have an impact on the interpretation of these findings. Of note, this study evaluated the treatment effects of two treatment methods on acne scarring alone. More studies are warranted to explore the use and utility of these methods for other skin conditions. Further, only 8 individuals were enrolled in the study, which limited the power to complete any statistical analyses. Therefore, the findings from this study may not be statistically significant. Future studies are necessary with larger sample sizes in order to confirm the generalizability of these findings.

Conclusions

The majority of study participants preferred the use of the Venus Viva™ technique for treating their acne scarring owing to its faster healing time and reduced degree of scarring following treatment. These findings provide support for results from previous studies, which show that the Venus Viva™ technique is ideal for treating conditions results from abnormal collagen formation, while promoting the formation of new dermal proteins to provide the appearance of smooth, clear skin that is free from scars. The Venus Viva™ device is believed to provide increased efficacy, owing to the unique ability for the operator to have control of both the power and pulse duration. This results in the device's improved control of tissue ablation and coagulation ration. Moreover, the reduced pin footprint is associated with decreased side effects following treatment. As such, the Venus Viva™ may be regarded as the ideal choice for the treatment of facial acne scarring.

Fig 1

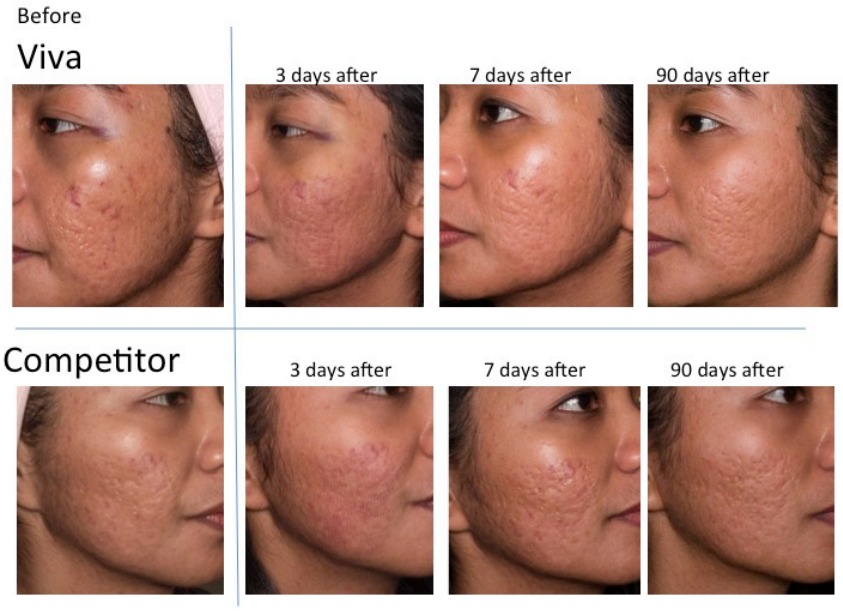
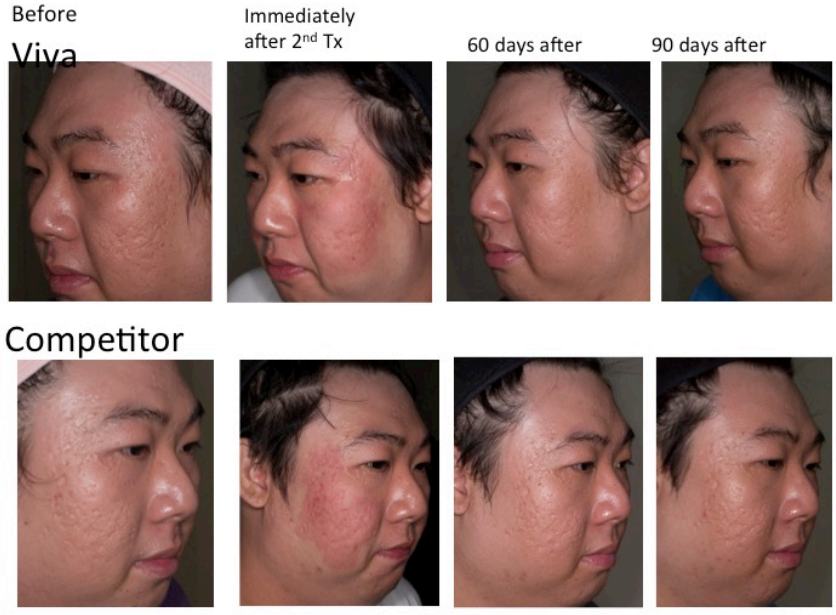

Before
Viva
3 days after
7 days after
90 days after
Competitor
3 days after
7 days after
90 days after

Fig 2


Before
Viva
Immediately after 2nd Tx
60 days after
90 days after
Competitor

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