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New Robotic Hair Transplantation Technology Provides Path to the Future

In recent years, surgical hair transplantation has been going through a significant, but quiet revolution. Follicular Unit Hair Transplantation, the standard strip excision method that is still widely used, and the more minimally invasive Follicular Unit Extraction (FUE) approaches are being challenged by a new technology that automates the harvesting process with more precision. This innovative robotic approach is accelerating expansion of the hair restoration market, indicating a paradigm shift in this industry.

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ARTAS Hair Studio and ARTAS Robotic
System Signal a Paradigm Shift in Hair Restoration

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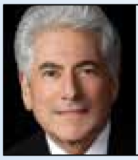

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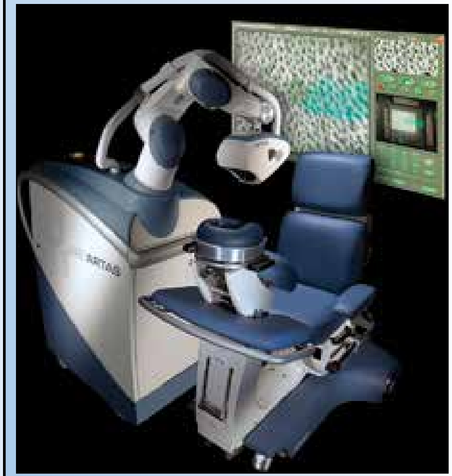
"There is no doubt that the ARTAS System is causing a paradigm shift. For physicians, and in particular hair transplant surgeons who are only doing the strip based procedure and not really doing FUE, from the start they will be much more efficient at using a robot."



ARTAS Robotic System

By Jeffrey Frentzen, Executive Editor

The ARTAS® Robotic System from Restoration Robotics, Inc. (San Jose, Calif.), harvests hair for transplant using a minimally invasive dissection process mounted on an image-guided robotic arm. Harvesting individual follicular units from the back of the head, this system provides an unparalleled level of precision, control, reproducibility and efficiency. Since only the most robust and viable hairs are selected to harvest, the system consistently and repeatedly provides very high quality grafts for transplant.

This minimally invasive procedure is proving to be the new standard for hair transplant patients. Unlike the traditional strip procedure, ARTAS does not require a large incision on the back of the head, sutures or staples to close the wound, so there is no risk of a linear scar. In addition, patients recover quickly, report minimal discomfort post-procedure and are able to return to daily exercise and other physical activities without limitations. Physicians are finding that these benefits bring new patients into their practices, asking for the ARTAS Robotic Procedure by name.

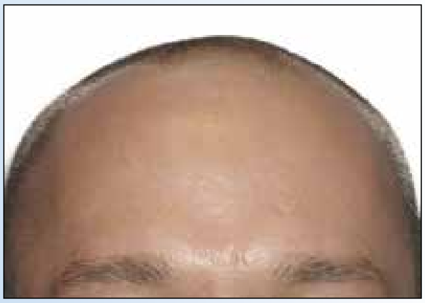
"There is no doubt that the ARTAS System is causing a paradigm shift," expressed Mark A. Bishara, M.D., a cosmetic surgeon in Mansfield, Texas. "For physicians, and in particular hair transplant surgeons who are only doing the strip-based procedure and not really doing FUE, from the start they will be much more efficient at using a robot than if they try to develop the hand-eye coordination necessary for manual procedures. The ARTAS Robotic System is definitely going to fill different voids in various practices."

"Increasingly, plastic surgeons and dermatologists are investigating the ARTAS Robotic System," noted Jim McCollum, CEO of Restoration Robotics. "They see the technology not only from the aspect of how patients will benefit, but also how this is a unique opportunity to substantially grow their practice revenues."

As with the introduction of any transformative technology, the physician community needs time to assess its value and potential for bringing in new patients. In the case of the ARTAS Robotic System, that time has come, according to Dr. Bishara. "I had a mixed practice of both cosmetic surgery and reconstructive surgery, along with hair restoration where we did around 50% strip procedures and 50% FUE," he said. "There is no doubt that the results we are achieving now from robotic transplantation – with the density and overall hair maps – are certainly acceptable to forego having a strip taken out of the back of your head. That is coming from somebody who performed the manual transplantation procedure for several years before purchasing the robotic system."

According to Gregory A. Turowski, M.D., Ph.D., F.A.C.S., a plastic surgeon in Skokie, Ill., the ARTAS Robotic System eases the tediousness of manual approaches and also dramatically speeds up the overall procedure. "I had used some FUE systems before, but they were manual systems that require a lot of experience and concentration for long periods of time, and they were relatively slow," he reported. "The main advantage of using the ARTAS Robotic System is that it is faster than transplanting manually, even for an experienced person, and it does not require a steep learning curve. One can become quite proficient compared with other approaches to FUE. More than that, I think it improves the quality of the grafts. They are more consistently not denuded and not stripped from the surrounding tissue. This combination of features has us using the robotic system more than the manual technologies."

Herbert S. Feinberg, M.D., a dermatologist in Englewood, N.J., implemented the ARTAS Robotic System in his practice to speed up the FUE process. "I found manual FUE too tedious," he said. "The ARTAS Robotic System allowed me to perform FUE with more competence that I could ever achieve manually. Certainly, it is also less physically demanding. I have now treated a number of patients who had traditional FUE or strip procedures in the past. All of them said they preferred the robotic transplant and they would never go back to a strip procedure if they needed more work in the future."



Before Tx

After ARTAS Robotic hair transplantation

Photos courtesy of Restoration Robotics, Inc.

Driving Patient Acquisition

In a 2013 Practice Census by the *International Society of Hair Restoration Surgeons* (ISHRS), hair transplantation is reported to be a $1.9 billion business worldwide, having grown 48% since 2008. In order to leverage this significant growth, Restoration Robotics has invested in a robust search engine marketing strategy, a social media campaign and patient outreach programs to drive market expansion and patient acquisition. "We are committed to growing the hair transplantation market," said Mr. McCollum.

When people start noticing their hair loss, they typically go online to search for information, Mr. McCollum continued. "In 2013, we generated over 27 million print and online ad impressions. We will accelerate this momentum by continuing to build upon our extensive search and print advertising campaigns. Anyone searching online in this category will find our information at the top of the search results page, driving them to visit our site and find a local ARTAS physician."

A recent poll by Restoration Robotics found that 9 out of 10 physicians using the ARTAS Robotic System report an increase in patient interest, Mr. McCollum shared. "Due to the dramatic increase in interest surrounding the

ARTAS Robotic Procedure, our website traffic has increased exponentially to 5,000 visits per week."

According to Dr. Bishara, "Since my adoption of the ARTAS Robotic System, my practice has grown from performing three to four hair transplantation cases per month to between 12 and 15 cases per month. To keep up with the patient demand, I decided to purchase my second ARTAS System a year later."

"In our experience, we have seen that ARTAS customers who perform as few as four procedures per month can pay off the robot in a year or less," Mr. McCollum advised. "Our case volume from 2012 to 2013 has quadrupled and we are seeing fantastic results so far in 2014."

For Dr. Turowski, Restoration Robotic's public relations efforts have impacted his practice. "They have always wanted to help us out in these ways, and I am happy to see they are now promoting the ARTAS Robotic System more thoroughly to the public and among physicians, too. The time seems right to do more to get the word out. At the outset, the company's marketing was geared around promoting physicians that use the robotic system, but now the outreach revolves around educating patients about the robotic technology itself."

Any time a company introduces a technology that is relatively new to the consumer the manufacturer bares a large majority of the burden to educate via public awareness and other campaigns. "Restoration Robotics has done exactly that," noted Dr. Bishara. "They have used cooperative advertisement agreements for more of the grassroots efforts, and have also taken on a large scale Google AdWords campaign for advertising the system and the procedure. Too many times, industry will focus just on the providers and leave it up to them to educate patients and the public on new techniques and technologies. However, Restoration Robotics is taking the lead in this case, and their efforts have led to a significant rise in patients asking for the robotic procedure."

The company's patient marketing program is a vital component for practice success, noted Dr. Feinberg. "The materials provided by Restoration Robotics are well thought out and professionally presented. Most important to me was the company's focus on Internet presence. While most of my patients were referred from traditional sources, such as other patients, physicians and barbers, the Internet has been the go-to medium for most people seeking information about robotic transplants. For example, a majority of my consults have come to me via the Internet."

"You will need all the help you can get when you're starting up something that is so new, unique and somewhat mysterious to most people," Dr. Feinberg

Before Tx

After ARTAS Robotic hair transplantation

Photos courtesy of Restoration Robotics, Inc.

Before Tx

After ARTAS Robotic hair transplantation

Photos courtesy of Gregory A. Turowski, M.D., Ph.D., F.A.C.S.

ARTAS Hair Studio

indicated. "Today, to make yourself visible in what has become a quite competitive environment you need professional assistance."

One goal of the company's outreach is to reel in physician skeptics, as more consumers learn about the ARTAS Robotic System and approach physicians with questions about it. "These physicians will be compelled to start buying into the concept of non-manual grafting," Dr. Bishara noted. "When you look at the skeptics you can scratch the surface and find out that there is usually some other type of fear motivating their behavior. This new technology needs to be truly embraced. Whenever you see such drastic game changing taking place in medicine and other fields as well, it induces a lot of fear. For instance, surgeons that are in different parts of their career and are not willing to convert, may feel that their craft is being lost or that all of their life's efforts have gone by the wayside. They feel like they are being replaced by something newer and better. But history has taught us that those courageous enough to be early adopters and embrace new things and new technology, are those that usually end up being laureates in the field."

Dr. Turowski agreed that the ARTAS Robotic System confronts the hair restoration surgeon with a radically new procedure and technology. "It makes sense that at first people would be somewhat skeptical. Though public awareness is a key to the success of this system, public perception and physician acceptance has also changed during the past several months for one other important reason," he said. "After two-and-a-half years of doing the procedure, I have demonstrated excellent results. We have the data and the before-and-after photographs to showcase to prospective patients that the procedure not only works, but works well."

ARTAS Hair Studio — New Product Launch

In addition to extensive global marketing support for practices, Restoration Robotics will also launch the ARTAS Hair Studio, which transforms the patient consultation experience and allows the physician to develop an individualized, personalized simulated aesthetic hair transplant design for their patient.

ARTAS Hair Studio enables physicians to create an onscreen photo-realistic three-dimensional (3D) model of the patient's head, Mr. McCollum explained. "You can turn the head around in any direction and see it from any angle. ARTAS Hair Studio also allows the physician to design the transplant, create a natural-looking hairline and demonstrate different levels of hair density," he stated. "It is an interactive tool that allows the physician to sit down with a patient and try out different simulations of what the patient's hair transplant could look like with varying numbers of grafts.

Setting appropriate patient expectations during the consultation will yield greater patient satisfaction."

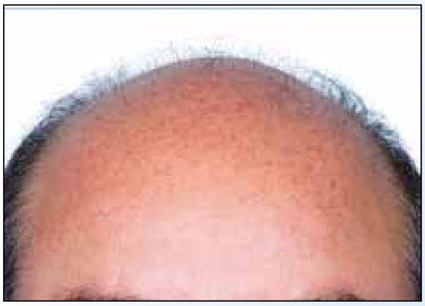
This new product will provide the patient with insight into what a hair restoration procedure can offer, Dr. Bishara advised. "In addition, the ARTAS Hair Studio turns out to be a great pre-operative planning device. Physicians will be able to easily predict the amount of grafts needed for a certain procedure. It is a superior integrated approach as well as an effective sales tool during the patient consultation. It should not extend the time of the consultation, rather it improves the quality of the consult, as well as the patient experience during the interaction with the physician."

For Dr. Feinberg, the new ARTAS Hair Studio impressed him enough to put in his order. Anything that can enhance a procedure that is already working so well, can only have a positive effect," he expressed. "The robotic system is very high-tech and that has been a strong selling point for many of my patients. Any improvement will create more interest from patients and acceptance as well. Also, for the 'techie' practitioner — and I speak as one of that species — these enhancements can be very stimulating and certainly a lot of fun."

The result of the company's effort, in part, will be that the public's perception of hair transplantation will move from older approaches to the ARTAS Robotic procedure. "There are some patients that definitely benefit from the strip procedure," noted Dr. Turowski, "but in my opinion if you have a choice of leaving a large scar on a patient's scalp versus no scar — or nearly invisible little scars — it is a pretty simple choice."

"Every surgeon who has one will tell you why they have it, and those that do not have one are going to tell you why they don't," said Dr. Bishara. "They will give you an excuse on why they have not purchased one. The fact remains is that it is worth making the switch to the next-generation. I think technology that a few years ago may have sounded very futuristic and unreal will become the new standard. Then, we will wonder how we lived without it."

Nevertheless, the thought process of arriving at that point varies depending upon the physician's orientation, Dr. Bishara added. "For surgeons that have been only doing hair, increasing productivity and clinical outcomes using this system can be beneficial and even allow them to expand their aesthetic offerings. As well, those who embrace the new and explore the ARTAS Robotic System, may ultimately be free to offer a wider scope of cosmetic surgery and other procedures, which can expand their business." ■



Before Tx

After ARTAS Robotic hair transplantation

Photos courtesy of Restoration Robotics, Inc.

Before Tx

After ARTAS Robotic hair transplantation

Photos courtesy of Gregory A. Turowski, M.D., Ph.D., F.A.C.S.

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ARTAS Robotic System Transforms Hair Restoration for Physicians and Patients

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"Fatigue and error are major contributors to transection, but the precision and accuracy of the ARTAS are unrivaled in terms of the human hand."

ARTAS Robotic System

By Desiree Ifft, Contributing Editor

As an FDA cleared, physician-controlled, computer-assisted technology for minimally invasive hair transplantation, the ARTAS Robotic System from Restoration Robotics (San Jose, Calif.) is a significant advancement in its field. Utilizing proprietary digital mapping and tracking technology, a minimally invasive dissection punch and an image-guided robotic arm, this system harvests follicular units from the patient's donor area, surpassing manual follicular unit extraction (FUE) in four crucial areas: precision, control, reproducibility and efficiency. In addition, it eliminates a major drawback associated with hand-held tools and automated hair restoration systems – physician fatigue.

The ARTAS Robotic System opens the field of surgical hair restoration to physicians willing to commit to mastering the art and science behind this in-demand service. By identifying and mapping the location of thousands of follicular units to be harvested in one session, and targeting them for dissection at the appropriate angle of approach, this system maximizes the likelihood of high-quality, transplantation-ready grafts and minimizes the transection rate. With the ARTAS System, the surgeon can adjust dissection settings, including puncture and coring depth, angle and speed, all without interrupting the procedure.

Providing a permanent, natural looking solution for hair loss that is safe and efficient, the ARTAS Robotic System transforms both the surgeon's and patient's experience. Unlike the strip harvesting approach to hair transplantation, the ARTAS procedure involves little or no discomfort. Patients can return to all of their normal activities in one to two days. Also, since there is no linear incision and resulting scar, they can continue to wear their hair in any length or style. Intelligent algorithms ensure the donor area maintains a natural appearance.

Mark Bishara, M.D., of Bishara Cosmetic Surgery & Hair Restoration in Mansfield, Texas, has used the ARTAS Robotic System for nearly 100 patients in a little over a year. In his experience it alleviates the repeated stress and strain on the surgeon's eyes and lumbar spine that are typically associated with manual FUE. "By eliminating operator fatigue, the potential for human error is reduced," he pointed out. "The robot simply does not tire."

Samuel Lam, M.D., of Lam Facial Plastic Surgery Center in Plano, Texas, agreed, noting that avoiding transection of the hair follicles is key to successful hair transplant. "Fatigue and error are major contributors to transection, but the precision and accuracy of the ARTAS are unrivaled in terms of the human hand," he said.

According to Gregory A. Turowski, M.D., Ph.D., F.A.C.S., medical director of New Horizons Center for Cosmetic Surgery and Medical Spa in Chicago, Ill., the ARTAS Robotic System is much more efficient than even an experienced surgeon using automated FUE. Experienced in using both automated and robotic FUE, he and his team prefer the robotic ARTAS System, which allows them to perform on average over 500 FUEs in an hour.

In Dr. Bishara's opinion, "Comparing automated FUE to ARTAS is like comparing apples and oranges. The automated FUE device is a hand tool guided by the physician who must rely only on his or her eyes to determine the appropriate angles of the individual hairs to be harvested. Conversely, ARTAS gives us real-time digital targeting down to the micron level and consistently harvests the hairs with its robotic arm to deliver healthy grafts every time."

Between 2008 and 2010 the worldwide market for hair restoration increased by 47.9%.* With this rapid growth, the ARTAS System is well-positioned to further expand the market. "Even patients who are not only thin shafted, but sparse in the universal donor area are now candidates for ARTAS Robotic Hair Transplantation," Dr. Bishara said. "In addition, now that a robot is used in the provision of this service, appropriately selected patients will enjoy a more widespread availability of hair restoration procedures that will not commit them to a linear scar, which for many of today's patients is considered aesthetically unacceptable."

Dr. Lam believes the introduction of the ARTAS System is helping to raise awareness of the latest solutions for hair loss that are available to patients. "The company is running direct-to-consumer ads, and a buzz has been created in the media," he said.

While purchasing the ARTAS System is a substantial investment for a practice, and the procedure cost for patients is considered relatively high, the market seems accepting. Today's patients are savvy, Dr. Turowski said. "They tend to research their options thoroughly and are willing to pay for solutions that provide true benefits and value."

Dr. Bishara agreed and compared it to other luxury items; "people are willing to purchase high-priced televisions if they want a high-definition experience, and televisions are far less permanent than a hair restoration procedure."

In Dr. Lam's practice, being able to offer the ARTAS procedure has expanded the hair restoration demographic to patients who would not have considered transplantation surgery otherwise. "Our business has tripled because of this," he said. "You have to be sure you will have a certain number of cases to justify bringing in the system, but the opportunity is there for someone who either doesn't perform hair transplantation at this time or wants to upgrade to a more sophisticated way of doing it."

For Dr. Turowski, his practice has achieved a favorable return on its ARTAS investment. "It helps to have a thriving practice to support it initially, including the necessary systems, such as marketing, personnel, etc., already in place," he stated. He views the ARTAS System as a technology that is moving both his practice and the field of hair restoration forward. "Poll results presented at a recent meeting of the *International Society of Hair Restoration Surgery* showed that a minority of transplantation procedures are currently FUE, but that is changing rapidly. I believe we are currently in a transitional period, where minimally invasive hair restoration procedures such as the ARTAS Robotic Transplant will explode," he shared. "This will be much like when there was resistance to new ways of performing liposuction, but eventually the older methods disappeared."

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Donor area before Tx

Donor area after ARTAS Robotic Tx
Photos courtesy of Restoration Robotics

Before Tx

After 900 grafts with ARTAS Robotic Tx
Photos courtesy of Restoration Robotics

Characteristics of robotically harvested hair follicles in Koreans

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Background: Recently, an automated robotic hair restoration device was developed and is increasingly being used for hair restoration.

Objective: We sought to analyze the hair follicles of Korean patients that were harvested by a hair restoration robotic device.

Methods: Data were reviewed from a total of 22 patients who underwent robotic follicular unit (FU) extraction hair restoration surgery at Seoul National University Bundang Hospital. Hair follicles collected from 3 grids in the central parts of the safe donor zone of each patient were analyzed.

Results: The total number of harvested FUs was 5213, and the total number of collected FUs was 4955. The average yield was 95.1% ± 3.5%. Among the 12,017 harvested hairs, 590 hairs were transected and the average transection rate was 4.91% ± 2.9%. FUs of double hairs made up the majority of harvested FUs (44.1%), followed by triple hairs (31.9%). The transection rate increases in FUs that contain multiple hairs.

Limitations: A relatively small sample size and lack of comparative study with conventional FU extraction modalities are limitations.

Conclusions: The robotic system qualifies for use in hair restoration surgery. It efficiently harvests not only single hairs but multiple hairs as well. (J Am Acad Dermatol http://dx.doi.org/10.1016/j.jaad.2014.07.058.)

Key words: androgenetic alopecia; follicular unit extraction; hair restoration surgery; robot; transection rate.

Hair is considered a major aspect of appearance, and consequently, hair restoration surgery for androgenetic alopecia has become an increasingly common procedure. The 2 main harvesting techniques for hair restoration surgery are follicular unit (FU) strip surgery and FU extraction (FUE). FU strip surgery produces grafts by excision of a linear strip of donor scalp with subsequent dissection to obtain individual FUs.[1,2] FUE is a harvesting method that extracts individual FUs using small and precise punches.[3] FUE has recently gained popularity because it offers many advantages over the strip method, such as the absence of linear scarring on the donor tissue, less pain, and shorter recovery time for the patient.[4] Furthermore, by using the FUE method, the exact number of hairs needed for hair transplantation can be harvested. However, FUE is still a time-consuming, technically difficult, and labor-intensive procedure for surgeons. An

Abbreviations used:

FDA:	Food and Drug Administration
FU:	follicular unit
FUE:	follicular unit extraction

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automated robotic hair restoration device was developed recently and received US Food and Drug Administration (FDA) 510(k) clearance on April 11, 2011. To date, there have been no published clinical data in peer-reviewed scientific journals using this robotic system to our knowledge. In the current study, the authors analyzed hair follicles harvested by the robot for hair restoration surgery in Korean patients.

METHODS

Robot system

The ARTAS robotic system (Restoration Robotics Inc, San Jose, CA) is an interactive, computer-assisted, and physician-controlled robotic system used for the FUE harvest. The robot system extracts individual FUs, one at a time, directly from a patient's safe donor area. The system is composed of a cart with a 6-axis articulated robotic arm (Fig 1, *A*). A needle mechanism is affixed to the end of the robotic arm to separate FUs from the scalp. The needle mechanism also houses stereo cameras and force sensors that guide the dissection and provide safety measures in real time. A specialized chair is used to position and stabilize the patient's head and body during the procedure.

The dissection system uses a needle-in-needle configuration in which a sharp bi-beveled needle (inner needle) is concentrically arranged within a blunt outer punch (Fig 1, *B*). A skin tensioner is integral to the dissection process (Fig 1, *C*). During a dissection, the inner needle makes a shallow scoring incision of 1 mm in diameter around the selected FU. The outer punch, which spins at between 400 and 800 rotations per minute, dilates the scoring incision and dissects deeper into the skin to separate the FU from the surrounding tissue. A suction system elevates the FU above the skin and thereby eases the extraction process. Stereo cameras and an image processing system are able to identify FUs on the scalp and precisely measure and calculate the angles and direction of each FU within its field of view. Imaging feedback allows the robot to dynamically track and harvest each hair even in the presence of motion caused by the patient's breathing and incidental head movements.

The details of the robotic procedure are as follows. The patient's hair in the donor area is shaved down to about 1 mm in length to reveal the FUs to be harvested. The surgeon injects a local anesthetic to numb the donor area. A tensioning device is placed over the area to be harvested to provide consistent skin tension. Optical targets are then established by the imaging system to guide the robot back and forth over the donor area as it dissects the follicles. Once the system is ready, the physician and assistant can initiate the dissection process. Generally, the robot determines directions and rotations per minute of the needle, and targets follicles to be extracted in a random pattern. However, the surgeons can optimize the dissection parameters, such as depths of the inner needle and outer punch and distance between harvest attempts, using a handheld remote control and a computer monitor. The surgeons also can choose follicles to be extracted or skipped in manual mode. After extracting FUs, the surgeon makes slits in the recipient area and the extracted follicles are inserted in the slits after proper processing. The patients are instructed to take oral antibiotics 2 hours before the surgery and for 3 days after the surgery for prophylaxis. The patients are also instructed to take oral acetaminophen and methylprednisolone to reduce pain and swelling until 3 days after procedure.

For this study, the ARTAS software, Version 4.8.2 (Restoration Robotics Inc) was used for harvesting hair follicles. We used the classic skin tensioner for this study: each dissection area (grid) defined by the classic skin tensioner is approximately 3.5×3.5 cm^2. The surgeon followed the distribution, direction, angle, and rotations-per-minute parameters, which were set automatically by the robot. The surgeon adjusted the depth of the inner needle and outer punch, and exercised the option of overriding the FU selection of the robotic system. To eliminate interoperator variability, the corresponding author conducted all of the surgeries and collected all of the analyzed hair follicles. The distance between harvested FUs was set to 1.9 mm.

Patients

A total of 22 patients who underwent robotic-assisted hair restoration surgery from September 2012 to March 2013 at Seoul National University Bundang Hospital with the robotic system were included in the current study. Medical records of the patients were reviewed after surgery.

CAPSULE SUMMARY

- Strip surgery and follicular unit extraction are 2 main harvesting techniques in hair restoration.
- The newly developed robotic device harvests multiple hairs with high yields and low transection rates.
- The robot harvests hairs efficiently, without the strip surgery's linear scar or time-consuming process of follicular unit extraction.

Fig 1. ARTAS robotic system (Restoration Robotics Inc, San Jose, CA). **A**, The system is composed of a cart with an articulated robotic arm and a specialized chair. **B**, Dissection system with a needle-in-needle configuration in which a sharp bi-beveled needle (inner needle) is concentrically arranged within a blunt outer punch. **C**, A classic tensioner. (Printed with permission from Restoration Robotics Inc.)

Table I. Demographics and clinical data of each patient

				No. of samples from 3 grids					
No.	**Sex**	**Age, y**	**Diagnosis**	**Punches**	**FUs**	**Hairs**	**Transected hairs**	**TR, %**	**Yield, %**
1	M	32	AGA	262	246	515	33	6.4	93.9
2	M	47	AGA	252	237	726	90	12.4	94.1
3	M	28	AGA	248	223	508	25	4.9	89.9
4	M	53	AGA	222	209	524	3	0.6	94.1
5	M	37	AGA	242	235	640	15	2.3	97.1
6	M	27	AGA	231	201	534	12	2.3	87.0
7	M	55	AGA	225	195	435	19	4.4	86.7
8	F	52	FTB	270	249	656	28	4.3	92.2
9	M	59	AGA	197	192	397	20	5.0	97.5
10	M	76	AGA	252	246	567	16	2.8	97.6
11	M	56	AGA	228	221	539	4	0.7	96.9
12	M	63	AGA	201	199	495	31	6.3	99.0
13	M	48	AGA	187	180	358	26	7.3	96.3
14	M	42	AGA	246	244	605	13	2.2	99.2
15	M	46	AGA	247	240	683	46	6.7	97.2
16	M	58	AGA	248	242	549	33	6.0	97.6
17	M	52	AGA	281	278	644	46	7.1	98.9
18	M	51	AGA	273	261	684	12	1.8	95.6
19	M	32	AGA	201	195	470	7	1.5	97.0
20	M	53	AGA	268	256	539	46	8.5	95.5
21	M	59	AGA	198	188	426	24	5.6	95.0
22	M	60	AGA	234	218	523	41	7.8	93.2
Total				5213	4955	12,017	590	4.9	95.1

AGA, Androgenetic alopecia; *F*, female; *FTB*, female-type baldness; *FU*, follicular unit; *M*, male; *TR*, transection ratio.

Evaluation

Typically, between 12 and 14 skin tensioner applications (grids) were required to harvest 1000 FU grafts. The superior border of the grids was set between the right and left reflection of the external ear and scalp. Hair follicles were collected from 3 grids (upper center, lower center, left lateral) to avoid variation between subjects, and were analyzed. This sampling method was performed on every patient and was meant to represent the harvest performance on the upper occiput, lower occiput, and lateral occiput regions of the scalp. As mentioned before, every follicle was collected by a single surgeon, and the follicles were analyzed under a microscope by 2 independent nurses. Yield was defined as the ratio of the number of collected implantable FUs to the number of total punches attempted. Transection rate was defined as the ratio of the number of hairs that are accidentally cut and damaged during the procedure to total hair count. In subanalysis, the

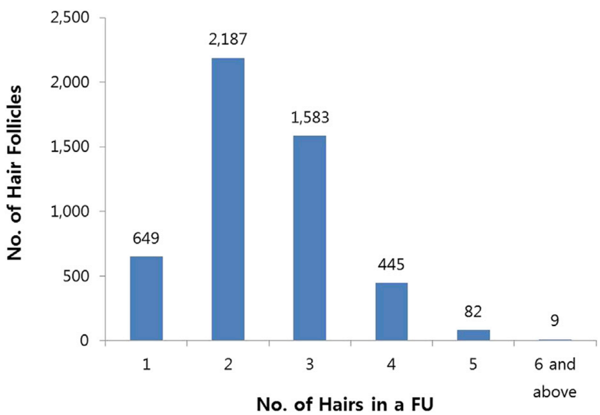

Fig 2. The number of hairs in a robot-harvested follicular unit (*FU*).

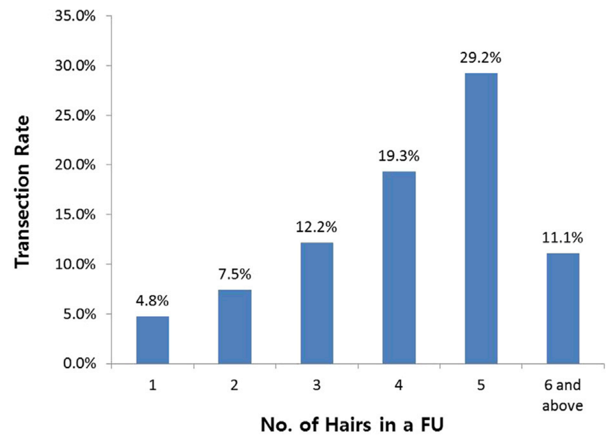

Fig 3. Transection rate according to the number of hairs in a follicular unit (*FU*).

multiplicity of FUs and the relationship between multiplicity and transection rate was assessed.

RESULTS

The mean age of patients was 49.4 ± 12.3 years. In all, 21 patients were male with androgenetic alopecia, and 1 patient was female with female-type baldness. The total number of attempted harvests for the entire study, including all 3 grids for each patient, was 5213, and the total FU grafts generated was 4955. The average yield was 95.1% ± 3.5%. Of the 12,017 harvested hairs with the FUs, 590 hairs were transected and the average transection rate was 4.9% ± 2.9%. Of the harvested hairs, 1244 (10.4%) were telogen hairs and 146 (1.2%) were vellus hairs. The average number of FUs per grid was 75.1 ± 9.1, and the average hair count per grid was 182.1 ± 32.6. Information for individual patients is presented in Table I.

The number of hairs in a robot-harvested FU ranged from 1 to 7, with an average of 2.4. As shown in Fig 2, of 4955 FUs, the majority were those containing 2-hair grafts (2187 FUs, 44.1%) followed by 3-hair grafts (1583 FUs, 31.9%). In all, 649 were single-hair grafts (13.1%) and 445 were 4-hair grafts (9.0%). In all, 82 were 5-hair grafts (1.7%) and only 9 were grafts of 6 hairs and above (0.2%). A total of 10.1% of robot-harvested FUs were partially or totally transected. Transection shows a tendency to correlate with multiplicity of hairs; 29.2% of quintuple hair follicles were transected, whereas only 4.8% of single-hair grafts resulted in transection (Fig 3).

No significant side effects or complications were detected during or after the surgery. There were no cases of infection or excessive scarring, and no patient reported severe pain.

DISCUSSION

Original FUE was performed manually using large (4-mm) handheld punches.[5,6] The size of the punch was gradually decreased to improve cosmetic outcome and survival of grafts. However, the handheld punches failed to gain universal acceptance because the procedure took too long to perform and was so laborious that the total number of hair follicles transplanted in a single surgical session was limited. Although motorized punch devices have been introduced recently, FUE is still a time-consuming, exhausting, and technically challenging job for surgeons and furthermore has a long learning curve. The FDA-cleared computer-assisted robotic system is used for the FUE harvest. It was developed to overcome some of the disadvantages of FUE.

In the current study, hair follicles collected from 3 grids in the central part of each patient's head were analyzed. The calculated yield was 95.1%. Some of the missing follicles had been drawn into the machine by the suction system, and others were uncollectable and remained attached to the scalp because of inadequate dissection. The transection rate by the robotic system in our study was 4.9%. In other studies conducted in the United States[7] and Japan,[8] the average transection rates were 8.0% and 5.9%, respectively. We attribute these differences to the variability of a patient's hair profile (eg, waviness, thickness, color) and the surgeon's minute control of the depth of punches. For example, we set the default puncture depth deeper (2.8-2.9 mm) than other studies (2.1-2.2 mm) (personal communication, James Harris, MD, Hair Sciences Center, Denver, CO, August 23, 2011). A comparison of the current study to these other 2 studies is presented in Table II.

The robot was also able to harvest FU grafts with multiple hair follicles. Two-hair grafts were the majority of harvested FUs (44.1%), followed by triple-hair grafts (31.9%). The average number of hairs in a harvested FU was 2.4, which is similar to the US study. This means that the robot harvesting

Table II. Comparison of data from 3 studies using ARTAS robotic system*

	Wasserbauer[7] (United States)	Kasai et al[8] (Japan)	Current study
Study size, no.			
Patients	33	42	22
FU samples	9062	33,516	4955
Characteristics of subjects			
Age, y	29-59	22-70	27-76
Sex	33 Male	40 Male and 2 female	21 Male and 1 female
Hair texture	Straight or wavy	Straight	Straight
Transection rate	8.0%	5.9%	4.9%
Range	(6.1%-10.9%)	(2.0%-12.0%)	(0.6%-12.4%)
No. of hairs/graft	2.4	N/A	2.4

FU, Follicular unit; *N/A*, not available.
*Restoration Robotics Inc, San Jose, CA.

procedure is quite efficient for multiple hairs as well. However, we should keep in mind that transection rate tended to increase according to the number of hairs within an FU; 29.2% of 5-hair grafts were transected partially or totally, whereas only 4.8% of single-hair grafts were transected.

There were no significant complications experienced during or after the surgery, such as infection or severe pain. There were also no side effects such as serious scarring or development of excessive contiguous holes.

Currently, strip surgery is still the most commonly performed hair restoration procedure by hair surgeons.[5] However, FUE is expected to become more popular following current trends that prioritize minimizing invasiveness. The robotic system remedies some of the major disadvantages of FUE by saving the surgeon time and labor, and reducing the learning curve.

The literatures include a few references about the time required for manual FUE. FUE operation time varies according to the surgeon's skill, total FUs needed, and the method of FUE used. In some articles, the authors reported the time needed for manual FUE ranged from 14.2 to 36 minutes to harvest 100 FUs,[9-11] which is significantly longer than our experience with robotic-assisted FUE, which is 6 to 9 minutes per 100 FUs.

The cost of this robotic system varies widely worldwide because of country-specific tariffs and taxes. In the United States, the system may cost over USD $265,000, depending on the product configuration.

To our knowledge, this is the first assessment of robot-harvested hair follicles. We believe these data will be beneficial for hair restoration surgeons, especially current users of the robotic system. Further investigations are still necessary, including studies using a larger sample size and longer-term follow-ups, to fully understand the transection rate of robotically harvests FUs. Furthermore, because this is a noncontrolled retrospective study, a comparative study with conventional FUE, mechanical hand engine, or mechanical pump should be conducted.

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Commentary on Robotic Follicular Unit Extraction in Hair Transplantation

In their excellent article, "Robotic Follicular Unit Extraction in Hair Transplantation," Avram and Watkin[1] give a review of the salient aspects of the newly evolving field of robotic hair transplantation. A significant contribution of this article is the data on transection rates. The authors found that the mean transection rate of robotic extraction is 6.6% in their 20 cases. This compares favorably with manual extraction techniques. They stress the need for well-designed long-term studies comparing the various harvesting techniques currently being used.

The authors, who perform both follicular unit transplantation (FUT) and follicular unit extraction (FUE) in their practice, point out that robotic FUE is an additional option for donor harvesting in patients who would like to be able to wear their hair short, or just prefer not to have a linear scar on their scalp. They still see a role for both types of procedures but note that FUE has expanded the number of male patients eligible for a hair transplant procedure, particularly younger patients.

It is important to stress that long-term planning in FUE can be complex because of the need for a donor area significantly greater in height than with traditional FUT strip surgery. This is a particular challenge in younger patients—the population most interested in wearing their hair short and who would benefit most from extraction. In younger patients, the long-term size and stability of the donor area is difficult to predict, even after a careful assessment of donor miniaturization using densitometry. With time, the candidacy of a patient for FUE can more easily be determined.

The field of robotic hair transplantation is changing so rapidly that even as this article is going to press, significant changes are occurring in the existing technology. For example, the newest robotic system has 2 punch-width options to accommodate different hair shaft diameters. It also has a larger tensioner and can harvest grafts about 20% more quickly. Both of these modifications contribute to a shorter total extraction time. The physician is also now able to program the robot to select out the larger follicular units to minimize wounding and to more closely mimic what is generally done using a hand-held device.

Before the end of the year, the robotic system will be able to create recipient sites. With this technology, the doctor delineates the surgical plan directly on the patient's scalp. This is photographed and converted to a 3D computerized model of the actual patient. Using the software, the physician then specifies the angle, direction, density, and randomness of the recipient site incisions, which can be made at a rate of up to 1,500 sites per hour.

As the authors state, the appeal of robotic FUE is part of the "inexorable trend" toward minimally invasive surgical procedures. As with any new technology, it is up to the practicing physician to make sure that it is used appropriately and to the maximum benefit of our patients.

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New York, New York

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Folliclular Unit Extraction Using Robot System (Artas™) in Asian

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[2] *Mojerim Hair Clinic, Seoul, Korea*

Introduction

- **Follicular unit extraction (FUE) provides many advantages over strip**
  - **absence of linear scar, much less pain, short recovery time.**
  - **But, time-consuming, technically hard job for surgeons.**
- **ARTAS™ system : Interactive, computer-assisted, physician-controlled robotic system used for the FUE harvest.**
- **There's no data for robot harvested follicles.**

Materials and Methods

- **22 patients who underwent FUE hair restoration surgery in SNUBH with ARTAS™ system. (Software version 4.8.2, Restoration Robotics, Mountain View, CA, USA)**
- **Analyzed all hairs from first 3 harvested grids from same standard sites were selected for analyze, to minimize variations in the patients.**
- **Follicular Unit Numbers(FUs), Hair Numbers, Transection rate(TR), Yield, and others were calculated.**

Results

- **Mean age : 49.4 ± 12.3 years old**
- **Yield of Harvest : 95.1%**

(Total Punch : 5,213, Collected FUs : 4,955)

- **TR : 4.9%**

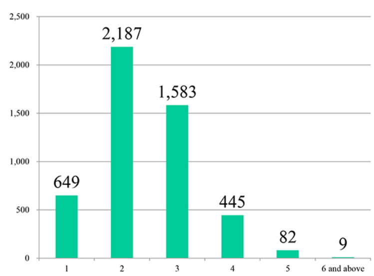
(Total Hairs : 12,017, Transected Hairs : 590)

- **Telogen Hairs : 1,244(10.4%)**

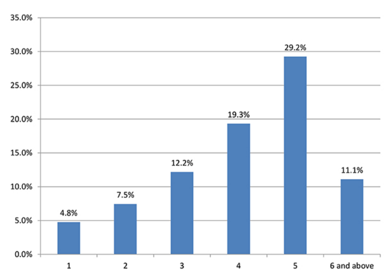
Vellus Hairs : 146(1.2%)

- **Average FUs/Grid : 75.1 ± 9.1**
- **Average Hairs/Grid : 182.1 ± 32.6**

- **Sub-analysis of Robot Harvested FUs**
  - **Hairs in a FU are variety : 1~7 hairs in a FU**
  - **Double hairs were majority (44.1%), and then triple follows(31.9%).**
- **Sub-Analysis of Transected FUs**
  - **10.1% of Robot Harvested FUs were transected.**
  - **Quintuple (29.2%) Vs. Single (4.8%)**



Sub-analysis of Robot Harvested FUs



Sub-Analysis of Transected FUs

- **No significant side effect or complication was detected during and after the surgery.**

Conclusion

- **Robot Harvesting System with ARTAS™ is good enough for hair restoration surgery.**
  - **Low TR and High Yield**
- **It Harvest multiple hairs, efficiently. But, TR is higher in multiple hairs than single hairs.**

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Robotic Follicular Unit Graft Selection

Robert M. Bernstein, MD* and Michael B. Wolfeld, MD†

BACKGROUND The use of robotic technology to harvest grafts in a follicular unit extraction (FUE) hair transplant procedure has been available since 2011. A new capability of the robotic system is to harvest follicular units based on the number of hairs they contain to increase the hair/wound yield.

OBJECTIVE To assess the benefit of follicular unit graft selection during a robotic FUE procedure.

MATERIALS AND METHODS This bilateral controlled study of 24 patients was designed to evaluate the ability of a robotic system to perform follicular unit graft selection.

RESULTS Compared with random follicular unit harvesting (the method performed by current robotic systems), robotic follicular unit graft selection produced more hairs per harvest attempt (2.60 vs 2.22) and more hairs per graft (2.72 vs 2.44). The clinical benefit of follicular unit graft selection (as measured by the increase in hairs per harvest attempt) was 17.0%. The clinical benefit (as measured by the increase in hairs per graft) was 11.4%. Results were statistically significant at $p < .01$.

CONCLUSION This study demonstrates the ability of robotic follicular unit graft selection to increase the amount of hairs yielded per donor wounds made in an FUE procedure.

The investigators hold equity interest in Restoration Robotics, Inc. In addition, R. M. Bernstein is a medical consultant to the company and is on its medical advisory board.

After years of relatively slow adoption since its introduction into the medical literature in 2002,[1] follicular unit extraction (FUE) is experiencing unprecedented growth. In 2006, FUE represented only 7.4% of all hair transplant procedures performed worldwide with a growth rate of a mere 0.4% over the 2-year period 2004 to 2005. By 2014, 48.5% of all hair transplant procedures were performed using FUE, with a biannual growth rate of 16.3%. This represents a 40-fold increase in growth over the earlier period.[2]

The first robotic follicular unit extraction (R-FUE) procedures were performed using the ARTAS system in late 2011, with only a handful of cases that year.[3] By 2014, 12.6% of all hair transplants and 26% of all FUE cases were performed using automated devices.[2] With the use of robotic devices increasing so rapidly (3 systems operating in 2011 and over 120 worldwide in 2015) (C. Holland, written communication, 2016) the interest in robotic technology has expanded from researchers and a few physician–early adopters to all those involved in surgical hair restoration.

Over the 5-year period since its introduction, robotic technology has advanced dramatically, with new systems being far more nuanced and user-friendly and having transection levels that continue to improve.[4] A significant limitation of the robotic system, however, has been its inability to select follicular units (FUs) while harvesting—something that is done intuitively when FUE is performed by the human hand.

When FUE is accomplished manually, the doctor visually chooses larger FUs to maximize the amount of hair harvested through the smallest number of recipient wounds. The current iteration of the robotic system used for FUE (ARTAS) randomly selects FUs irrespective of their hair content.[4,5] A new

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capability of the robot is to select FUs based on the number of hairs they contain to increase the hair/wound yield when harvesting FU grafts. This article examines the new technology for R-FUE and presents data from a bilateral controlled study, designed to evaluate its benefits.

In robotic FU graft selection, the discriminatory features of the robotic optical system are used to identify the hair content of each FU and then an algorithm is used to automatically select the desired larger FUs for harvesting. The technology has the ability to preferentially select FUs of 2 or more hairs (enable mode). This study examines the effects of skipping only 1-hair FUs as these have the lowest hair-to-wound ratio, they are the easiest for the robot to select optically, and skipping 1-hair FUs does not significantly decrease the total yield (number of hairs).

In follicular unit transplantation (FUT) through strip harvesting, the entire harvested tissue is used; therefore, the number of hairs/graft will be approximately the same as the ratio of hairs per FU that occurs naturally on a person's scalp (i.e., on average approximately 2.2–2.4 hairs/FU). Most hair transplant procedures are designed with this in mind.

In FUE, the benefit of FU graft selection is to obtain the maximum amount of donor hair through the smallest number of donor wounds. When performed efficiently by robotic FU graft selection, the resultant number of hairs per graft produced can often exceed what is needed for a specific hair restoration procedure. For example, at 2.7 hairs/graft, the FUs are too large for all of them to be transplanted intact. In this case, there may be too many 4-hair units for a natural distribution and too few ones for the hairline.

In these cases, the doctor can (1) program the robot to be less specific, (2) make a "second pass" to harvest additional 1-hair grafts, or (3) use stereomicroscopic dissection to divide the largest FUs into smaller ones. In all 3 scenarios, the hair-to-wound ratio (most hair per recipient wound) can still be superior to randomly selected FUs.

The robot can be programmed to skip as many 1 s as possible, even at the expense of significantly limiting the number of grafts per field (high setting), or skip only some 1 s in order not to substantially reduce the total number of grafts harvested (low setting). The low setting also operates at a slightly faster speed than the more discriminatory high setting. This study uses the algorithm that skips as many 1 s as possible (high setting). At present, the discriminatory ability of the robot is imperfect and some 1-hair grafts still appear, even in the high setting.

Another variation of FU graft selection is a "2-pass" technique (2-pass enable mode). In the first pass, the doctor harvests all FUs that contain more than 1 hair (using either the high or low setting described above) and in the second pass, the robot automatically goes back and harvests any 1 s skipped in the first pass. This may be important in situations where the physician desires to harvest the maximum amount of grafts in a given area or to maximize the total grafts for the procedure. Another indication would be for patients with a large number of 1-hair grafts, such as Asians, for whom skipping all 1 s would yield too few grafts.

Although initially it may be counterintuitive, the 2-pass technique yields higher hair content than if FUs were randomly selected. The reason is that selecting a 1-hair graft on the first pass can block the robot from harvesting a larger FU in close proximity since a minimum distance (generally 1.7 mm) is required between harvests (Figures 1 and 2). This study looks at both the first and second passes of a 2-pass technique and compares it to random FU graft harvesting (disable setting).

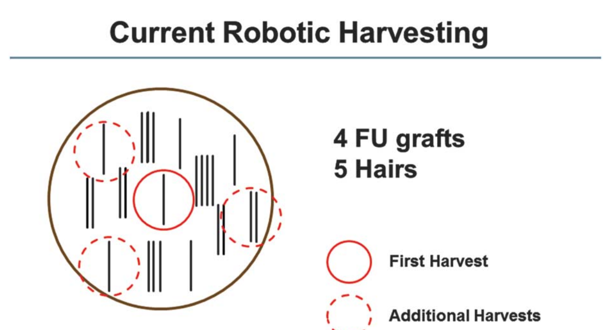

Figure 1. Random graft harvesting.

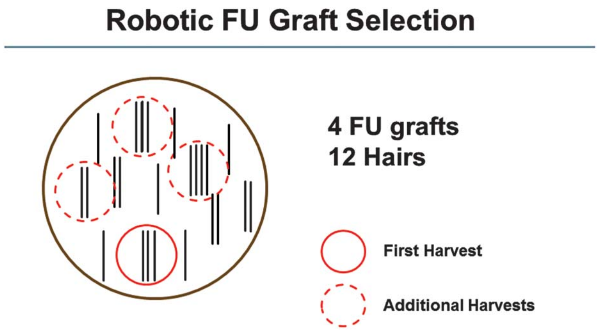

Figure 2. Selective graft harvesting.

Figure 3. Donor area showing experimental design.

Materials and Methods

This study was performed on 24 first-time hair transplant patients undergoing R-FUE for androgenetic alopecia. The ARTAS robotic system (version 7.x) was used for graft harvesting. A 19-gauge dual-punch system was used, which consisted of a 0.9-mm (internal diameter) sharp punch and a 1.1-mm (internal diameter) dull, punch rotating at 3,000 rpm. The donor sites were spaced a minimum of 1.7 mm apart.

The study used a bilateral controlled, randomized design. On the experimental side, FUs were harvested using a high selection setting and a 2-pass technique (enable mode). On the control side, FUs were selected randomly (disable mode). A 3 × 3 cm skin tensioner with fiducial markings was used to stabilize the skin and allow the robotic device to create 4 non-overlapping harvested areas (of approximately 2 × 2.5 cm) on each side (Figure 3). After the doctor examined the results of the study and control areas, the remainder of the harvesting was completed using the algorithm that best suited the needs of the patient.

The measurements include the number of harvest attempts (HAs), the number of grafts, and the number of individual hairs. Hair and graft counts were made using a Meiji stereomicroscope at ×10 resolution. The calculated values were hairs/HA and hairs/graft.

The study measured the percent change (increase) in hairs/HA after one pass of the 2-pass algorithm compared with the random (disabled) mode and the percent change (increase) in hairs/HA after the 2-pass technique compared with the random (disabled) mode. The same calculations were performed for hairs/graft. Any percentage increase of either the one pass or 2-pass techniques over the random mode, with respect to hairs/HA and hairs/graft, was considered to represent the "clinical benefit" of FU graft selection.

Results

Results showed that, compared with random FU harvesting (disable mode), robotic FU graft selection produced more hairs per HA (one pass 2.60 and total for 2 pass 2.50 vs random 2.22) and more hairs per graft (one pass 2.72 and total for 2 pass 2.60 vs random 2.44). Results were statistically significant at $p < .01$ using an unpaired 2 sample *t*-test (Figures 4 and 5).

The clinical benefit of FU graft selection (as measured by the increase in hairs per HA) after one pass compared with the random mode was 17.0%. The clinical benefit of the 2-pass technique compared with random harvesting (disable mode) was 12.3%. The clinical benefit (as measured by the increase in hairs per graft) after one pass compared with the random mode was 11.4%. The clinical benefit of the 2-pass technique compared with random harvesting (disable mode) was 6.4%. Results were statistically significant at $p < .01$ using an unpaired 2 sample *t*-test (Table 1).

Discussion

Follicular unit graft selection allows the clinician the ability to select larger FUs during the harvest phase of an FUE procedure to maximize hair content

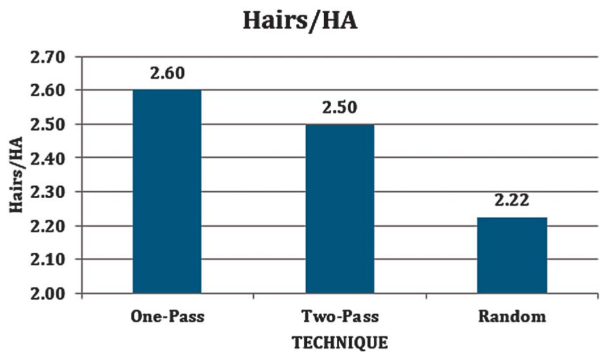

Figure 4. Hairs per HA.

and minimize wounding. Until now, this technique could only be performed by hand. The new functionality of the robotic system allows the automation of this important aspect of FUE and provides more versatility to the robotically performed hair restoration procedure.

The successful application of robotic FU graft selection is predicated on the team's skill in stereomicroscopic dissection. Ironically, this is a skill that is best developed from years of dissecting donor strips (i.e., expertise in FUT). In all cases of FUE, it is incumbent on physicians to train their staff in stereomicroscopic dissection to trim, count, and sort the FU grafts accurately. When the technique of FUE graft selection is used to minimize donor wounds, the same skills are required to divide the grafts atraumatically into smaller units or single hairs. Of course, this is a challenge for doctors who perform any of the FUE

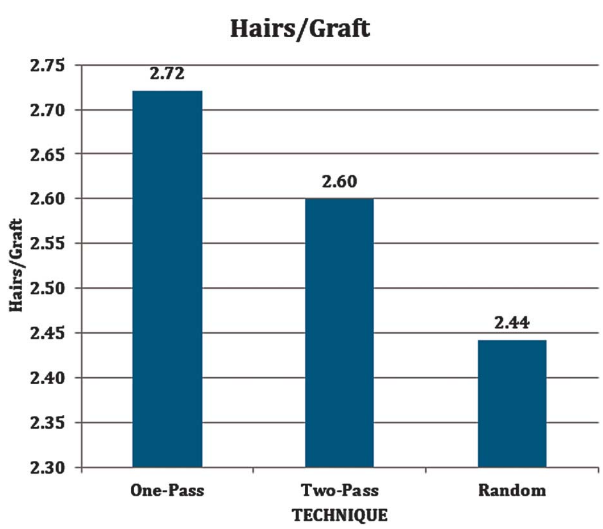

Figure 5. Hairs per graft.

Table 1. Clinical Benefit

	One Pass vs Random, %	*Two Pass vs Random, %*
Hairs/HA	17.0	12.3
Hairs/graft	11.4	6.4

techniques (manual, motorized, or robotic) to the exclusion of FUT and, therefore, these authors recommend that a physician and his team be skilled in both types of procedures.

In this study, the initial pass of the 2-pass technique (in a high setting) yielded a hairs/graft content of 2.72. This is significantly greater than the approximately 2.2 to 2.4 hairs/graft generally needed for a hair transplant. If one dissected the FU grafts of 4 hairs or greater, into 2-hair and 3-hair grafts, the hair/graft count can be reduced to the normal 2.24 hairs/graft. In this example, the total number of grafts would be increased by 21%, without increasing the number of donor wounds.

The higher number of hairs per graft (that exceeds the natural average) necessitates that a portion of the larger grafts are dissected into smaller grafts, both to be able cover a larger area of scalp and to generate enough 1-hair grafts for the frontal hairline. For the patient to benefit from this technique, the staff must thus be facile in stereomicroscopic dissection. Since dividing FUs involves some potential risk to the viability of FU grafts, the physician must decide the risk versus reward benefit of this technique on a case-by-case basis.

Another thing to consider is the nature of the FUs harvested. For example, a compact 3-hair FU should rarely be subdivided, whereas the patient who wears his hair short and has significant hair loss will almost always benefit from dividing loose, 4-hair units into two 2 s, or dividing 5-hair "follicular unit families" into 3 and 2 s.[6] In the authors' practice, decisions on FU dissection are made based on the patient's needs and real-time feedback during the dissection regarding the quality and composition of that patient's grafts.

With the one-pass algorithm, the number of harvests per unit area is approximately 10% to 15% less than with random harvesting. With the 2-pass algorithm, the number of harvests per unit area is approximately 5% to 8% less than with random harvesting.

The time required to process a grid is slightly increased when using the FU graft selection algorithm. With the 2-pass algorithm, after the first pass, the robotic arm takes approximately 5 seconds to return to the start position for the second pass. In addition, the harvesting speed of the second pass is a bit slower because the 1-hair grafts harvested during the second pass are more spread out and, therefore, the arm has a slightly further distance to travel between harvests. This adds an additional 10 seconds to an average grid. For a 2,000-graft procedure (approximately 20 grids), the total additional time for the 2-pass algorithm compared with the random harvesting of an equivalent number of grafts is approximately 5 minutes for the entire procedure ([5 seconds +10 seconds] × 20 = 300 seconds).

Follicular unit graft selection will have the potential to deplete the donor area more rapidly than random graft selection. The authors have found that setting a minimum distance between harvests of 1.7 mm insures that the area will not be overharvested, regardless of the patient's density and hair characteristics (as long as they are candidates for FUE). This distance is generally increased for the second hair transplant session, depending on how the patient looks clinically (the authors wait a year between sessions if the same area is accessed) and how short he wants to wear his hair. In the authors' experience, a third session in the same area is generally not possible.

The data presented in this study are from the third iteration of this technology. Each modification has increased the specificity of the graft selection and further improvements are in progress. As the technology evolves, the clinical benefit of graft selection (i.e., the amount of hair yielded compared with the number of donor wounds made) should continue to increase.

Robotic FU graft selection allows the clinician 2 main capabilities to maximize the hair content of the FUs for specific cosmetic purposes that need high density (e.g., increased density of forelock) and to dissect these FUs microscopically to create a greater number of grafts using the minimal number of HAs.

Since the introduction of robotic FUE in late 2011, a number of significant advances have been made in R-FUE technology. These include an improved optical system, refinements of the punch design, smaller punch sizes, faster punch rotation, a simplified user interface, and recipient site creation.[7–9] Robotic FU graft selection is another advance in the ever-evolving robotic system that continues to make the FUE procedure more accurate in the hands of clinicians and more beneficial to patients.

Acknowledgments The algorithms used to perform the robotic functions used in this study were developed by Gabe Zingaretti, PhD, at Restoration Robotics, Inc., San Jose, CA. Statistical analysis was performed by Natalie J. Suder, Tulane University, New Orleans, LA.

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ROBOTIC, AI-ASSISTED FOLLICULAR UNIT EXCISION AND IMPLANTATION FOR HAIR RESTORATION WITH ARTAS® IX

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INTRODUCTION

Medical robotic systems are assisting an increasing number of surgical procedures across multiple medical specialties. In 2011, the first robotic platform for hair transplantation was introduced, enabling follicular unit excision of hair grafts (ARTAS, Venus Concept Inc, San Jose, CA). Recently, a new robotic system was developed that, in addition to harvesting follicular units, also creates recipient sites and implants grafts. (ARTAS iX, Venus Concept, San Jose, CA).

Robotic hair transplantation allows for electronic visualization of the harvest and recipient areas, contains an Artificial Intelligence algorithm that helps in optimizing the procedure, but perhaps most importantly, allows for repeated preciseness of excision and implantation with no reduction in quality as can happen with increasing physician fatigue in manual hair transplantation. Furthermore, less graft handling is necessary, which limits the chance of damage to the follicle.

OBJECTIVE

The objective of this case study was to evaluate the use and efficacy of the new robotic ARTAS iX System in both harvesting and implantation of follicular units in hair transplantation surgery.

METHODS

A 46-year-old male with light brown straight hair presented with androgenic alopecia, Norwood Grade 3, and elected to undergo a Follicular Unit Extraction (FUE) hair transplantation procedure using the ARTAS iX System (Fig. 1). The study protocol was received IRB approval.

The patient was prepped and given the standard anesthesia protocol, which includes a ring block for the harvest area and a supraorbital nerve block followed by a ring block for the recipient area. The physician created a 3-D preoperative plan design using the ARTAS Hair Studio graphical user interface. This graphical user interphase allows the physician to customize the harvesting and implantation parameters.

Fig. 1 ARTAS iX System

VERO HAIR | ARTAS® iX ROBOTIC HAIR RESTORATION

For the harvesting procedure, a tensioner was placed on the scalp to provide uniform skin tension and fiducial guidance for the robot. Using machine vision image guidance, and following the device AI established treatment algorithm, the system excised predetermined individual follicular units with a combination of a 1.0mm needle and rotating coring punch (Fig. 2a). The grafts were harvested, counted, trimmed, and placed in linear cartridges of 25 grafts each. The cartridges were then loaded individually into the implantation mechanism of the system. Temporary fiducial markers were applied around the recipient area of the scalp spaced 2-3cm apart. A tensioner was also used to provide tension on the scalp skin during the implantation procedure. Using a 0.9mm (19G) implantation needle and “stick and place” technique, the ARTAS iX implanted the grafts by simultaneously creating a recipient site (Fig. 2b) and inserting a graft from the cartridge according to the digital plan prescribed by the physician. After the treatment, the patient was discharged under standard protocol, and returned home. The patient returned for follow up photographs 12 months after the procedure.

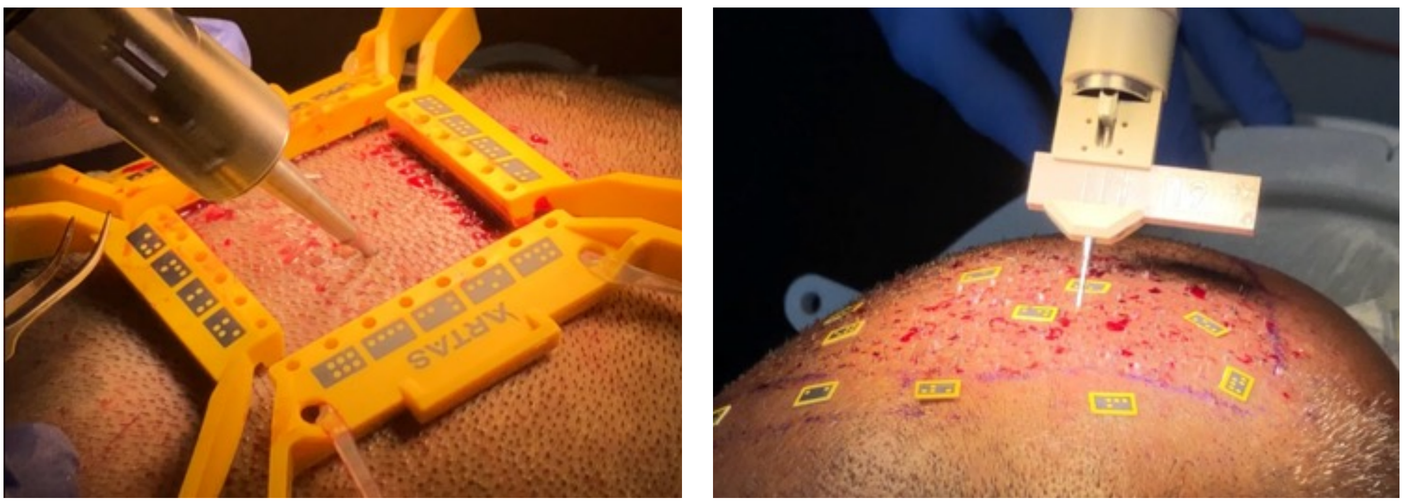

Fig. 2 a) ARTAS iX excising an individual follicular unit. b) ARTAS iX creating a recipient site and inserting a graft from a loaded cartridge.

RESULTS

During the transplantation procedure, 2412 follicular unit grafts containing 5910 terminal hairs (average of 2.45 hairs/graft) were harvested from the patient's donor area using the robotic system at an average harvesting speed of 1093 grafts/hour, with peaks as high as 1318 grafts/hour. The total harvesting time was thus just over 2 hours long. Thereafter, the grafts were implanted robotically at an average rate of 468 grafts/hr., with peak rates at 794 grafts/hour for a total implantation time of approximately 5 hours. No adverse events or post-operative complications were reported. The patient returned for follow up, up to 12 months after the procedure (Fig. 3).

Fig. 3 Photographs before (left) and 12-months after (right) the hair transplant procedure using the ARTAS iX Robotic System.

DISCUSSION

Manual FUE is a widely used and clinically proven technique in hair transplantation. However, the procedures are often long and require thousands of precise repetitive motions to accurately excise and implant individual grafts. Fatigue can cause pain and discomfort for the clinician,[1] and potentially lead to human error and higher transection and reduced yield rates,[2] particularly towards the end of long cases. Furthermore, manual implantation requires a significant amount of graft handling at the bulb of the hair follicle. Given the relative fragility of the follicles, increased handling can lead to a higher risk of damaging the follicle.[3] The amount of handling and hence opportunity for the graft to be damaged is limited with the use of the robotic implanter. Use of an image-guided, AI controlled robotic system, such as the ARTAS iX to assist in the procedure, addresses many of the physical limitations of human vision, decision of the location from which to excise or where to implant, physical fatigue, and motor skill precision. At the same time, ARTAS iX produces comparable 12-month results to those achieved using manual techniques by an experienced surgeon. The stick and place method of implantation used by ARTAS iX (placing the graft immediately after incision) reduces bleeding, and eliminates the need for continual cleaning of the recipient sites of blood as is common when sites are premade.[4],[5] With no fibrin occluding the recipient site, it is smoother and softer potentially improving graft acceptance. Issues such as leaving empty holes or placing two grafts in the same hole and/or planning errors such as making more holes than available grafts are non-existent.[4]

Minimizing the amount of overall operative time is of interest to both the patient and the physician. ARTAS iX was able to excise hairs at a rate of 1093 grafts/hour which is at the top of the range possible by an experienced surgeon doing a manual hair transplant. Typical excision rates vary between 100-1000 grafts/hour for the manual method. The implantation rate was 468 grafts/hour, which is significantly faster than manual stick and graft or separated needle stick and graft placement rates of about 371 grafts/hour.[6]

This case study demonstrates that the ARTAS iX can provide clinically efficient surgical workflows that are superior to manual techniques, with the potential to reduce total case time for FUE procedures, while at the same time reducing graft manipulation thanks to the stick and place technique used by the device.

CONCLUSION

The ARTAS iX System is a novel robotic hair restoration platform that provides safe, effective, and clinically efficient follicular unit harvesting and implantation functionalities.

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Robot-Assisted FUE May Be The Future Of Hair Transplantation

James A. Harris, M.D., F.A.C.S., principal investigator for Restoration Robotics, explains why

For years, robots have been the stuff of comic books, fantasy toys and science fiction movies. But today, they are very much a part of modern medicine.

In spring 2011, a robot developed by Restoration Robotics in Palo Alto, California was cleared by the FDA for hair transplantation. Men and women may be aware of other medical robotic systems such as the da Vinci and Sensei Robotic Catheter System, but this is the first time a robot has been applied to the delicate and painstaking task of identifying and extracting individual follicular units for hair restoration surgery.

The research took over 5 years and required the talent of computer scientists, mechanical engineers and hair restoration surgeons, not to mention some very deep pockets.

In a recent article published in Hair Transplant Forum, *doctors Miguel Canales and David Berman estimated that over 45% of all prostate cancer surgeries in the United States are performed using the robotic da Vinci surgical system. Could the hair transplant industry embrace robotics with the same enthusiasm? To find out,* The National Hair Journal *talked with James A. Harris, MD, one of the lead researchers in the development of the ARTAS™ hair restoration system and himself a distinguished hair transplant surgeon.*

NHJ: Dr. Harris, every day our lives are being influenced by automated devices and technologies we could not have even imagined only a few years ago. Most of us are aware of computer-assisted surgery, and robotically-assisted surgery, but we probably did not realize just how far this technology has progressed.

As the new robots have become more sophisticated, they have even been given human names. There is the famous “da Vinci product,” the “Acrobot” that shapes bone, and, reflecting the importance of women in medicine, a “Sofie” robot developed by the Eindhoven University of Technology in Europe. Just to keep in tune with Hollywood, there’s even a “Robodoc” for orthopedics. Your robot doesn’t have a nickname yet, but is part of the “ARTAS System.” Did you help select this name?

JH: I was not involved in naming the robot, but the company wanted to create an identity that had multiple meanings or significance. They wanted something that would communicate artistry and technique along with advanced technology.

NHJ: Since we're giving the robot an identity, I have to ask what it looks like? Does it have a human form or is it simply a device?

JH: That's a good question. It does not have a human form, per se, but it does have some human characteristics. For instance, there is an arm that sits upon a controlling box. The arm is maybe twice the size of a human arm, and the working part of the apparatus, the actual part that does the dissection, is a little bit smaller than a shoebox. The control unit itself is the size of two small refrigerators put together. The place where the patient sits looks like a technologically advanced massage chair and is designed to align the patient in the correct position for the robotic application. It also keeps them comfortable for the duration of the procedure.

NHJ: What was the driving force behind the development of the ARTAS™ System?

JH: There were several forces. The first one was patient-driven. There was a new hair transplant technology, follicular unit extraction (FUE) that was becoming popular. More and more patients were requesting this procedure, but it was time consuming and required tremendous precision and dexterity. This conundrum provided an impetus, or at least an opening, for someone to ask, "Can I (or we) fill a need here?" The second factor was the lack of technology in the hair restoration field.

Follicular unit extraction is not complex, but it is a procedure that requires a high degree of eye-hand coordination. To become adept at this procedure a physician must spend a significant amount of time practicing to become proficient. The FUE procedure doesn't lend itself to being easily adopted into a lot of physicians' practices. So these two forces – people wanting this procedure, but a lack of physicians being able to provide it – created an opening for a new technology that would allow an average physician to perform follicular unit extraction in an efficient, safe manner and meet patient demand.

NHJ: Restoration Robotics is located in Palo Alto in the heart of Silicon Valley. Is that because that is where technology comes from, or because that's where the venture capitalists live?

JH: It's just happenstance. The chief technological officer, Mohan Bodduluri, was there in Silicon Valley, and he is one of the founders of this company. It's an area known for its great thinkers and its scientific expertise, so I think it seemed to make sense to keep it there.

NHJ: What precisely is the ARTAS System robot able to do?

JH: It is extremely adept at assisting the physician identify, target and perform the dissection of follicular units from a patient's scalp.

NHJ: Let's pretend I'm a medical assistant assisting with hair transplantation. Should I be applying for another job, or is my career safe?

JH: Your career is safe. The ARTAS System may actually help you broaden your horizons. Medical assistants have been confined to certain aspects of hair restoration – the implantation and dissection of grafts, and so forth – but this adds a whole new level of expertise. I rely heavily on my assistants to help me, and they're now being trained in robotic control, manipulation of the hardware to change out the disposable equipment, removing grafts and assisting in logging the numbers of hairs per graft. So the ARTAS System is actually dependent on the medical assistant and it is broadening their role in the practice.

> **"With the ARTAS System, I can show a doctor how to perform the surgery using this new technology in about 20 minutes, and they can become relatively proficient in less than an hour."**

NHJ: Do you see it as a complementary device or a replacement device in your surgery?

JH: Definitely complementary. I've been doing follicular unit extraction for over eight years and I find it is actually helping me perform that surgery better. It's been built on the experience I've accumulated over eight years in terms of analyzing a patient's donor area, making decisions about angles and directions, and using eye-hand coordination to apply the dissecting tool to the scalp. ARTAS System assistive technology is very accurate and precise and that allows me to use my skills and judgment in other areas. It's freed up a lot of time as well as mental and physical energy. Doing three or four hours of extractions by hand is physically demanding.

NHJ: So, the patient gets the best of artistry and precision, while you stay fresh and alert.

JH: That's absolutely correct. That's certainly one of the major advantages of using this type of assistive technology. But remember, the robot is not making decisions on its own. It's drawing on our experience, then using its technology – its vision systems, its algorithms and the computers – to make accurate assessments of the hair follicles and their emergent angles very quickly and then apply a dissection tip to dissect the grafts out.

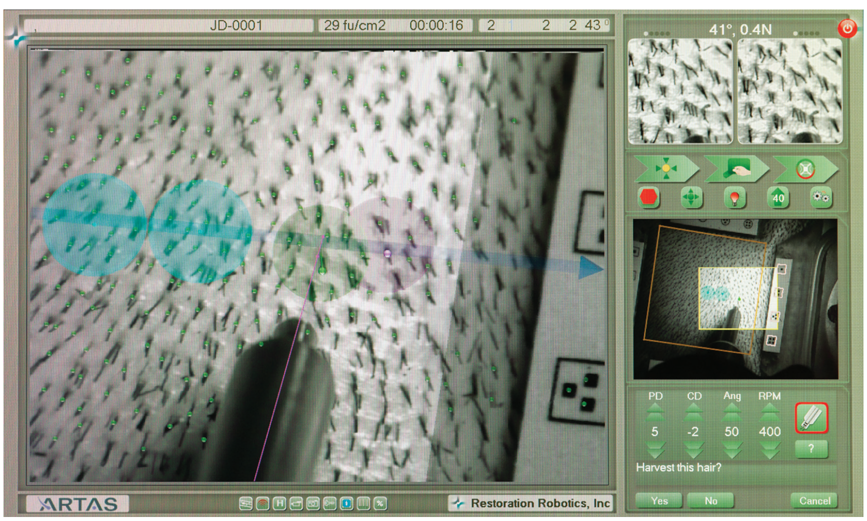
NHJ: This is not an easy technology. How did you go about testing each step along the way?

JH: It went through cycles. The basic robot was put together in California. Initially, we used models, dummy heads with implanted fibers that the robot would track. Once we got to the point where we were authorized by an institutional review board to conduct human studies, we had a prototypical robot made and brought to my clinic in Denver.

There were two test sites, one here and another in California. Every time the team came to Denver there was a plan for what was to be tested or reviewed; we were very focused on what we wanted to accomplish. If we had a certain type of tip, or dissection protocol, we closely examined them during each patient session and made detailed notes about how the robot responded.

We asked questions like were there any problems or technological enhancements we could make for the next cycle? We would usually do three or four patients procedures during the week, and then we'd have a session to talk about how everything went. Then, we would devise a plan of what needed to be changed in terms of hardware or software or patient comfort. We would always try to implement those changes before the next visit, which was usually a month later.

The technical research conducted by Restoration Robotics has been going on for about five years now and we've been doing clinical testing for three and a half years. During that time, we have been conducting transplant procedures every three to four weeks. The evolution over those three and a half years of patient testing has brought us to the level we're at now. When I stand back and look at it, I still find the capabilities of the ARTAS™ System amazing!



The ARTAS System pinpoints the exact location of each follicular unit on the patient's scalp and then targets it for harvesting at the optimal approach.

NHJ: When you were doing the early testing on model heads they remained static. But patients move. What happens if a patient sneezes?

JH: That's a great question. The best way to answer it is with a short background story. When they were testing the robot on a dummy head, it was obviously motionless and the robot worked very well. But when the first patient sat in the chair and the robot started to look at it, even the smallest movement sent it into halt mode. It couldn't track the target follicular units because of subtle motions, like breathing.

So, the robotics team actually modeled how a patient moves and then they created a dummy system that made the dummy head move like it was a human breathing. After they had analyzed the movements, they developed software so the robot could track the targeted follicular unit and move with the patient.

Now the robot has the capability of tracking an individual follicular unit in the real world, and if the motion becomes too great, the robot just says, "Hey, I'm not seeing what I'm supposed to" and pulls back and waits until everything settles down or waits for a command that it can commence again. So, if a patient sneezes, the robot will just pull back and wait for everything to settle down.

One of the things we built into the system was this safety net. Safety for the patient and safety for the follicular unit. As an added precaution, we also have a soft, rubber safety strap that we put on the back of the patient's head to remind them that there's something going on behind them. If they fall asleep, which most patients do, and they become startled – they're not sure where they are for a second or so – and if they lift their head, the safety strap helps them remain in position.

NHJ: All this meticulous research led to a happy conclusion in the spring of this year when the FDA cleared the device. What does it mean when they "clear" a device?

JH: We had to prove that there was a sufficient degree of safety so patients undergoing these procedures would not have any adverse outcomes. Safety is always the FDA's top concern. We'd done over 300 patients during the testing process and not seen any adverse events as a result of being operated on by the ARTAS System, so we were confident about this requirement.

The second thing was efficacy. Could the ARTAS System deliver to patients the same results that physicians were achieving manually? To answer this, we conducted handheld follicular unit extractions in parallel throughout the trials and compared them to the robotic procedures. We were able to demonstrate that the robot was producing at least as good or better results than doing it by hand.

NHJ: When a patient visits your clinic for robot-assisted surgery, what is different about the procedure?

JH: Everything starts the same way for every patient. We sit down and discuss the surgical plan – what the patient's desires are, and how we plan to meet them. We confirm the number of grafts we hope to produce that day.

The difference starts when I tell them about the new technology we will be using and the seating arrangement. For follicular unit extractions, I typically have the patient lie facedown in a prone position. They are probably not accustomed to this. I explain that we have a special chair that allows many adjustments and they will be in a seated position, leaning forward, with their head face down on a small pillow like one of the massage chairs they might have seen at a spa or massage facility. I also explain that they may be in this chair for several hours. Then I tell them where the robot is located and explain that when we bring it into position, it will be behind their head.

They also need to be told in advance what they might feel and hear during the procedure. The actual prepping of the donor area is the same as for a standard follicular unit extraction. We have to trim the hair short, down to a millimeter and a half and numb up the area just like we would normally do and I explain this is because the robot has to see what it's working on and be guided to the donor area. To do this, we have something we call a skin tension device, or "tensioner." It is a small, plastic, spring-loaded apparatus that we apply to the back of the scalp. It creates slight tension that keeps the skin stable in the target area. This area is a small square and on its outer margins there are what we call "fiducial markings," which are black and white markings that the robot has been taught, through computer programming, to recognize as the target area. Attached to the skin tensioner are the rubber reminder straps I mentioned earlier that in turn hook onto the chair, so not only does the skin remain stable, the patient is also reminded that we're working back there.

After the skin tension device is placed on the back of the patient's head, I will explain that they're going to hear me request my assistant to issue commands to the robot about its position or inputting certain settings regarding depths, speeds and angles. Then, I'll bring the robot arm into a position where it can see the skin tension device and those fiducial markings, and I'll instruct it through a remote control to look for those fiducials. The robot will then look at the tensioner through a wide-angle camera, and start to read the fiducial markings around the identified area. Once that is completed, it will analyze the data of every single hair and follicular unit and start assessing angles and directions.

When I give the command to proceed, the robot will start the dissection process. The patient will hear some mechanical noises and pneumatic sounds which are simply the mechanism itself doing what it needs to do to get the punches to the scalp and complete the dissection.

Other than those sounds, the only other sensation the patient is likely to experience is a slight pushing sensation against the scalp and I usually tell them that they'll probably get bored after the first three or four of those and fall asleep.

Once we're done with the first donor area, we move the skin tension device to another position and repeat the process. We usually get between 90 and 120 grafts at each application. We continue to move the tensioner along different areas of the scalp to get the number of dissections needed. After that, we remove the graft and prepare the patient for placement. Fromthe patient's perspective, it's a benign experience. They're just sitting in a massage chair, hanging out for most of the day.

NHJ: What about the placement of the follicular units? Does the robot design and place the hair?

JH: Those are things for the future. Right now, our goal is accurate dissection of the follicular units. This is the major impediment for physicians wanting to provide follicular unit extractions. We've intentionally focused our attention on this portion of the procedure. But now that we've done this, I can tell you that further endeavors are underway to develop the robot's ability to create recipient sites and implant the grafts. Meanwhile, the profession must rely on the physician and his or her artistic abilities to create hairlines and gauge density.

". . . the few of us who do offer FUE are inundated with patients from outside our geographic regions and we're having a hard time meeting the demand."

NHJ: How do your patients feel psychologically when you tell them that you are going to be assisted by a robot?

JH: They fall into two groups. One of them embraces technology; they already have their iPods and their iPhones. As you mentioned earlier, robots are becoming commonplace in industry and in the medical fields, so they're aware of the da Vinci system, LASIK eye surgery and micro-current wound healing. This group welcomes technology and is confident it will help them get the cosmetic results they want. Probably 70 to 75 percent of my patients feel that way. The other 20% to 25% are more comfortable trusting the hand of the surgeon.

I always outline the two options to everyone and let them decide. I explain that robot-assisted surgery is not experimental technology anymore. It's out of clinical trials and achieving great results, but I don't try to sway them from choosing me doing the surgery alone or having the robot assist me.

NHJ: Do you have a sense of how many ISHRS members currently offer FUE?

JH: I don't think I've seen any hard data on this, but going by what people tell me when they call from around the world trying to find someone to do this surgery, I'd have to say less than 10 percent of the ISHRS members offer FUE. And of that 10 percent, probably only half of them feel really comfortable performing the procedure. So, it's a very small number. This alone has dealt a blow to FUE, because when patients call looking for physicians doing FUE, they run into a roadblock. That means the few of us who do offer FUE are inundated with patients from outside our geographic regions and we're having a hard time meeting the demand.

NHJ: Does ARTAS™ System now open the door wider to FUE?

JH: Absolutely. I've trained a lot of doctors to perform FUE, but because of the amount of effort and time it takes to become proficient, many physicians are still reluctant to do this. With the ARTAS System however, I can show a doctor how to perform the surgery using this new technology in about 20 minutes, and they can become relatively proficient in less than an hour. It's an amazingly simple system to use, and it gives consistently reliable results in terms of graft production and great graft quality. When doctors around the world see this, I think they are going to realize this could be their entree into hair transplantation.

Patient Hairline Pre-Procedure

Patient Hairline 9 Months Later

NHJ: Does robotics lead to significant economies for the clinic... and its patients?

JH: That's one of the reasons I purchased an ARTAS System myself. I see it as a great way to achieve new efficiencies and leverage my resources. If I have members of my team who aren't actively assisting me in surgery, I can now have them work with the ARTAS System in a second operating room. I'm also finding that the technology is drawing new patients into the clinic who were hesitant before. It was for all those very reasons that I acquired the first ARTAS System in the world.

NHJ: You have invested a huge amount of time perfecting your surgical skills. Are these now going to be put at risk as the ARTAS System makes hair restoration surgery available to physicians without that specialist training?

JH: Both Restoration Robotics and I feel that this should only be put into the hands of physicians who are trained in hair restoration. The last thing we want to do is provide sophisticated technology to untrained individuals because we know that even though we can produce high quality grafts, only the expertise of someone trained in hair restoration can deliver the results that patients really want.

So, the target market for the ARTAS System is physicians experienced in hair restoration that have a track record of results that are pleasing to their patients. Those are the physicians that we want the system to go to. Now, you asked earlier about the advances in robotics and what we hope to be able to do in the future. While the technology today is designed to support experienced physicians, tomorrow's technology may be able to offer harvesting and placement assistance. This could open up the field to new hair transplant physicians by creating perfect hairlines for them and making the angles of the recipient sites correctly, and so forth. We're hoping that this assistive technology, the ARTAS System, will help all of us become better hair restoration surgeons.

NHJ: Do you envisage an ARTAS certification program?

JH: There will certainly be training programs. As for an official diploma or something like that, I don't know if we're headed in that direction today. However, as we evolve this technology, we will have to develop some very specific instruction and education programs and that could lead to some kind of recognition that would indicate that a physician is now certified to provide robotic or assistive ARTAS System technology to hair transplant patients.

NHJ: How many locations are currently using the ARTAS System?

JH: One. I'm the one and only physician to have the ARTAS System in the world. As a member of the team that developed this, if ARTAS System wasn't a technology I could confidently integrate into my practice, I would not be involved in its marketing and I wouldn't be talking to you or any other news providers. I'm not paid by Restoration Robotics to say anything about the ARTAS System. I do this as a way to advance the field of hair restoration.

NHJ: If I was a physician reading this interview and wanted to bring robotics into my clinic, what should I do next?

JH: Contact Restoration Robotics. They will provide some basic information about the system and invite you to visit my office to observe a surgery being performed. Already, right through September, I have visiting physicians scheduled for every one of my surgeries.

NHJ: Without giving away any privileged information, how much should a medical director budget to acquire an ARTAS System?

JH: I don't think Restoration Robotics has any secrets about the cost of the system. They charge $200,000.00 for the device. The system also requires a per-graft, or graft attempt, payment to Restoration Robotics. When you purchase a certain number of graft attempts, you also get disposable kits, which include dissecting tips, the tubing for suction, plus the skin tension device. It is not cheap, but if clinics look at the number of patients they've turned away because they couldn't offer FUE, they could easily pay for the system. If an average procedure comprised 1,000 grafts, this could easily cover a monthly lease payment. If they do two patients a month, they've paid for the system, plus started to reap a profit from it.

NHJ: Looking over the horizon, where do you think we will be in 24 or 60 months?

JH: Within that timeframe, several things are going to happen. Patients' awareness of this technology is going to increase and you will see an increase in patient demand. When this happens, you are going to find an ARTAS™ System in every major city. You'll also begin to see some price reductions. Today, doctors doing manual FUE are putting a high premium on the procedure because of the complexity and the cost of their time. But as people achieve efficiencies with the robotic system, we'll see those cost benefits passed on to their patients.

NHJ: Is FUE going to become the hair transplant procedure of choice?

JH: FUE offers something that many physicians are having trouble providing – surgery that is less invasive than the strip and heals quicker. Within about two days, my patients feel like nothing ever happened to their donor area.

The mild to moderate postoperative pain that patients experience with strip surgery is basically eliminated. The FUE procedure produces mild soreness for a day or two, and that's about it. Most of my patients will just take a Tylenol or Motrin for one night and don't need anything after that. The numbness and tightness that people experience with the strip has also been eliminated.

I'm not going to say it's scarless, because it's not, but the small, dot-like scars are easily camouflaged with hair that's an eighth of an inch long. As more clinical results come out and men and women see the quality of hair transplants created by FUE, many of them are going to take a second look and conclude that this may be the way to go. In terms of product development, within 24 to 60 months, I think we're going to see the ARTAS System making recipient sites and possibly even starting to do some implantation of the grafts themselves.

NHJ: On a more trivial note, and with apologies to Stanley Kubrick, have you ever woken up from a nightmare where your ARTAS machine is leaning towards you saying, "I'm sorry, Jim, I can't do that"?

JH: There's a big, red button on the machine, another one on the remote in my hand and one for my medical assistant on the control panel. If the robot "says" anything unexpected we hit the big, red button and everything stops.

NHJ: So the humans are still firmly in control...

JH: This system requires specific input from the physician and staff to function. But what I've told patients jokingly is that the worst thing that could happen is that they'll get more hair! ▪

James A. Harris, MD has been performing hair restoration for over 14 years. He is the medical director of the Hair Sciences Center of Colorado, and a clinical instructor at the University of Colorado Medical School in the Department of Otolaryngology and head and neck surgery. He was the principal investigator for Restoration Robotics and the development of the ARTAS System.

Dr Harris designed and developed the Safe System for follicular unit extraction, which is the technological platform that the ARTAS System uses for its dissection. ▪

About the Company

Restoration Robotics, Inc., a privately held medical device company, is dedicated to revolutionizing the field of hair transplantation by developing and commercializing a state-of-the-art image-guided system (ARTAS System) that enables follicular unit extraction. ▪

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Robotic Follicular Unit Extraction in Hair Transplantation

Marc R. Avram, MD,* and Shannon A. Watkins, MD†

BACKGROUND In recent years, there has been a shift toward minimally invasive procedures. In hair transplantation surgery, this trend has manifested with the emergence of follicular unit extraction (FUE). Recently, a robot has been introduced for FUE procedures.

OBJECTIVE To determine the transection rate of a robotic FUE device.

MATERIALS AND METHODS The authors discuss the procedure, technical requirements, optimal candidates, advantages, and disadvantages of robotic FUE compared with the standard ellipse.

RESULTS Optimal candidates for robotic FUE are those with dark hair color who can sit for 45 to 120 minutes and are willing to shave a large area for donor harvesting. The main advantages of robotic FUE compared with the standard ellipse are its minimally invasive nature and the lack of a linear scar. The average transection rate with the robot to date is 6.6% (range, 0.4%–32.1%).

CONCLUSION The robot is a new and innovative method for FUE hair transplantation of which hair transplant surgeons should be aware.

The authors have indicated no significant interest with commercial supporters.

In the 1990s, hair transplant surgery underwent a revolution in the graft size used for transplantation. From the 1960s into the mid 1990s, 2 to 4 mm grafts containing 10 to 20 hair follicles were the standard graft used in the procedure. In spite of its scientific success, they were often a cosmetic failure because they resulted in a "pluggy" unnatural appearance. In the 1990s, there was a shift toward smaller graft sizes. Currently, the follicular unit, which contains 1 to 4 hair follicles, is the standard graft size used in transplant surgery.[1,2] This shift in graft size has allowed patients to consistently grow naturally appearing transplanted hair, as it mimics the natural size of follicular groupings on the scalp[1] (Figure 1). In addition, the use of follicular groupings eliminates textural changes and scarring in the recipient area. Large grafts containing 10 to 20 hair follicles required larger recipient sites, which resulted in unnatural "cobblestone" scarring on the scalp. Recipient sites for follicular groupings are less than 1 mm in diameter and create no visible scarring in the recipient zone of the scalp.[1]

In the era of follicular unit transplantation, the only visible scar on the scalp is the linear scar left from the donor ellipse. For the majority of men and women, a linear scar in the posterior scalp has no short or long-term practical effect. Their existing donor hair will camouflage the scar. A linear scar can create an issue, however, for some patients who wear their hair shorter or want the option of a shorter hairstyle in the future. In addition, there has been an inexorable trend in all surgical procedures toward minimally invasive procedures, which result in less scarring and quicker recovery times.

Donor Harvesting Techniques

Over the past several years, the focus of discussion in the field has begun to shift away from the size of the

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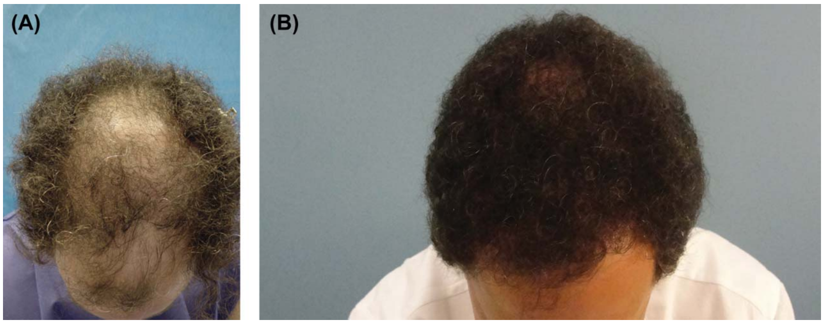

Figure 1. The same patient before (A) and after (B) hair transplantation, in whom 1,900 grafts in total were transplanted.

graft used to transplant hair toward the harvesting method used to obtain the donor grafts. For decades, 2 to 4 mm punch trephines were used to obtain donor hair from the posterior scalp. Typically, the grafts were removed and wounds were allowed to heal by secondary intention. This resulted in widespread "honeycomb" scarring (Figure 2). In 1994, the concept of elliptical donor harvesting, also known as strip harvesting, was introduced and has been the standard method for obtaining donor grafts.[3] It is based on the same dermatologic surgery techniques used in removing nevi, skin carcinomas, and cysts. It allows efficient harvesting of hundreds to thousands of follicular groupings. As with any cutaneous excision, there is a scar created from removing the donor ellipse. For the majority of patients, this is neither a medical nor a cosmetic issue. For a minority of patients, medical and cosmetic challenges may arise. A small percentage of patients will develop hypertrophic or broad scars. Others feel limited in the hair styling options because of the donor scar. For these reasons, and because of the general trend toward less-invasive procedures in medicine, alternate donor harvesting methods were investigated.

Figure 2. Honeycomb scarring.

Follicular Unit Extraction Versus Elliptical Donor Harvesting

The concept of follicular unit extraction (FUE) was introduced in the early 21st century and refined over the past decade.[4–6] Follicular unit extraction used the same concept of using a steel trephine to harvest donor hair, but instead of being 2 to 4 mm in diameter as was used in the past, the FUE punches range from 0.8 mm to 1.2 mm. This technique is a natural extension of the concept of follicular unit hair transplantation—the utilization of individual follicular groupings in the recipient *and* donor sites.

Challenges of this technique include the following: increased risk of transection of hair follicles, operator fatigue when harvesting hundreds of follicular groupings, and appropriate spacing of harvested grafts to yield the maximum amount of donor hair without creating the appearance of a depleted donor density.[6] Throughout the posterior scalp, the angle of hair growth varies, which presents a challenge to surgeons. Magnification and excellent lighting reduce but do not eliminate the risk of transecting follicles. Compounding this challenge is the need to remove dozens to many hundreds of follicular groupings for each case. Harvesting larger numbers of grafts can result in increased operator fatigue and a higher rate of transected hair follicles. Some experienced surgeons are able to harvest large numbers of follicular groupings with minimal transections, but others are unable to do so.

To improve the accuracy and efficiency of FUE, numerous FUE devices have been developed; of which some are motorized, some are suction assisted, and some are single user-directed robotic system. The NeoGraft automated hair transplant system,[7–9] SAFE (surgically advanced follicular extraction) system,[10] and ARTAS Robotic System (Restoration Robotics, Inc, San Jose, CA) are a few of the more well-known FUE devices on the market. In this article, the authors discuss about robotic follicular unit extraction with the robot.

Robotic Follicular Unit Extraction

Technical Aspect

The robotic system was approved by the Food and Drug Administration for hair transplantation in 2011.[11] This robotic device is used to harvest follicular units from the donor region (Figure 3). A 1-mm punch is attached to the robotic arm consisting of a "needle-within-needle"; there is a sharp inner punch surrounded by a blunt outer punch. The sharp inner punch creates a shallow 1-mm incision, subsequently, the blunt outer punch spinning at 400 to 800 rpm dissects deeper and separates the follicular units from surrounding tissue. A suction system attached near the punch elevates the follicular unit from the surrounding skin allowing for easier extraction of the graft. A combination of stereoscopic cameras managed by image processing software allows the sharp and blunt punches to identify the precise angle and direction of hair growth. This continuous imaging feedback allows the robot to precisely harvest each follicular grouping. Because of the high level of automation, the robot is able to remove 400 to 600 grafts per hour.[11–13] The software requires a minimum distance of 1.6 mm between extracted follicular groupings to minimize the risk of overharvesting donor hair. In Table 1, the authors compare strip harvesting with robotic FUE for donor harvesting.

Procedure

Donor Region

Patients must trim their hair 1 to 1.5 mm in length for proper removal of follicular groupings whether performed using traditional manual punch FUE, a motorized FUE device, or robotic FUE. The area of trimming needed to harvest equal numbers of follicular groupings is *far greater* with traditional or robotic FUE than with a donor ellipse. This is of minimal practical concern for patients who can wear their hair shorter, but it is a major concern for those who wear their hair longer (Figure 4). In the authors' practice, all patients choosing robotic FUE to date have been men. No women have yet been willing to trim an extensive area of their posterior scalp for donor harvesting. The authors continue to prefer a donor ellipse for their hair transplant. In Table 2, they summarize the ideal qualities of a candidate undergoing robotic FUE.

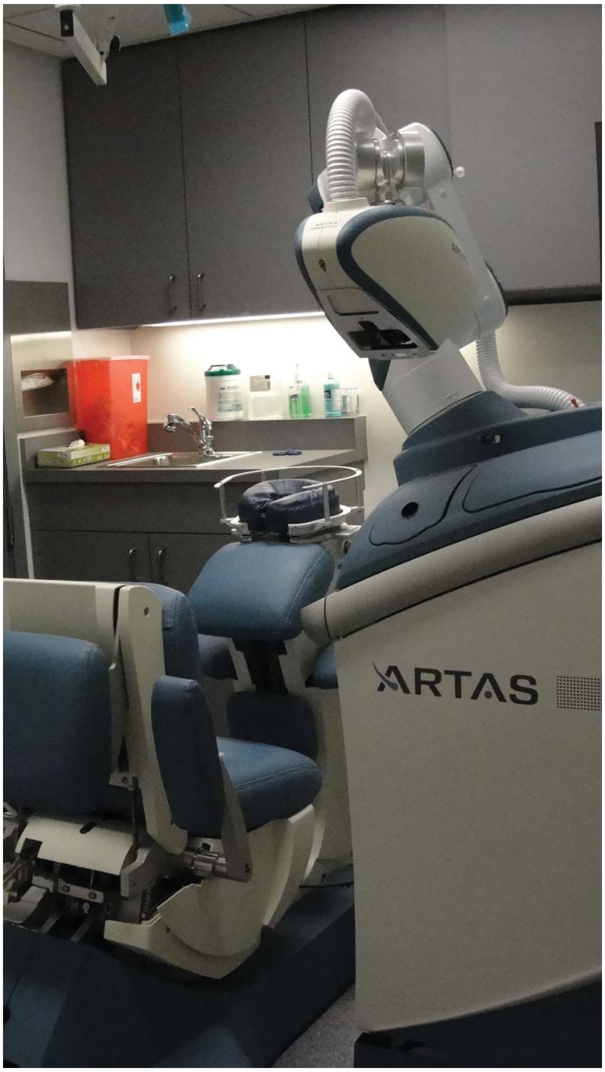

Figure 3. The robotic device.

TABLE 1. Comparison of Strip Harvesting to Robotic FUE Harvesting

	Strip Harvesting	*Robotic Follicular Unit Extraction*
Scarring	Linear scar	No linear scar
Time to harvest grafts	10–20 minutes for 300–2,000 grafts	45–60 minutes for 300–600 grafts; 60–120 minutes for 600–1,200 grafts
Healing time	7–10 days	3–5 days
Cost	Minimal	Significant to purchase machine (approximately $240,000) and additional per surgery fee for each harvest attempt (approximately $1/harvest attempt = attempt to extract 1 FUE)
Transection rate	Low with experienced team; widely variable with inexperienced team	Low to low–moderate
Physician skill	Standard skin excision techniques	Knowledge of software program and robot
Technician skill	Skilled technician mandatory to create follicular units with low transection rate	Skilled technician needed to remove grafts from scalp and assess quality under magnification before placing in the recipient site
Reliability	Technician + physician dependent	Technician + physician + robot dependent
Area of donor site shaved	1.5 cm × 8–10 cm	4–8 cm × 10–20 cm
Space requirement	Can be done in office space used for standard excisions	Minimum office space: 10 foot × 10 foot; large procedural space Robot dimensions Cart: length 48 inches, width 27 inches, height 68 inches Chair: length 57 inches, width 33 inches, height 48 inches Weight: cart = 872 lbs, chair = 550 lbs
Electrical requirement	Power supply of a standard patient room	1. 208 VAC ± 10%, single phase, 50/60 Hz, 10 A. Required power outlet configuration is NEMA L6-20R twist lock
Technical requirements	None	1. Ethernet port, no Wi-Fi 2. Personal computer 3. Secondary monitor, with HDMI cables from robot to monitor 4. Desk (workstation), at least 2′ x 3′ working surface

VAC, volts of alternating current.

The sensors and cameras in the robot require pigment in the hair for optimal harvesting with minimal transection. Consequently, patients with blond, red, or gray hair have the donor hair dyed in the authors' office before administering local anesthesia. After trimming, and dying if necessary, the donor region is anesthetized with local anesthesia. After anesthetizing the donor region, the patient finds a comfortable position in a chair specially designed for the robot. A skin tensioner measuring approximately 3 × 3 cm is

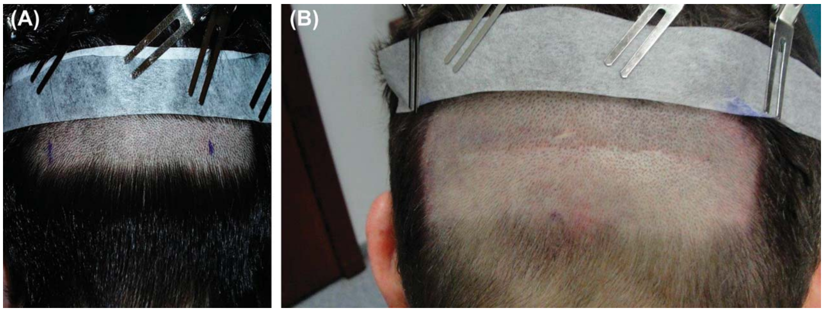

Figure 4. Donor region trim for strip harvesting (A) and for robot harvesting (B). Note that approximately the same number of hair follicles was transplanted in both cases.

TABLE 2. Robotic FUE Candidate Selection

	Ideal Candidate	*Suboptimal Candidate*
Area of donor site shaved	Willing to shave a large area for donor harvesting	Not willing to shave a large area for donor harvesting
Patient personality	Able to sit still for 45–120 minutes while grafts are harvested	Unable to sit still for long periods of time
Donor site density	High	Low*
Hair color	Brown, black hair	White, blonde, red hair†
Hair length	Short hair	Long hair
Patient's scar preference	A patient preferring no evidence of linear scar on their scalp after the procedure	A patient who does not mind a linear scar

*Note: more difficult to harvest large numbers of follicular units.
†Note this can be overcome by dying hair.

placed on the skin, which creates turgor necessary for optimal harvesting (Figure 5). The physician and assistant use a hand-held remote control and a computer monitor to control all aspects of the harvesting process. The spacing between harvests, needle depth, and the area to be harvested are controlled and adjusted if needed during the procedure. During the harvesting, the patient rests their head on a pillow similar to

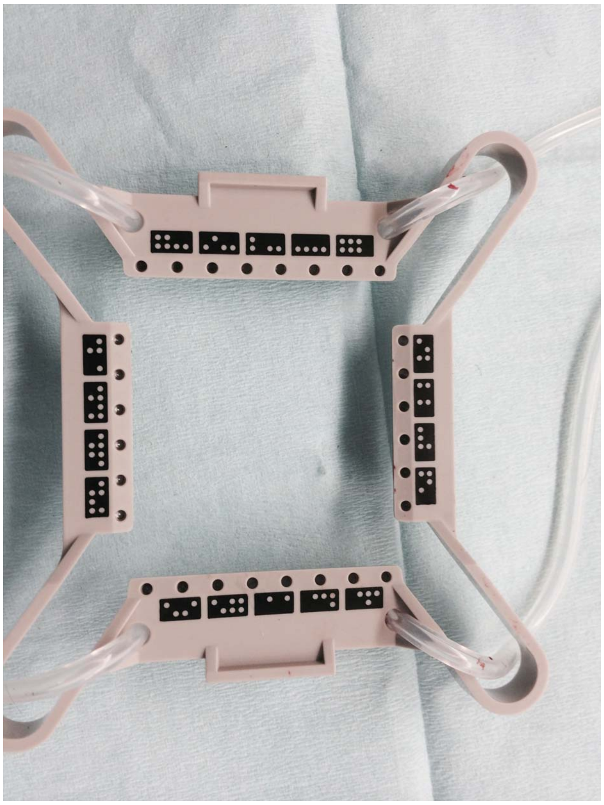

Figure 5. Skin tensioner for the robot.

that found on a message chair. After each section is harvested, the physician moves the tensioner across the back of the scalp until the desired number of grafts is obtained. Each 3 × 3 cm tensioner harvests an average of 90 to 120 follicular groupings. Therefore, if a patient with an average density needs 800 grafts for the procedure, the tensioner will be moved 7 to 9 times across the donor region. While harvesting grafts, the robotic device displays the angle of hair growth, density of hair in the region, and counts the number of grafts obtained.

Once all the grafts are created, the robotic arm is retracted and the grafts are removed by technicians from the donor region using microvascular forceps. After the last graft is removed, a temporary dressing is applied and the patient can stand up, stretch, and get ready for the placement of the grafts into the recipient zone. The remainder of the procedure from hairline design to recipient site creation and graft placement is the same as with nonrobotic hair transplant surgery.

Processing of Grafts and Transection Rate

The grafts are kept in chilled saline and inspected under magnification. Each graft is inspected for damage to the follicular unit. In Table 3, there is a summary of the case-by-case transection rates noted over 20 consecutive robotic FUE cases. All 20 cases were performed by one operating physician and the same 3 hair transplant technicians. The ethnicity of the patients varied and included many races, including white, Asian, Middle Eastern, and Indian. The patients' hair colors included white, gray, black,

TABLE 3. Twenty Individual Case Statistics and Transection Rates

Patient	No. Grafts Harvested	No. Grafts Transected	Total Number Transplanted	Transection Rate (No. Grafts Transected/ No. Grafts Harvested)
1	377	27	376	27/377 (7.2%)
2	236	1	241	1/236 (0.4%)
3	301	3	226	3/301 (1.0%)
4	550	4	599	4/550 (0.7%)
5	351	33	356	33/351 (9.4%)
6	223	1	234	1/223 (0.4%)
7	397	9	NA	9/397 (2.3%)
8	250	1	276	1/250 (0.4%)
9	477	30	623	30/477 (6.3%)
10	454	72	399	72/454 (15.9%)
11	358	28	384	28/258 (10.9%)
12	446	20	492	20/446 (4.5%)
13	430	30	492	30/430 (7.0%)
14	385	28	305	28/385 (7.3%)
15	206	5	212	5/206 (2.4%)
16	479	45	405	45/479 (9.4%)
17	536	52	545	52/536 (9.7%)
18	200	1	215	1/200 (0.5%)
19	504	20	598	20/504 (4.0%)
20	632	203	568	203/632 (32.1%)
Average	389.6	30.65	397.2	6.6%*

*Note: 6.6% is the mean of transection rates for each individual case.
NA, not available.

brown, and blond hair, and all the patients had relatively straight hair. The grafts were evaluated by technicians with more than 15 years of experience each. Grafts noted to have more than 1 follicular grouping (often, 1 FUE graft may contain 3–4 hairs) were split into individual follicular groupings. It is not uncommon for 1 FUE to yield 2 grafts once split into follicular groupings. The total number of grafts harvested, grafts transected, and grafts transplanted were recorded. Grafts were counted as transected if any part of the hair follicle was missing (bulb, isthmus, or infundibulum). Capped hair follicles (hair follicles that had only the epidermis present) were also counted as transected. The transection rate ranged from 0.4% to 32.1%. The average transection rate was 6.6%. In the literature, strip harvesting using the "donor dissection" technique with an experienced hair transplant staff has been reported to have a 1.59% transection rate. In the "donor dissection" technique, direct visualization of hair follicles is used to minimize the transection rates.[14] With traditional 0.8- to 1.2-mm steel punch FUE or motorized FUE devices, there are some data regarding transection rates. One study by Onda and colleagues[15] comparing the use of a novel powered FUE (P-FUE) device to manual FUE reported a 5.4% transection rate with P-FUE versus a 17.3% transection rate with manual FUE. Another study by Harris[10] using the SAFE (Surgically Advanced Follicular Extraction) System reported an average transection rate of 6.14% with a range of 1.5% to 15%.

Discussion

Robotic FUE allows a physician to transplant many hundreds to thousands of follicular groupings from the donor region into the recipient area without creating a linear scar on the patient's scalp. This is a major technical advance in the procedure. For years, manual and motorized FUE have been performed with success around the world. The challenge for many physicians with manual and motorized FUE is efficiently harvesting hundreds to thousands of follicular groupings with minimal transection. The robot allows 400 to 600 follicular groupings to be harvested per hour with transection rates comparable with those of grafts created from an ellipse by experienced surgical assistants. There is no doubt that some physicians may be able to harvest large numbers of grafts using a manual punch or motorized device with transection rates similar to those of the robot. The expense, space requirements, and ongoing maintenance costs of a robot are not needed for these skilled physicians. Also, many physicians cannot efficiently harvest follicular groupings with low transection rates using manual or motorized FUE, and the robot will allow them to efficiently harvest high-quality grafts. The combination of stereoscopic cameras managed by image processing software allows the robot to accurately and efficiently harvest follicular units. Because of the high level of automation with the robot, there is a minimal learning curve compared with that of manual or motorized FUE. The robot also eliminates the issues of operator fatigue, which often results in higher transection rates with manual and motorized FUE. The robot is consistently able to remove 400 to 600 grafts per hour. Unfortunately, well-designed long-term studies comparing techniques such as the robot FUE to non-robotic FUE do not exist to date.

Currently, the robot is an additional option for donor harvesting. It has *not* replaced traditional elliptical donor harvesting or manual/motorized FUE. For patients who wear their hair short, want the option to wear it short, or simply do not want sutures or a linear scar on their scalp, robotic FUE is an efficient and safe method for harvesting follicular units. The auhtors report that the biggest practical hurdle for some of their patients has been the need to trim an extensive part of the donor region. To date, no women have opted for the robot, all have chosen the strip harvesting. Men have been evenly split between the ellipse and robot. The majority of men who have had an ellipse in the past have chosen an ellipse for repeat procedures because of high satisfaction with the previous result and the existing scar on their scalp. The majority of men who have not undergone a previous strip procedure have chosen robotic FUE to avoid sutures and a linear scar.

To date, the authors have had no known medical or surgical complications with any of their robot patients. Possible complications and side effects include a small risk of infection and bleeding, as with any surgical procedure. There will be pinpoint scars at the sites of follicular extraction. Additionally, proper spacing and removal of follicular groupings is necessary to reduce the risk of a "moth-eaten" or pseudo-syphilitic" appearance, and improper spacing can also result in necrosis, and cyst formation.[16,17]

The authors have also found that the number of grafts harvested by the robot does not always directly correlate with the numbers of grafts transplanted. In some cases, higher transection rates have resulted in fewer grafts transplanted, whereas in other cases closely, spaced follicular groupings within a 1-mm harvested graft have allowed more grafts to be placed than were harvested by the robot. As can be seen in Table 3, the transection rates of the 20 cases varied considerably, and ranged from 0.4% to 32.1%. In the authors' experience, suboptimal tension and turgor when using the tensioner of the robot can lead to increased rates of transection. Careful placement of the tensioner and additional injection of saline for added turgor will reduce this risk. The authors did not notice any differences based on hair color or ethnicity. All patients reported by the authors had relatively straight hair. The authors suspect that in Case 20 with a 32.1% transection rate, suboptimal tension and turgor compounded with a "mushy dermis," a term used to describe the characteristics of a dermis that lacks stiffness, may have contributed to the extraordinarily high transection rate.

Follicular unit extraction has expanded the number of patients eligible for a hair transplant procedure. In the past, younger patients in their twenties or early thirties who expressed a desire to wear their hair short or possibly wear their hair short in the future were not operated on because of the concern that a linear scar could present a problem in the future. Follicular unit extraction, by avoiding a linear scar, allows more diverse hair styling options for men undergoing the procedure. With FUE, if a patient opts to shave their hair, there should be no evidence of a hair transplant procedure. In addition, patients with extensive scarring from large punch grafts and/or donor ellipse scars can benefit from FUE. The robot can harvest individual follicular groupings without creating another large full-thickness scar that may not heal well (Figure 6).

As with most technological advances, including contemporary dermatologic lasers and radiofrequency devices, the device comes with a considerable price tag, and a cost–benefit analysis should be performed for each practitioner before purchasing the device. Space is another concern in some practices because as the device occupies a considerable amount of space.

Future of Hair Transplantation

The era of robotic hair transplantation has begun. In the near future, the authors expect the robot to be able to harvest more grafts more rapidly and with even greater precision. They look forward to more data in the literature regarding experience of others with the robotic device. The current size of the tensioner (3×3 cm) mandates large areas of donor hair to be trimmed. The option of tensioners with different dimensions would allow greater flexibility in hair trimming and open the procedure to a greater number of patients.

Unfortunately, the authors anticipate complications from the robot as with any procedure. Hair transplantation is limited by the amount of donor hair available. Overzealous donor harvesting may create an iatrogenic pseudo-syphilitic appearance with "moth-eaten" donor regions. The robot's software will not allow the machine to harvest hair closer than 1.6 mm during any one procedure. This ensures naturally appearing regrowth of hair in the donor region. Data regarding second and third procedures and the potential for thinning of the donor region do not exist. Until these data exist, a conservative approach to donor harvesting should be followed. Lack of a linear scar may also entice physicians to harvest hair from regions of future hair loss. This will result in the loss of those transplanted hairs in the future and relative thinning of transplanted hair in the frontal scalp. Additionally, follicular cysts have been described as a complication of other methods of FUE due to buried or subluxed grafts. They typically present 6 months—2 years after the FUE procedure.[16] Theoretically, this same complication can result from robotic FUE, although the authors have not experienced these complications with the robot to date.

Figure 6. Robotic FUE in a patient with honeycomb scars from 3 to 4 mm punches and linear scars from the donor ellipse.

The ultimate goal of robotic hair transplantation is for the robot to perform donor harvesting, recipient site creation, *and* graft placement. Currently, robotic FUE harvesting requires less staff time to create follicular grafts than a strip harvesting. Robotic FUE directly produces follicular groupings, however a team of experienced surgical assistants is needed to process an ellipse into follicular units. An experienced team is still required to place grafts into the recipient sites, which precludes some physicians from performing the procedure. The ability of a robotic device to harvest grafts, create recipient sites, and place grafts, may dramatically increase the number of physicians who are capable of performing the procedure.

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Robotic FUE hair transplants

MR EDWARD BALL was the first hair surgeon in Europe to introduce a hair transplant robot to his practice. He discusses the technology, its development, its benefits and limitations and a look to the future

A robotic system can provide a precise and efficient solution

Patients desire full and natural looking hair. For years we have been able to achieve these goals with the strip technique, which involves removing a piece of skin from the back of the head. However, patients also want minimal scarring—it's no good having a great hair transplant with a troublesome scar.

The development of follicular unit extraction (FUE) has been a huge step forward because the removal of individual follicular units leaves tiny dot scars, rather than the linear scar from a strip procedure. This gives far more flexibility in hair style or length. However, there are limitations to FUE. It is a skill that takes time to learn and it is labour intensive. Each follicular unit is extracted individually in a process that can take several hours. This can lead to patient and surgeon fatigue and a potential loss of graft quality.

Hair surgery involves fine precise movements of a repetitive nature and this is an area in which robots excel. A robotic system can provide a solution that is precise, consistent and efficient and, of course, robots do not fatigue. A robotic harvest can produce robust, high quality grafts thousands of times in a single session. This accuracy and consistency can enhance the patient and surgeon experience whilst optimising graft survival and growth.

A robot for hair surgery

I use the ARTAS system, which utilises an image-guided robotic arm, which assists the surgeon by

dissecting the individual follicular units, allowing them to be extracted by a manual forceps technique. The remainder of the hair transplant process is currently no different to manual FUE surgery.

A magnified image of the patient's scalp is displayed on a 55 inch screen, providing detailed visual access to the donor area. Viewing the skin in three dimensions, the ARTAS Robotic System uses programmed algorithms to select the follicular units, adjusting for variations in hair angle and direction, as well as skin texture and depth, to achieve a consistent harvest. Taking readings 50 times per second, the robot is able to safely compensate for any patient movement.

It has a unique two punch system—an inner sharp needle and an outer rotating dull punch. The sharp needle scores the skin, anchors the punch and opens the way for the outer, blunt punch to dissect down around the follicle. Minimising the sharp dissection reduces the risk of transection damage to the follicle. The surgeon is able to adjust the settings without interrupting the procedure, producing extraction rates of approximately 400-800 grafts per hour, depending on the patient's hair and skin characteristics.

Patients are prepared for the robot in much the same way as for a manual FUE procedure. Their hair must be cropped short (grade 0) at the back and sides. We dye the donor hair if it's fair, grey or white because the robot has to be able to see the hairs. Without the need for stitches, patients can experience a comfortable recovery and may return to work within a few days of the procedure.

A team of four individuals is required to operate the robot. This comprises the surgeon with a handset controller (responsible for tensioner placement and managing dissection parameters, follicle selection and graft quality), a technician manning a desktop computer (assisting the surgeon), a technician performing forceps extraction of the dissected grafts alongside the robotic punch mechanism and a technician at a microscope who inspects and counts the grafts and performs any limited graft trimming as required.

Origins

The ARTAS System, developed by Restoration Robotics, showed during the preliminary studies a transection rate of 8% was compared to a figure of 26% for manual FUE.

There have been numerous updates to the software that has seen increases in efficiency and automation. The transection rate is now close to 5% and with the latest update we are able to achieve harvests 500 to 1000 grafts per hour.

Robot-assisted surgery certainly reduces fatigue and patients enjoy the aesthetic and comfort benefits associated with a lack of stitches or linear scarring. Patients can potentially undergo larger sessions than might be achieved manually, therefore creating greater recipient density and coverage.

> 66 A magnified image of the patient's scalp is displayed on a 55 inch screen, providing detailed visual access to the donor site 99

Limitations

Some patients find the chair uncomfortable during longer sessions. In order to enable the robot to access various areas of the head, the chair requires positional adjustments during the case. The tensioner device, which stretches the skin and orientates the robot, can be tricky to position well in certain

We dye the donor hair if it is fair, grey or white because the robot has to be able to see the hairs parts of the scalp and in patients with very lax or mobile skin. The requirement to shift the tensioner each time a new area of donor hair is to be harvested can slow down the extraction process. Some parts of the head can present a challenge to harvest with the robot, highlighting the importance of a surgeon's competence in the manual FUE techniques.

The 1.0mm diameter of the sharp inner needle is larger than some manual FUE devices and may, therefore, leave slightly larger dot scars. However, the patient's skin characteristics tend to hold more influence over scar appearance than small variations in punch diameter. The robot's larger needle may, in fact, help to produce more robust grafts with greater tissue support.

Future developments

So what's next? A smaller punch has just become available. It measures 0.9 mm and will provide greater flexibility, enabling the surgeon to tailor the punch size to the patient's hair calibre and donor density.

I'd like to see some more surgeon control, including the ability to choose precisely which units are to be harvested and to specify a certain number of one, two or three hair follicular unit grafts. I expect this will soon be possible. In the US, the robot can already make recipient site incisions and I have little doubt that it will ultimately be able to actually extract the grafts and place them into the recipient area.

I find it is an amazing piece of technology which is capable of producing remarkable hair restoration results. With the right patient it produces excellent grafts with efficiency and consistency. However, I don't think there will ever be one solution to all patients' needs. I believe that a hair surgeon should also be skilled in the manual FUE technique, allowing them to select the best approach for each particular patient. It is hard to beat the artistic skills of an experienced doctor but a robot is certainly an excellent tool that has a great deal to offer both surgeons and patients. I have no doubt that robotic hair restoration is here to stay and it's going to be very exciting to see where it takes us in the future.

Mr Edward Ball is a hair transplant surgeon in London and clinical director for Ziering UK

Robot-assisted surgery reduces fatigue and patients benefit from lack of stitches or linear scarring

Robotic Follicular Unit Extraction in Hair Transplantation

Marc R. Avram, MD,* and Shannon A. Watkins, MD†

BACKGROUND In recent years, there has been a shift toward minimally invasive procedures. In hair transplantation surgery, this trend has manifested with the emergence of follicular unit extraction (FUE). Recently, a robot has been introduced for FUE procedures.

OBJECTIVE To determine the transection rate of a robotic FUE device.

MATERIALS AND METHODS The authors discuss the procedure, technical requirements, optimal candidates, advantages, and disadvantages of robotic FUE compared with the standard ellipse.

RESULTS Optimal candidates for robotic FUE are those with dark hair color who can sit for 45 to 120 minutes and are willing to shave a large area for donor harvesting. The main advantages of robotic FUE compared with the standard ellipse are its minimally invasive nature and the lack of a linear scar. The average transection rate with the robot to date is 6.6% (range, 0.4%–32.1%).

CONCLUSION The robot is a new and innovative method for FUE hair transplantation of which hair transplant surgeons should be aware.

The authors have indicated no significant interest with commercial supporters.

In the 1990s, hair transplant surgery underwent a revolution in the graft size used for transplantation. From the 1960s into the mid 1990s, 2 to 4 mm grafts containing 10 to 20 hair follicles were the standard graft used in the procedure. In spite of its scientific success, they were often a cosmetic failure because they resulted in a "pluggy" unnatural appearance. In the 1990s, there was a shift toward smaller graft sizes. Currently, the follicular unit, which contains 1 to 4 hair follicles, is the standard graft size used in transplant surgery.[1,2] This shift in graft size has allowed patients to consistently grow naturally appearing transplanted hair, as it mimics the natural size of follicular groupings on the scalp[1] (Figure 1). In addition, the use of follicular groupings eliminates textural changes and scarring in the recipient area. Large grafts containing 10 to 20 hair follicles required larger recipient sites, which resulted in unnatural "cobblestone" scarring on the scalp. Recipient sites for follicular groupings are less than 1 mm in diameter and create no visible scarring in the recipient zone of the scalp.[1]

In the era of follicular unit transplantation, the only visible scar on the scalp is the linear scar left from the donor ellipse. For the majority of men and women, a linear scar in the posterior scalp has no short or long-term practical effect. Their existing donor hair will camouflage the scar. A linear scar can create an issue, however, for some patients who wear their hair shorter or want the option of a shorter hairstyle in the future. In addition, there has been an inexorable trend in all surgical procedures toward minimally invasive procedures, which result in less scarring and quicker recovery times.

Donor Harvesting Techniques

Over the past several years, the focus of discussion in the field has begun to shift away from the size of the

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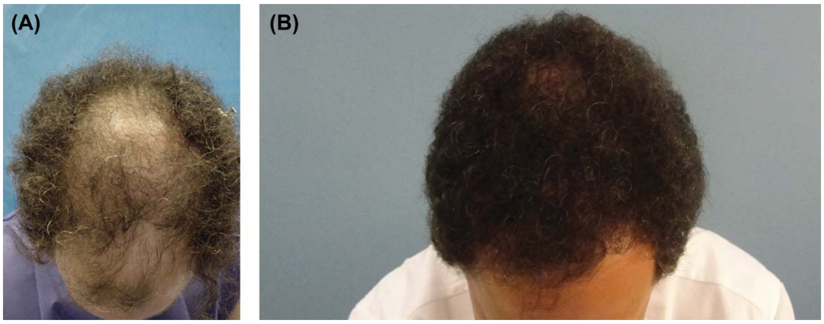

Figure 1. The same patient before (A) and after (B) hair transplantation, in whom 1,900 grafts in total were transplanted.

graft used to transplant hair toward the harvesting method used to obtain the donor grafts. For decades, 2 to 4 mm punch trephines were used to obtain donor hair from the posterior scalp. Typically, the grafts were removed and wounds were allowed to heal by secondary intention. This resulted in widespread "honeycomb" scarring (Figure 2). In 1994, the concept of elliptical donor harvesting, also known as strip harvesting, was introduced and has been the standard method for obtaining donor grafts.[3] It is based on the same dermatologic surgery techniques used in removing nevi, skin carcinomas, and cysts. It allows efficient harvesting of hundreds to thousands of follicular groupings. As with any cutaneous excision, there is a scar created from removing the donor ellipse. For the majority of patients, this is neither a medical nor a cosmetic issue. For a minority of patients, medical and cosmetic challenges may arise. A small percentage of patients will develop hypertrophic or broad scars. Others feel limited in the hair styling options because of the donor scar. For these reasons, and because of the general trend toward less-invasive procedures in medicine, alternate donor harvesting methods were investigated.

Figure 2. Honeycomb scarring.

Follicular Unit Extraction Versus Elliptical Donor Harvesting

The concept of follicular unit extraction (FUE) was introduced in the early 21st century and refined over the past decade.[4–6] Follicular unit extraction used the same concept of using a steel trephine to harvest donor hair, but instead of being 2 to 4 mm in diameter as was used in the past, the FUE punches range from 0.8 mm to 1.2 mm. This technique is a natural extension of the concept of follicular unit hair transplantation—the utilization of individual follicular groupings in the recipient *and* donor sites.

Challenges of this technique include the following: increased risk of transection of hair follicles, operator fatigue when harvesting hundreds of follicular groupings, and appropriate spacing of harvested grafts to yield the maximum amount of donor hair without creating the appearance of a depleted donor density.[6] Throughout the posterior scalp, the angle of hair growth varies, which presents a challenge to surgeons. Magnification and excellent lighting reduce but do not eliminate the risk of transecting follicles. Compounding this challenge is the need to remove dozens to many hundreds of follicular groupings for each case. Harvesting larger numbers of grafts can result in increased operator fatigue and a higher rate of transected hair follicles. Some experienced surgeons are able to harvest large numbers of follicular groupings with minimal transections, but others are unable to do so.

To improve the accuracy and efficiency of FUE, numerous FUE devices have been developed; of which some are motorized, some are suction assisted, and some are single user-directed robotic system. The NeoGraft automated hair transplant system,[7–9] SAFE (surgically advanced follicular extraction) system,[10] and ARTAS Robotic System (Restoration Robotics, Inc, San Jose, CA) are a few of the more well-known FUE devices on the market. In this article, the authors discuss about robotic follicular unit extraction with the robot.

Robotic Follicular Unit Extraction

Technical Aspect

The robotic system was approved by the Food and Drug Administration for hair transplantation in 2011.[11] This robotic device is used to harvest follicular units from the donor region (Figure 3). A 1-mm punch is attached to the robotic arm consisting of a "needle-within-needle"; there is a sharp inner punch surrounded by a blunt outer punch. The sharp inner punch creates a shallow 1-mm incision, subsequently, the blunt outer punch spinning at 400 to 800 rpm dissects deeper and separates the follicular units from surrounding tissue. A suction system attached near the punch elevates the follicular unit from the surrounding skin allowing for easier extraction of the graft. A combination of stereoscopic cameras managed by image processing software allows the sharp and blunt punches to identify the precise angle and direction of hair growth. This continuous imaging feedback allows the robot to precisely harvest each follicular grouping. Because of the high level of automation, the robot is able to remove 400 to 600 grafts per hour.[11–13] The software requires a minimum distance of 1.6 mm between extracted follicular groupings to minimize the risk of overharvesting donor hair. In Table 1, the authors compare strip harvesting with robotic FUE for donor harvesting.

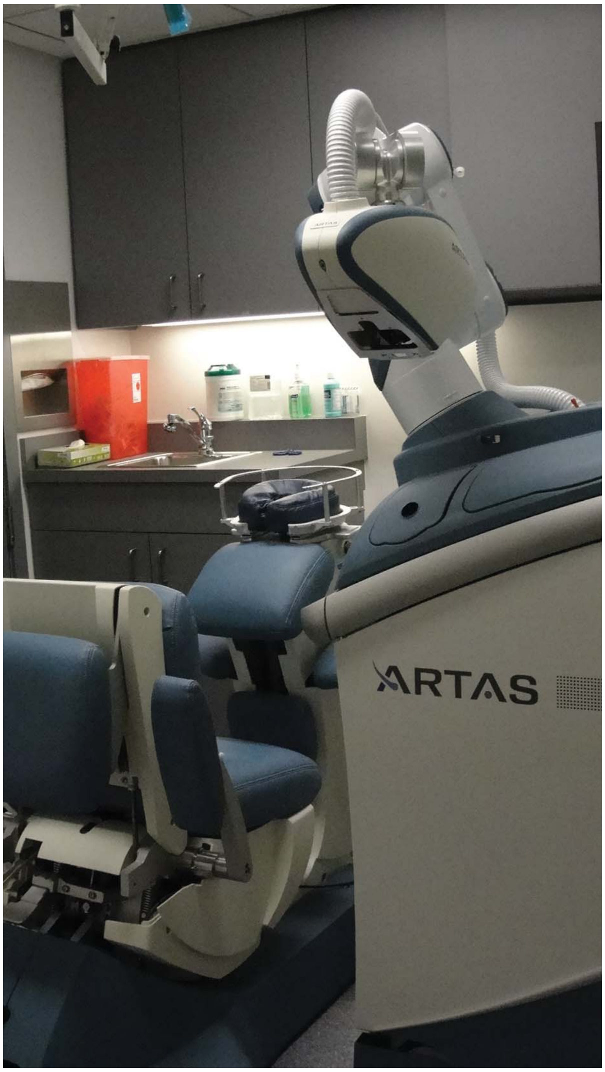

Figure 3. The robotic device.

Procedure

Donor Region

Patients must trim their hair 1 to 1.5 mm in length for proper removal of follicular groupings whether performed using traditional manual punch FUE, a motorized FUE device, or robotic FUE. The area of trimming needed to harvest equal numbers of follicular groupings is *far greater* with traditional or robotic FUE than with a donor ellipse. This is of minimal practical concern for patients who can wear their hair shorter, but it is a major concern for those who wear their hair longer (Figure 4). In the authors' practice, all patients choosing robotic FUE to date have been men. No women have yet been willing to trim an extensive area of their posterior scalp for donor harvesting. The authors continue to prefer a donor ellipse for their hair transplant. In Table 2, they summarize the ideal qualities of a candidate undergoing robotic FUE.

TABLE 1. Comparison of Strip Harvesting to Robotic FUE Harvesting

	Strip Harvesting	*Robotic Follicular Unit Extraction*
Scarring	Linear scar	No linear scar
Time to harvest grafts	10–20 minutes for 300–2,000 grafts	45–60 minutes for 300–600 grafts; 60–120 minutes for 600–1,200 grafts
Healing time	7–10 days	3–5 days
Cost	Minimal	Significant to purchase machine (approximately $240,000) and additional per surgery fee for each harvest attempt (approximately $1/harvest attempt = attempt to extract 1 FUE)
Transection rate	Low with experienced team; widely variable with inexperienced team	Low to low–moderate
Physician skill	Standard skin excision techniques	Knowledge of software program and robot
Technician skill	Skilled technician mandatory to create follicular units with low transection rate	Skilled technician needed to remove grafts from scalp and assess quality under magnification before placing in the recipient site
Reliability	Technician + physician dependent	Technician + physician + robot dependent
Area of donor site shaved	1.5 cm × 8–10 cm	4–8 cm × 10–20 cm
Space requirement	Can be done in office space used for standard excisions	Minimum office space: 10 foot × 10 foot; large procedural space Robot dimensions Cart: length 48 inches, width 27 inches, height 68 inches Chair: length 57 inches, width 33 inches, height 48 inches Weight: cart = 872 lbs, chair = 550 lbs
Electrical requirement	Power supply of a standard patient room	1. 208 VAC ± 10%, single phase, 50/60 Hz, 10 A. Required power outlet configuration is NEMA L6-20R twist lock
Technical requirements	None	1. Ethernet port, no Wi-Fi 2. Personal computer 3. Secondary monitor, with HDMI cables from robot to monitor 4. Desk (workstation), at least 2′ x 3′ working surface

VAC, volts of alternating current.

The sensors and cameras in the robot require pigment in the hair for optimal harvesting with minimal transection. Consequently, patients with blond, red, or gray hair have the donor hair dyed in the authors' office before administering local anesthesia. After trimming, and dying if necessary, the donor region is anesthetized with local anesthesia. After anesthetizing the donor region, the patient finds a comfortable position in a chair specially designed for the robot. A skin tensioner measuring approximately 3 × 3 cm is

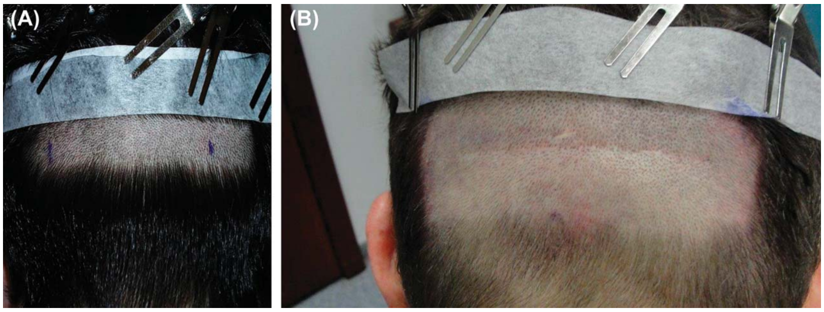

Figure 4. Donor region trim for strip harvesting (A) and for robot harvesting (B). Note that approximately the same number of hair follicles was transplanted in both cases.

TABLE 2. Robotic FUE Candidate Selection

	Ideal Candidate	*Suboptimal Candidate*
Area of donor site shaved	Willing to shave a large area for donor harvesting	Not willing to shave a large area for donor harvesting
Patient personality	Able to sit still for 45–120 minutes while grafts are harvested	Unable to sit still for long periods of time
Donor site density	High	Low*
Hair color	Brown, black hair	White, blonde, red hair†
Hair length	Short hair	Long hair
Patient's scar preference	A patient preferring no evidence of linear scar on their scalp after the procedure	A patient who does not mind a linear scar

*Note: more difficult to harvest large numbers of follicular units.
†Note this can be overcome by dying hair.

placed on the skin, which creates turgor necessary for optimal harvesting (Figure 5). The physician and assistant use a hand-held remote control and a computer monitor to control all aspects of the harvesting process. The spacing between harvests, needle depth, and the area to be harvested are controlled and adjusted if needed during the procedure. During the harvesting, the patient rests their head on a pillow similar to that found on a message chair. After each section is harvested, the physician moves the tensioner across the back of the scalp until the desired number of grafts is obtained. Each 3 × 3 cm tensioner harvests an average of 90 to 120 follicular groupings. Therefore, if a patient with an average density needs 800 grafts for the procedure, the tensioner will be moved 7 to 9 times across the donor region. While harvesting grafts, the robotic device displays the angle of hair growth, density of hair in the region, and counts the number of grafts obtained.

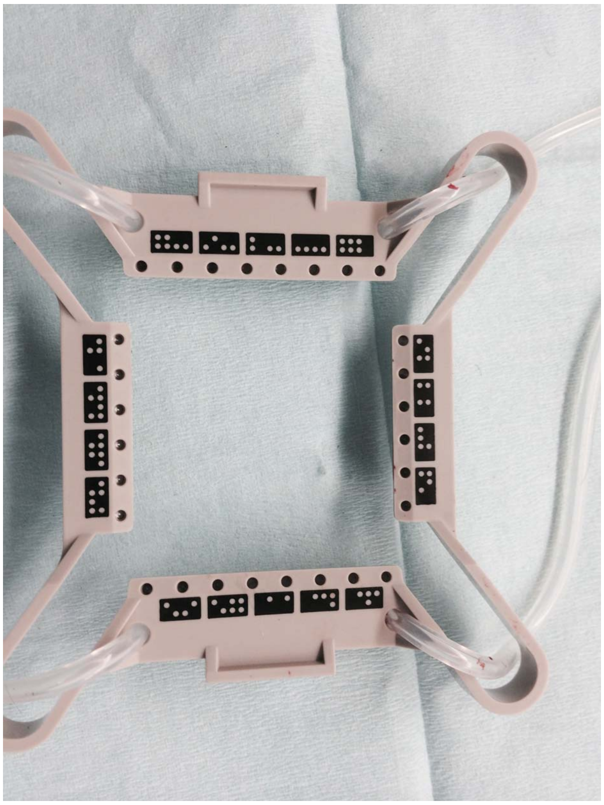

Figure 5. Skin tensioner for the robot.

Once all the grafts are created, the robotic arm is retracted and the grafts are removed by technicians from the donor region using microvascular forceps. After the last graft is removed, a temporary dressing is applied and the patient can stand up, stretch, and get ready for the placement of the grafts into the recipient zone. The remainder of the procedure from hairline design to recipient site creation and graft placement is the same as with nonrobotic hair transplant surgery.

Processing of Grafts and Transection Rate

The grafts are kept in chilled saline and inspected under magnification. Each graft is inspected for damage to the follicular unit. In Table 3, there is a summary of the case-by-case transection rates noted over 20 consecutive robotic FUE cases. All 20 cases were performed by one operating physician and the same 3 hair transplant technicians. The ethnicity of the patients varied and included many races, including white, Asian, Middle Eastern, and Indian. The patients' hair colors included white, gray, black,

TABLE 3. Twenty Individual Case Statistics and Transection Rates

Patient	No. Grafts Harvested	No. Grafts Transected	Total Number Transplanted	Transection Rate (No. Grafts Transected/ No. Grafts Harvested)
1	377	27	376	27/377 (7.2%)
2	236	1	241	1/236 (0.4%)
3	301	3	226	3/301 (1.0%)
4	550	4	599	4/550 (0.7%)
5	351	33	356	33/351 (9.4%)
6	223	1	234	1/223 (0.4%)
7	397	9	NA	9/397 (2.3%)
8	250	1	276	1/250 (0.4%)
9	477	30	623	30/477 (6.3%)
10	454	72	399	72/454 (15.9%)
11	358	28	384	28/258 (10.9%)
12	446	20	492	20/446 (4.5%)
13	430	30	492	30/430 (7.0%)
14	385	28	305	28/385 (7.3%)
15	206	5	212	5/206 (2.4%)
16	479	45	405	45/479 (9.4%)
17	536	52	545	52/536 (9.7%)
18	200	1	215	1/200 (0.5%)
19	504	20	598	20/504 (4.0%)
20	632	203	568	203/632 (32.1%)
Average	389.6	30.65	397.2	6.6%*

*Note: 6.6% is the mean of transection rates for each individual case.
NA, not available.

brown, and blond hair, and all the patients had relatively straight hair. The grafts were evaluated by technicians with more than 15 years of experience each. Grafts noted to have more than 1 follicular grouping (often, 1 FUE graft may contain 3–4 hairs) were split into individual follicular groupings. It is not uncommon for 1 FUE to yield 2 grafts once split into follicular groupings. The total number of grafts harvested, grafts transected, and grafts transplanted were recorded. Grafts were counted as transected if any part of the hair follicle was missing (bulb, isthmus, or infundibulum). Capped hair follicles (hair follicles that had only the epidermis present) were also counted as transected. The transection rate ranged from 0.4% to 32.1%. The average transection rate was 6.6%. In the literature, strip harvesting using the "donor dissection" technique with an experienced hair transplant staff has been reported to have a 1.59% transection rate. In the "donor dissection" technique, direct visualization of hair follicles is used to minimize the transection rates.[14] With traditional 0.8- to 1.2-mm steel punch FUE or motorized FUE devices, there are some data regarding transection rates. One study by Onda and colleagues[15] comparing the use of a novel powered FUE (P-FUE) device to manual FUE reported a 5.4% transection rate with P-FUE versus a 17.3% transection rate with manual FUE. Another study by Harris[10] using the SAFE (Surgically Advanced Follicular Extraction) System reported an average transection rate of 6.14% with a range of 1.5% to 15%.

Discussion

Robotic FUE allows a physician to transplant many hundreds to thousands of follicular groupings from the donor region into the recipient area without creating a linear scar on the patient's scalp. This is a major technical advance in the procedure. For years, manual and motorized FUE have been performed with success around the world. The challenge for many physicians with manual and motorized FUE is efficiently harvesting hundreds to thousands of follicular groupings with minimal transection. The robot allows 400 to 600 follicular groupings to be harvested per hour with transection rates comparable with those of grafts created from an ellipse by experienced surgical assistants. There is no doubt that some physicians may be able to harvest large numbers of grafts using a manual punch or motorized device with transection rates similar to those of the robot. The expense, space requirements, and ongoing maintenance costs of a robot are not needed for these skilled physicians. Also, many physicians cannot efficiently harvest follicular groupings with low transection rates using manual or motorized FUE, and the robot will allow them to efficiently harvest high-quality grafts. The combination of stereoscopic cameras managed by image processing software allows the robot to accurately and efficiently harvest follicular units. Because of the high level of automation with the robot, there is a minimal learning curve compared with that of manual or motorized FUE. The robot also eliminates the issues of operator fatigue, which often results in higher transection rates with manual and motorized FUE. The robot is consistently able to remove 400 to 600 grafts per hour. Unfortunately, well-designed long-term studies comparing techniques such as the robot FUE to non-robotic FUE do not exist to date.

Currently, the robot is an additional option for donor harvesting. It has *not* replaced traditional elliptical donor harvesting or manual/motorized FUE. For patients who wear their hair short, want the option to wear it short, or simply do not want sutures or a linear scar on their scalp, robotic FUE is an efficient and safe method for harvesting follicular units. The auhtors report that the biggest practical hurdle for some of their patients has been the need to trim an extensive part of the donor region. To date, no women have opted for the robot, all have chosen the strip harvesting. Men have been evenly split between the ellipse and robot. The majority of men who have had an ellipse in the past have chosen an ellipse for repeat procedures because of high satisfaction with the previous result and the existing scar on their scalp. The majority of men who have not undergone a previous strip procedure have chosen robotic FUE to avoid sutures and a linear scar.

To date, the authors have had no known medical or surgical complications with any of their robot patients. Possible complications and side effects include a small risk of infection and bleeding, as with any surgical procedure. There will be pinpoint scars at the sites of follicular extraction. Additionally, proper spacing and removal of follicular groupings is necessary to reduce the risk of a “moth-eaten” or pseudo-syphilitic” appearance, and improper spacing can also result in necrosis, and cyst formation.[16,17]

The authors have also found that the number of grafts harvested by the robot does not always directly correlate with the numbers of grafts transplanted. In some cases, higher transection rates have resulted in fewer grafts transplanted, whereas in other cases closely, spaced follicular groupings within a 1-mm harvested graft have allowed more grafts to be placed than were harvested by the robot. As can be seen in Table 3, the transection rates of the 20 cases varied considerably, and ranged from 0.4% to 32.1%. In the authors’ experience, suboptimal tension and turgor when using the tensioner of the robot can lead to increased rates of transection. Careful placement of the tensioner and additional injection of saline for added turgor will reduce this risk. The authors did not notice any differences based on hair color or ethnicity. All patients reported by the authors had relatively straight hair. The authors suspect that in Case 20 with a 32.1% transection rate, suboptimal tension and turgor compounded with a “mushy dermis,” a term used to describe the characteristics of a dermis that lacks stiffness, may have contributed to the extraordinarily high transection rate.

Follicular unit extraction has expanded the number of patients eligible for a hair transplant procedure. In the past, younger patients in their twenties or early thirties who expressed a desire to wear their hair short or possibly wear their hair short in the future were not operated on because of the concern that a linear scar could present a problem in the future. Follicular unit extraction, by avoiding a linear scar, allows more diverse hair styling options for men undergoing the procedure. With FUE, if a patient opts to shave their hair, there should be no evidence of a hair transplant procedure. In addition, patients with extensive scarring from large punch grafts and/or donor ellipse scars can benefit from FUE. The robot can harvest individual follicular groupings without creating another large full-thickness scar that may not heal well (Figure 6).

As with most technological advances, including contemporary dermatologic lasers and radiofrequency devices, the device comes with a considerable price tag, and a cost–benefit analysis should be performed for each practitioner before purchasing the device. Space is another concern in some practices because as the device occupies a considerable amount of space.

Future of Hair Transplantation

The era of robotic hair transplantation has begun. In the near future, the authors expect the robot to be able to harvest more grafts more rapidly and with even greater precision. They look forward to more data in the literature regarding experience of others with the robotic device. The current size of the tensioner (3×3 cm) mandates large areas of donor hair to be trimmed. The option of tensioners with different dimensions would allow greater flexibility in hair trimming and open the procedure to a greater number of patients.

Unfortunately, the authors anticipate complications from the robot as with any procedure. Hair transplantation is limited by the amount of donor hair available. Overzealous donor harvesting may create

Figure 6. Robotic FUE in a patient with honeycomb scars from 3 to 4 mm punches and linear scars from the donor ellipse.

an iatrogenic pseudo-syphilitic appearance with "moth-eaten" donor regions. The robot's software will not allow the machine to harvest hair closer than 1.6 mm during any one procedure. This ensures naturally appearing regrowth of hair in the donor region. Data regarding second and third procedures and the potential for thinning of the donor region do not exist. Until these data exist, a conservative approach to donor harvesting should be followed. Lack of a linear scar may also entice physicians to harvest hair from regions of future hair loss. This will result in the loss of those transplanted hairs in the future and relative thinning of transplanted hair in the frontal scalp. Additionally, follicular cysts have been described as a complication of other methods of FUE due to buried or subluxed grafts. They typically present 6 months—2 years after the FUE procedure.[16] Theoretically, this same complication can result from robotic FUE, although the authors have not experienced these complications with the robot to date.

The ultimate goal of robotic hair transplantation is for the robot to perform donor harvesting, recipient site creation, *and* graft placement. Currently, robotic FUE harvesting requires less staff time to create follicular grafts than a strip harvesting. Robotic FUE directly produces follicular groupings, however a team of experienced surgical assistants is needed to process an ellipse into follicular units. An experienced team is still required to place grafts into the recipient sites, which precludes some physicians from performing the procedure. The ability of a robotic device to harvest grafts, create recipient sites, and place grafts, may dramatically increase the number of physicians who are capable of performing the procedure.

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Robotic Hair Restoration

Paul T. Rose, MD, JD*, Bernard Nusbaum, MD

KEYWORDS

- Follicular unit extraction • Follicular isolation technique • Robotic hair transplantation
- Follicular units • Transection • Strip harvesting

KEY POINTS

- The robotic system of hair restoration is an important addition to the techniques used for hair restoration surgery.
- Robotic hair restoration is based on the follicular unit extraction/follicular isolation technique (FUE/FIT) harvesting process and provides the means to obtain such grafts in a reliable and efficient manner while maintaining low transection rates.
- The advantages and disadvantages associated with the robotic device are similar to those of manual or mechanized FUE/FIT harvesting.
- Using the robotic system a physician can more easily add hair replacement to his or her practice and not have to markedly increase staffing.

INTRODUCTION

The use of robotic mechanisms that assist in surgery have been available for more than two decades. The most prominent system is the Da Vinci system (Intuitive, Sunnyvale, CA) whereby a physician directs the movement of the robotic apparatus in various surgical procedures.

An advantage of a robotic system is that it can perform repetitive maneuvers with great precision. This ability to perform repetitive movement lends itself particularly well to the performance of hair restoration procedures when follicular unit extraction/follicular isolation technique (FUE/FIT) is used. The robot assumes some of the tasks that would require several assistants if a strip harvesting procedure is undertaken. The system also requires less time to be proficient with FUE/FIT compared with learning to do manual FUE/FIT surgery.

The ARTAS system (Restoration Robotics, Sunnyvale, CA) is a robotic device developed specifically for the FUE/FIT procedure. It is cleared by the Food and Drug Administration (FDA) and approved for use only in men for the purpose of hair transplantation.

FUE/FIT is a form of follicular unit grafting[1] and is a technique for removing hair grafts based on obtaining intact follicular units[2] or intact parts of a follicular unit from the donor area of a patient's scalp and then implanting the grafts into appropriate recipient sites (**Figs. 1** and **2**). The technique is essentially the old fashioned punch-graft procedure[3] but performed with small punches, usually 0.7 to 1.2 mm in size. Whereas the 4- or 5-mm punches used in the older punch technique harvested multiple follicular units, which may or may not have been totally intact, the FUE/FIT process is designed to remove single follicular units or intact parts of a follicular unit.[4–6]

The primary attraction for patients who seek FUE/FIT is that it is considered to be a less invasive or minimally invasive procedure compared with strip harvesting and most importantly, a linear scar is avoided. The patient may be able to wear his hair shorter than if a strip harvest was performed but there is a limitation to this, because

Disclosures: Dr Rose has been a consultant to Restoration Robotics; Dr Rose owns stock in Restoration Robotics; Drs Rose and Nusbaum have an ARTAS system in their office.
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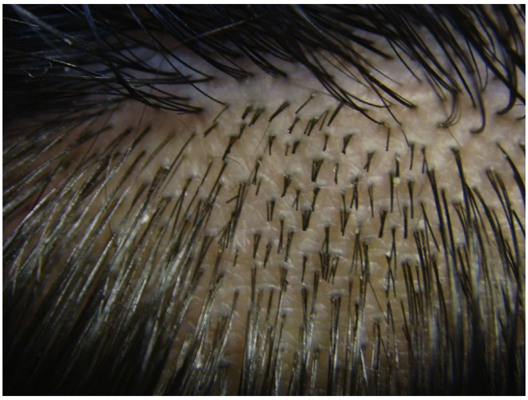

Fig. 1. Normal appearance of hairs in the scalp. It is important to notice that the hairs generally occur in groupings, referred to as "follicular units."

the wounds from FUE can be visible if the head is closely shaved. The appearance of the scar from strip harvesting depends on multiple factors, such as donor density, strip width, tension on closure, scalp laxity, surgical technique, and the patient's healing characteristics.

Some advocates of FUE/FIT believe that the recovery time is shorter and patients can assume strenuous activities sooner.[7] They also suggest that the procedure is less painful than with strip harvesting. The wounds from FUE do tend to appear closed in 4 to 5 days, whereas a strip harvest patient has sutures or staples in place for 7 to 14 days.

The FUE/FIT procedure is considered well suited for a young patient who is uncertain as to whether he will ever want to shave his scalp or proceed with additional hair transplants. If he were to have a strip harvest, concealing the resultant scar could be a possible concern. Thus, the FUE technique gives the patient more flexibility in the future as to whether to have more procedures. FUE is also very helpful when the scalp is tight in the donor area after strip harvesting and therefore the number of grafts that can be obtained with further strip procedures is limited. FUE/FIT can also be very useful in obtaining grafts for insertion into existing linear strip harvest scars. FUE/FIT can also be used to harvest body hairs.[8]

In regard to postoperative pain, the authors have found that with strip harvesting pain is well controlled with medication, such as oxycodone. Furthermore, with the use of liposomal-encapsulated bupivicaine (Exparel; Pacira Pharmaceuticals, Parsippany, NJ) postoperative pain is less commonly an issue with strip harvesting. The liposomal-encapsulated bupivicaine lasts up to 72 hours.

For the physician, an advantage to performing FUE is that fewer personnel are required compared with strip harvesting. This is because large strip harvest cases require several assistants to dissect the follicular unit grafts from the harvested donor strip tissue. With FUE, the procedure can be done with only one or two additional assistants whose role is to simply clean the grafts and sort them into follicular unit groups containing one, two, or three or more hairs.

The manual technique involves using a biopsy punch of some type and manually harvesting the follicular unit grafts. Many physicians use a sharp punch, whereas some use a combination of a sharp punch to enter the epidermis and then a dull punch to go into the dermis and fat.[6,9] Some physicians use a motorized drill with a punch attachment for this type of harvesting.[10] There are several variations of a motorized drill on the market (**Fig. 3**). The use of a motorized drill

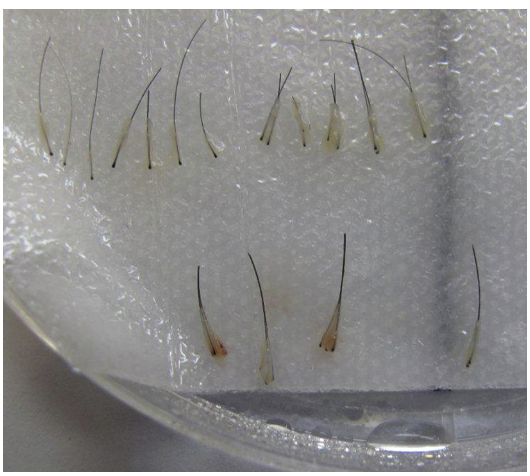

Fig. 2. Follicular unit grafts are depicted. Typically the grafts contain one hair, two hairs, or three hairs. On occasion follicular units with greater numbers of hairs in the unit occur.

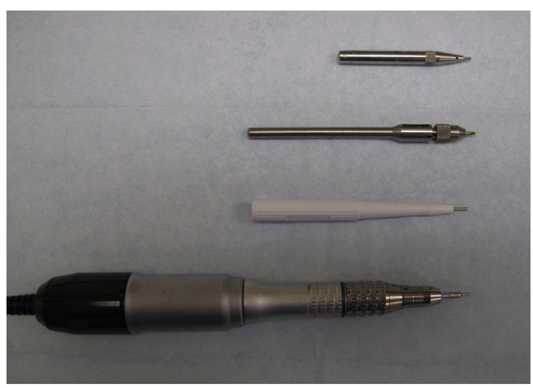

Fig. 3. Different types of punches used to harvest FUE/FIT grafts. A motorized drill with a punch is also shown.

can help skilled physicians harvest quickly and maintain low transections rates, with some physicians attaining harvest rates in excess of 400 grafts per hour with transection rates below 10%. It can be difficult, however, for some clinicians to develop the necessary skill set to attain low transection rates and adequate speed to perform the procedure efficiently. Additionally, FUE can be a tedious and tiring procedure for physician and patient.

At times transection rates can be quite high. In one FDA study the transection rate of manual FUE was noted to be about 26%, whereas the robotic procedure was rated to be 8%.[7,11] The authors have found lower transection rates with their approach to FUE/FIT and believe that physicians can develop the skill to accomplish lower transection rates with the manual process than that reported by the FDA. In the authors' own experience the transection rate for the robot can exceed 8%.

As a side note, it is important to make sure that the definition of transection rate is agreed on by all surgeons performing FUE. The author defines transection as a graft where any of the target hairs are severed. If the surgeon attempts to obtain a three-hair graft and harvests only two of the hairs while the third hair is damaged, then a transection has occurred. Some define a transection as a graft where none of the hairs were obtained.

THE ROBOTIC SYSTEM

The robotic system is FDA approved for male patients with brown or black hair. It consists of a proprietary imaging technology, computer interface terminal, multiple video cameras, video display, the robotic arm device, a suction system to lift up the harvested grafts, and an ergonomic chair that positions the patient in the proper orientation for the robot. The chair is adjustable for height, rotation, and head position (**Fig. 4**).

The robot scans and digitizes the visual characteristics of the donor area and characterizes each follicular unit. Based on a mathematical algorithm that can be adjusted to some extent, the machine randomly harvests follicular units.[12–14] Spacing is such that the harvested grafts are adequately spaced apart so as to decrease the chance that the graft sites would be visible if the patient wears his hair quite short. The computer program also calculates follicular unit density and hair angulation.

The robotic arm has a dual-bore needle apparatus that includes a sharp needle tip to enter the skin and a surrounding coring blunt needle that then goes deeper into the tissue to limit the chance

Fig. 4. The Restoration Robotics ARTAS system includes the robotic arm, ergonomic chair, and video monitors. (*Courtesy of* Restoration Robotics, Inc, San Jose, CA; with permission.)

of transection of hairs and allow for easier removal of the selected follicular units. The sharp needle has graduated markings to allow the physician to assess the depth of penetration.

The system is designed for use by a physician in conjunction with an assistant working at a computer terminal. Together the physician and assistant can continually make adjustments as needed to facilitate harvesting.

The robotic system has pressure sensors that assess forces generated to penetrate tissue. The system ceases operation and requires a resetting of the parameters if the threshold of force needed to penetrate the tissue is exceeded. The device has several other safety features. The safety system of the robot prohibits the robotic arm from touching other parts of the robotic arm that might hinder advancement of the needle apparatus or cause damage to the robotic arm. The robot is designed to prevent any possible injury to the patient by restricting the movement of the arm if necessary. It is noted that more than 350 patients were treated in the clinical trials and there were no safety-related issues.[15] The physician and assistant have emergency stop buttons to cease operation of the machine. The emergency stop button is located on the "pendant" handpiece that the physician uses to control the various functional parameters of the device (**Fig. 5**).

Patient movements are monitored by the robotic system allowing the machine to move to some extent with the patient. If movement is excessive the robot indicates that it cannot adequately recognize the follicular units and ceases harvesting.

THE ROBOTIC PROCEDURE

Medical and Surgical History

As with other surgical procedures the patient's medical and surgical history are obtained before the procedure. A diagnosis of male-pattern hair loss is confirmed by appropriate examination. In some cases the diagnosis of a hair loss condition apart from male-pattern hair loss may also be suitable for hair transplantation. Depending on physician preference, laboratory work, such as complete blood count, complete metabolic profile, prothrombin time and partial thromboplastin time, and hepatitis and HIV status, may be obtained before surgery.

Preoperative Photographs and Marking

At the time of the surgery, photographs are taken of the patient's scalp from the front, sides, back, and top of the head. Appropriate informed consent is provided.

The recipient area is designed and marked and then the area to be harvested is marked out and shaved to a length of approximately 2 mm. Photographs are once again taken to demonstrate the recipient area design and the marked donor area.

In most patients the proposed donor area conforms to the safe area of hairs that are expected to survive throughout the patient's life.[16] In some instances the physician may decide to harvest outside of the recognized safe area if he or she believes that the patient's hair loss will be limited and allow removal of grafts from beyond the safe zone.

The authors often divide the donor area into sections. Usually four sections are marked out, two central portions and two lateral portions. The area to be harvested is anesthetized in sections so that the smallest amount of anesthetic agent is used at any one time throughout the course of the surgery. The authors use 1% lidocaine with epinephrine 1:100,000 for this purpose.

Anesthetic

The patient is typically provided some form of sedation, such as diazepam or similar medication. Pain medication may also be given. Some

Fig. 5. The "pendant" that is held by the physician provides an ability to adjust the various harvesting parameters of the robotic device. There is an emergency stop button should the physician need to stop the machine while in motion.

physicians elect to give preoperative antibiotics routinely, whereas some give antibiotics depending on the patient's health status. Some physicians use intravenous sedation, which allows for easier maneuverability of the patient and limits ill-timed patient movements that slow down the use of the robotic device.

Robotic Technique

- After the patient is positioned in the chair, in a semiprone orientation, the surgeon applies a tensioner to the initial area selected to be harvested. The tensioner measures approximately 10 to 11 cm^2 and it is crucial that the skin be stretched before application of the tensioner and that the tensioner be placed securely on the desired area (**Fig. 6**).
- To increase the rigidity of the tissue in the area, fluid, such as saline or saline with epinephrine 1:100,000, is injected into the dermis to provide a firmer surface so that the robot can incise into the skin more easily.
- The physician works with an assistant stationed at a computer terminal. The robot is then directed to identify borders of the tensioner (**Fig. 7**). The tensioner has fiducial markings that allow the robot to track patient movement and ensure proper alignment for the robot to recognize the area and the grafts in the enclosed space. With the tensioner in place the robot then scans the image of the enclosed donor area. The robotic cameras then send the image to the computer to recognize the follicular units, angle of hairs, and the follicular unit density within the tensioner area (**Fig. 8**).
- After the follicular units are identified the robot can then begin to select units for harvesting. The robot determines the angle of the hair follicles and a suitable angle for the robotic needle to approach the follicular unit. The surgeon can control the machine by a "pendant" that has various buttons controlling the harvesting parameters (see **Fig. 5**). The person operating the computer terminal, which can be the physician or an assistant, also has the ability to control some aspects of the harvesting process. In the course of harvesting the physician has the ability to select or skip units chosen by the robot.

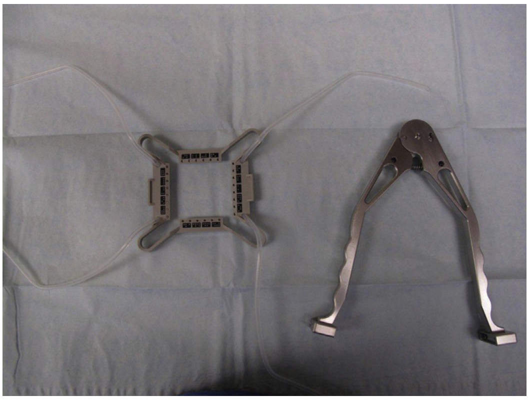

Fig. 6. The tensioner and the tool used to place the tensioner onto the donor skin.

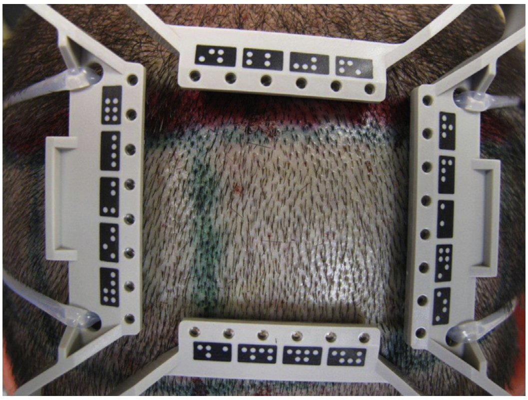

Fig. 7. The tensioner is positioned onto the skin for donor harvesting. The fiducial markings are seen along the periphery of the tensioner. These marking allow for orientation of the robot by the imaging system.

- The robotic arm has at its end a sharp 1-mm needle that initially penetrates or "scores" the skin, just entering the epidermis. This portion of the needle has clearly visible gradation markings on the monitor to allow the physician to control the depth of penetration. A second blunt punch then enters the skin to a greater depth to core out the graft. The depth of the needle penetration and the depth of the coring blunt punch can be adjusted as needed by the physician. Additionally, the speed of the drill tip can be adjusted. The vacuum assist helps to raise the grafts up facilitating harvesting and also allows visualization of the harvested grafts below their epidermal surface to adjust parameters and optimize graft quality.
- After several grafts have been incised, the physician assesses from the video screen the quality of the graft harvesting (**Fig. 9**). Several grafts can also be examined by collecting them from the tensioner enclosed area. If the physician is satisfied with the grafts the robot can be placed on automatic mode and the machine will harvest at speeds generally ranging from 300 to 500 grafts per hour.

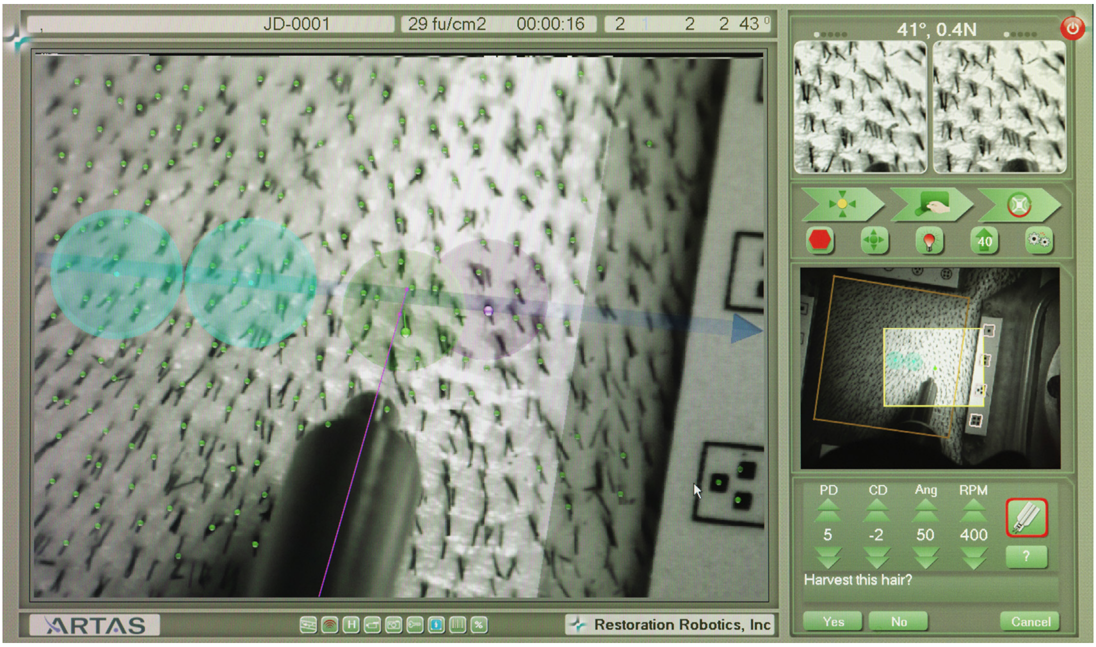

Fig. 8. View of the video screen as observed by the physician. The screen shows parameters that are considered to harvest the tissue. CD, coring depth of the outer blunt needle; PD, punch depth of the needle. The speed of rotation can be adjusted (RPM) and the angle of attack can also be observed on the video screen. (*Courtesy of* Restoration Robotics, Inc, San Jose, CA; with permission.)

Graft harvest speeds in excess of these numbers are reported.

- After the initial tensioner area is harvested the tensioner is removed and the grafts are collected, examined, and trimmed under a microscope if necessary. The tensioner is then moved to an adjacent area and the same process discussed previously is repeated. Logistically, it may be helpful to harvest several grids and collect the grafts while another grid is operated on. At times the suction component may not be able to elevate the incised grafts. Such grafts are often tethered to underlying tissue and it may be necessary to free up the graft. Using a 19-gauge needle can be helpful in releasing the graft.

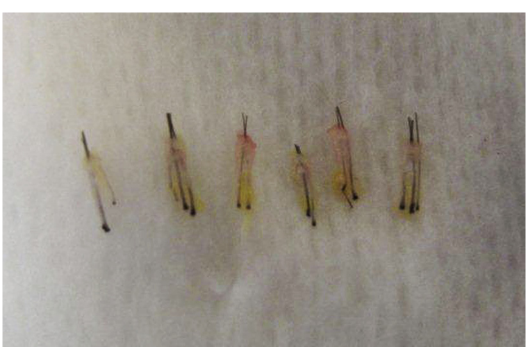

Fig. 9. Typical grafts harvested by the robotic device.

An average Norwood type V or VI patient is able to have 1500 to 2000 grafts harvested in a single session. Some physicians have reported harvesting in excess of 3000 grafts from some patients. In such instances the patient may have a particularly high follicular unit density, large head, and therefore an extended surface area of harvesting available. It may be that the surgeon has decided to exceed the safe donor zone and/or grafts are cut down to smaller sizes.

It is noted that graft harvest speed is not directly correlated to the time it takes to complete the procedure. Graft harvest speeds apply only to the rate the robot is incising grafts at the time it is in the automatic mode. Time is added by having to manually collect the grafts, reposition the tensioner, make recipient sites, and place grafts. Therefore, if 1500 grafts could actually be harvested in 3 hours there would still be several additional hours needed to place all the grafts in the recipient site. A 1500-graft case might take 5 to 6 hours to complete.

Recipient Site

After the grafts are collected they are placed into recipients sites. This step is performed in the identical fashion as when follicular unit transplantation grafts are obtained from strip harvesting. The recipient sites are made for one-, two-, three-, and four-hair follicular units. Many physicians make recipient sites with custom-cut blades ranging from 0.7 to 1.5 mm in size. Others use premade blades or use needles, such as a 19-gauge, to make recipient sites. The same aesthetic considerations are followed as with any other hair restoration procedure.

Some physicians elect to make some or all of the recipient sites the day before the procedure to shorten the operative time on the subsequent operative day. This means that the surgeon has predetermined to a large extent the number of one-, two-, and three-hair grafts and what size the recipient sites will be before knowing for certain what the sizes of the harvested follicular units are at the actual time of surgery.

Postoperative

Postoperatively patients apply antibiotic ointment and alternate with a water-soluble lubricating jelly to the donor area. After 1 week we suggest the use of a product such as Mederma (Merz Pharmaceutical, Greensboro, NC).

Advantages

The use of a robotic device to perform FUE can be advantageous for various reasons. The procedure done manually requires significant skill that can take a substantial time to learn because the surgeon must account for hair direction, exit angle, density of skin, and selection of grafts. The process itself can be physically taxing for the physician. These issues are resolved with the use of the robot because it excels at such repetitive actions. The robot obviously does not experience fatigue and it has sufficient accuracy to ensure acceptable transection rates. The learning curve for proper use of the robotic device is significantly shorter than that for learning manual FUE/FIT.

For a physician entering the field of hair restoration an important advantage of the robotic procedure is that fewer personnel are needed compared with a strip harvest.[11] An assistant is used to help manipulate the robot by a computer terminal. At the same time the physician directs the device and is able to control the various parameters for harvesting.[14] The grafts recovered have a small amount of tissue on them so that further trimming is minimal, if needed at all. The placement of the grafts can be done by the surgeon and the assistant or in most instances two assistants place the harvested grafts.

From a patient point of view the robotic device advantages are akin to FUE/FIT whether manual or robotic. It is a procedure that is ideal for a patient who is averse to an incision and the idea of a linear scar. In a young patient who is uncertain as to whether he may want to have multiple hair transplant procedures or simply shave the scalp in the future, the robotic technique provides an ability to be more flexible in decision making. The patient can have a procedure and perhaps later decide not to have any more procedures, yet still be able to wear his hair quite short without evidence of a surgical procedure in the donor area. The patient would probably be reluctant to shave his head because the remnants of the punch wounds might be evident as hypopigmented dots.

The wounds with FUE seem to heal more quickly compared with strip harvesting where the donor site is sutured. There may be less postoperative pain in the first 24 hours but this may be a moot issue with the author's use of liposomal marcaine in strip surgery.

With strip harvesting there can be a period of tightness and paresthesia in the donor area, whereas a sense of tightness generally does not occur with the robotic procedure or FUE/FIT. In general, there may be a lower incidence of postoperative parasthesias but these seem to be of little consequence in strip harvesting because the parasthesias are infrequent and resolve quickly. Because no sutures are used with robotic harvesting or FUE/FIT there is no suture removal discomfort and one less visit to the clinic.

For the patient with a naturally occurring very tight scalp or tightness because of previous surgery, FUE/FIT is often the preferred way to harvest grafts and ensure avoiding a wide scar yet still harvest a significant number of grafts. Similarly, some patients have natural thinning in the supra-auricular area. That could allow a linear scar to be conspicuous. The FUE/FIT technique may allow harvesting without the possible appearance of linear scarring.

Disadvantages

As with any procedure there are advantages and disadvantages. The disadvantages of the robotic procedure are few but the physician needs to be aware of them. The robotic system relies on the machinery being able to adjust to patient movement and the ability to harvest along a curved surface, the skull. If the patient is moving to a great extent the robotic system will have difficulty properly aligning and a considerable time can be expended before the harvesting can occur. The sweet spot for manual FUE is generally believed to be the center occipital area and this is also true for robotic harvesting. As the harvesting moves to the lateral areas, particularly supra-auricular areas, the angle of hair growth can be difficult for the robot to align with and transection rates tend to be somewhat higher. Areas of varying hair direction can be a problem for the robot and working in the softer tissue of the nape yields reduced numbers of viable grafts, as is also true with manual FUE.

With continued harvesting (often multiple sessions) one notices with FUE and probably with robotic surgery that it becomes increasingly arduous to harvest large amounts of hair and higher transection rates may result from hair angle changes that result from adjacent scar tissue.

With manual FUE the surgeon can pick out particular grafts or particular types of grafts, such as two- or three-hair follicular units. This is much more difficult to do with the robot; however, recent changes to the software may allow this to be accomplished.

As with manual FUE/FIT, it is more difficult to harvest curly and particularly kinky hair as seen in blacks. In such situations or in situations where transection rates are unacceptable the surgeon may need to abandon the procedure and possibly perform strip harvesting if the patient has so consented.

Because the robot is a complex and sophisticated device with a computer interface there is a potential for mechanical, software, or hardware breakdown. If this should occur the surgeon needs to stop the procedure and have the patient return when the problem is fixed or have the patient consider manual FUE or even a strip procedure.

Because studies for the robotic system were done on males the FDA has approved its use to only male patients. Also, because the robotic system relies on the contrast between hair and the skin to identify hair clusters the system is only approved for use in patients with brown or black hair. If the patient has white or very blond hair this issue can be overcome by dyeing the patient's hair.

Although FUE/FIT is often advertised as a no scar or minimal scar procedure the mathematics prove otherwise.[17,18] The wounds created by FUE whether robotic or from manual FUE produce round scars where little or no hair grows. These spots are often hypopigmented and larger than the punch diameter used. If the patient wears his hair quite short or shaved, the scalp has an appearance of having been struck by buckshot (**Fig. 10**).

Fig. 10. After harvesting of FUE/FIT graft whether manually or with a drill or robotic device the donor wound scars may hypopigment leaving a buckshot appearance to the donor area.

Although a 1-mm punch may be used for harvesting the resultant scar is often greater than 1 mm and may approach 2 mm or more. If one takes 1000 grafts and calculates the area of scar even with 1-mm circles the area is 1000 × pi × radius squared. This equals 7.85 cm^2. For the same number of grafts a linear scar in a patient with 80 follicular units per square centimeter density, scar length of 12.5 cm, and a scar width of 2 mm, the total area would be 2.5 cm. Thus, the total area of scar created with FUE is generally greater than with strip harvesting given the same amount of grafts harvested.

As with other forms of FUE, if there is continued harvesting in successive sessions the donor area becomes thin and less dense. There can be a "step off" from the harvested donor safe area to the zone above that has not been harvested and is at least temporarily denser. For this reason it may be wise to perform low-density harvesting into the more superior areas to blend the densities of the safe donor area with the more superior hair.

When multiple sessions or excessive harvesting takes place, the donor area can have a moth-eaten appearance. Again, this is not a problem associated with the robotic device but rather the FUE approach, because nothing is being put back in place of the hairs taken out of the donor area. The author has used suction applied to the wounds to further improve healing of FUE/FIT wounds and decrease the size of the scars.

An issue inherent to FUE is that fewer grafts can generally be harvested in a single session compared with strip harvesting. This is because, to allow for adequate spacing between extraction sites, the surgeon can only remove approximately 12% to 20% of the grafts available in the first harvest session without the human eye detecting the pattern of wounds if the hair is cut very short.[17] With subsequent sessions the percentage that can be harvested decreases further. There have been reports from several doctors using the robotic system of cases in excess of 3000 grafts in one session. It seems that the surgeon is going beyond the traditional safe donor zone and may be cutting down grafts to smaller sizes.

The author has observed that the robotic system does not seem to work well in patients with previous strip harvesting. The area around the scar is often significantly less dense and the area of fibrosis makes it difficult for the robot to penetrate the skin. Also, the hair direction may be altered in the area adjacent to the scar and so transection rates may increase.

When large numbers of grafts are needed, the robotic surgery can be tiring for the patient. Some patients feel a sense of claustrophobia in the chair. There are patients who simply move too much for harvesting to proceed at a reasonable rate and acquire high-quality grafts. These patients tend to be very anxious at the outset and such patients might be best suited for having the procedure performed with intravenous sedation in an appropriate facility.

ADVERSE REACTIONS AND COMPLICATIONS

The complications associated with robotic surgery are essentially the same as with any FUE process.[18]

Buried Grafts

At times the use of a small-diameter punch inadvertently pushes the incised tissue further into the skin. The result is a graft that is buried in the adipose tissue. Oftentimes these grafts tend to be pushed off to the side adjacent to the incision. The surgeon can attempt to find the graft by probing the area with a mosquito hemostat or forceps. Making an incision with a #11 blade into the space created from attempting to remove the graft and pushing down on the surrounding tissue may force the graft upward and outward, allowing recovery of the graft. Sometimes injecting saline into the area may push the graft out. If one is unable to retrieve the graft, it is left alone. If the graft remains buried there may be a subsequent foreign body reaction or possibly a cyst may form and may need drainage or excision.

Transection

Transection results in damaged hair follicles and in some instances entire follicular unit grafts that are not usable. Some physicians argue that transection may not be important but could be beneficial because some hair might regrow at the FUE wound site. This would serve to camouflage to some extent the harvesting that has been performed. The surgeon should be aware of the degree of transection throughout the procedure and make adjustments of the various parameters of the robotic system to remedy the problem should it occur.

Although most physicians would agree that transection should be kept to a minimum, the question of what is an acceptable rate is crucial. Many who perform manual FUE believe that transection rates less than 10% are reasonable.

Thinning of the Donor Area Hair

As a result of FUE harvesting, the wounds result in areas in which no hairs grow. If the patient elects to wear his hair very short the resultant scars may be evident as an appearance of multiple dots with no hair, reminiscent of buckshot wounds. In some areas where the grafts have been harvested in close proximity in one or multiple sessions there can be a visible thinning of the hair in the donor area and a step off of hair density from the higher density above the harvest zone. There may also be an impression of a moth-eaten appearance to the scalp in areas where concentrated harvesting has occurred.

Hypopigmentation and Hyperpigmentation

The scars that occur with FUE whether by robotic device or manual harvesting are usually hypopigmented dots. These wounds, when they heal, might not induce activation and migration of melanocytes to restore normal skin color. This is most evident in patients with darker complexions. On rare occasions there may be hyperpigmentation.

Folliculitis

Occasionally, a folliculitis may occur at the donor site. This may be secondary to hair spicules that are left behind in the skin or partially transected hairs trying to grow through the healed donor sites. Treatment with warm soaks and opening of any pustules can be helpful. On occasion the use of suitable antibiotics may speed recovery. If an infection is suspected in the area, a culture and sensitivity study may be appropriate.

DISCUSSION

The use of a robotic device to perform FUE-type hair transplantation is an important innovation in hair restoration. The machine is in itself a remarkable technical achievement combining a computer interface, imaging analysis, and a robotic arm.

For patients, the attraction to this type of a procedure is severalfold. The process is considered to be less invasive than strip harvesting and does not involve the creation of a linear scar. There may be quicker healing and the patient may have an earlier resumption of strenuous activities compared with strip harvesting. Compared with manual FUE, robotic harvesting is often more consistent and generally more rapid while still maintaining acceptable levels of transection.

From the authors' perspective, the ideal candidates for the robotic procedure or simply FUE/FIT include young patients who have not had prior harvesting and need a relatively small amount of grafts. Such patients can then have a greater chance of wearing their hair quite short if they decide not to proceed with further grafting. Other candidates include those people averse to the concept of strip excision and those with tight scalps that preclude strip harvesting.

For physicians desiring to include hair restoration procedures in their practice or for those who want to add FUE to an existing "strip" practice, the robot solves some of the key issues involved in learning how to perform the procedure. With proper instruction the physician can produce a reasonable number of grafts in a short time and achieve acceptable levels of transection. The robotic system also allows the physician to perform hair transplantation with a limited staff.

For those who adopt the robotic system early on, there is a perception that such doctors are in the vanguard. Whether that is true or not there may be marketing appeal coincident with having the device. Tangential to this point is that the FUE process, whether done with a manual technique or with a drill or the robotic system, is sometimes marketed as a procedure that allows the patient to wear his hair at any length. Such statements are false and misleading. When a significant number of grafts are harvested, if the scalp is shaved, the scars from the procedure are obvious to the naked eye.

It should be evident that the robotic system is not the perfect answer for all hair transplantation efforts. There are shortcomings and these are essentially similar to those encountered in FUE. A prominent concern is the thinning of the donor area with continued harvesting and the appearance of hypopigmented scars if the hair is cut too short.

Importantly, the use of the robotic machine does not eliminate the need for the physician to be able to diagnose male-pattern hair loss and other hair disorders. The physician must still learn the aesthetic aspects of the hair restoration process and how to approach various levels of hair loss to achieve successful outcomes.

It is the authors' opinion that it behooves the physician to know how to perform manual FUE/FIT and strip harvesting in the instance that there is an intraoperative need to abandon the robotic procedure.

The authors urge anyone unfamiliar with hair restoration, who desires to perform hair restoration surgery, to learn about the various aspect of hair loss diagnosis and treatment and seek appropriate training. The International Society of Hair Restoration Surgery (www.ishrs.org) is an excellent source and the society offers numerous courses around the world.

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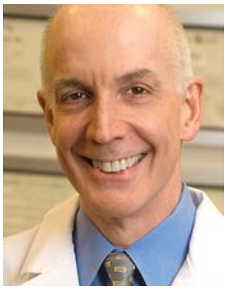

Robotic Hair Transplants

by: Robert M. Bernstein MD, FAAD, ABHRS

Follicular Unit Extraction (FUE) is a method of harvesting donor hair where individual follicular units (naturally occurring groups of 1-4 hairs) are removed directly from the scalp. This method differs from the standard Follicular Unit Transplantation (FUT) procedure where one thin, long strip is removed from the back of the scalp and is then dissected into individual follicular units with the aid of stereomicroscopes.

In FUE, an instrument is used to make a small, circular incision in the skin around a follicular unit, separating it from the surrounding tissue. The unit is then removed from the scalp, leaving a tiny hole. This process is repeated until the desired number of follicular unit grafts is obtained. The holes, approximately 1-mm in size, heal over the course of seven to ten days, leaving tiny white scars that are camouflaged by the hair in the back and sides of the scalp.

Tiny "recipient sites" are made in the balding area of the scalp, using a fine needlepoint instrument, where the extracted grafts will be inserted. The creation of recipient sites and the placing of follicular unit grafts are essentially the same in FUE and FUT. The differences between the procedures lie in the quality and quantity of grafts obtained as well as the appearance of the donor area.

Follicular Unit Transplantation

In FUT, the removal of a donor strip from the back of the scalp leaves a long, thin scar. While the scar is usually camouflaged by the person's hair, it can be a problem if the patient wants to wear his or her hair very short. A linear incision can also be a problem for a very athletic person who doesn't want any limitations to physical activity post-op. In FUE the resultant tiny white scars are easily hidden; even with relatively short hair. The lack of a linear incision enables the active person to resume most activities immediately after the procedure.

History and Instrumentation in FUE

The use of direct extraction to harvest follicular units was initially conceived by Dr. Ray Woods in Australia and called the "Woods Technique," but he did not disclose the details of his procedure. The technique was first described in the medical literature by Drs. Rassman and Bernstein in their 2002 publication, "Follicular Unit Extraction: Minimally Invasive Surgery for Hair Transplantation." This paper gave the procedure its current name and described the FOX test that is used to identify patient variability in harvesting, an issue that continues to be a significant challenge for doctors today.

Follicular Unit Extraction is an instrument-dependent procedure. Therefore, the type of tool that is used significantly affects the results. The earliest methods of extraction consisted of a small, round cutting instrument, called a "punch," to separate the follicular units from the surrounding tissue. Dr. Jim Harris advanced a significant refinement in the procedure when he added an extra step using a blunt instrument for the part that penetrates deeper into the skin. This extra step of blunt dissection substantially reduced transection (damage) to the hair follicles.

FUE instrumentation continues to evolve as more physicians gain experience with the technique. Currently, there are a wide variety of instruments used in FUE. These instruments include punches of different diameters and sharpness and instruments that are rotated by hand or are motor driven. Some techniques require the separated grafts to be removed from the skin with forceps and others use suction. Some surgeons utilize the single step method and others the two-step technique. However, no method was able to avoid the human error and fatigue associated with removing the hundreds to thousands of individual follicular units needed for a single hair restoration procedure.

Robotic FUE

Follicular Unit Extraction consists of two main steps: Separation of the follicular units from the surrounding skin, and extraction (removal) of the follicular units from the scalp. Step one is a highly repetitive and labor-intensive process that requires great precision. This step requires the centering of the punch over the follicular unit and the alignment of the dissecting instrument with the follicles to prevent damage. Since this process must be repeated hundreds to thousands of times in a typical FUE hair transplant, the patient is subjected to significant human variability and error on the part of the physician.

A major advance in FUE came in the Fall of 2011 with the introduction of the first robotically controlled extraction device that automates this crucial first step of FUE. The robotic system increases the accuracy of graft harvesting, which in turn minimizes damage to hair follicles and reduces harvesting time. Each of these factors potentially contributes to increased graft survival. The new technology also enables FUE to be performed on a wider variety of patients.

The current robotic technology is based on the two-step method of extraction. It uses a sharp punch to penetrate the skin and a dull rotating punch to separate the deeper part of the follicular unit from the surrounding tissue. The main difference from the older devices is that it uses a very precise, image-guided robotic arm to operate the dual-needle punch mechanism, ensuring a high degree of accuracy and precision.

Compared to manual systems, the robot is also more versatile in its ability to harvest grafts from patients with different hair characteristics, patients

from various ethnic backgrounds and hair from different parts of the scalp. It is particularly useful in extracting grafts from the sides of the scalp, where the hair lies flatter on the skin.

Introduction of the Robotic system into a physician's practice can present a formidable challenge. Besides the expense of the technology, the robot requires an operating room larger than those that exist in many doctors' offices and requires that the room be dedicated to this purpose. In addition to special training required to operate the system, the FUE procedure itself should be modified so that grafts are kept out of the body for as short a time as possible and kept in an environment that will ensure maximum growth. This can be accomplished by making recipient sites prior to the robotic harvesting and by using special biologic solutions to hold the grafts.

Dr. Bernstein performing Robotic FUE

Indications for Robotic FUE

Since FUE does not leave a linear scar, it is useful for patients who want to wear their hair very short. It is also advantageous, when compared to FUT, for those, such as professional athletes, who are involved in very strenuous activities and who must resume these activities very soon after their procedure. The technique is also useful for patients who have healed poorly from traditional strip harvesting or who have a very tight scalp and so are not indicated for a strip procedure.

Another application of FUE is the camouflaging of a linear donor scar from a prior hair transplant procedure. In this technique, a small amount of hair is extracted from the area around a linear donor scar. It is then placed directly into the scar, making it less visible as the transplanted hair grows in the scar tissue. FUE potentially allows the surgeon to remove hair from parts of the body other than the donor scalp, such as the beard or trunk, although there are many limitations with this process.

Some patients desire FUE simply because they have heard that it is non-surgical. The reality is that FUT and FUE both involve surgery and in both cases the depth of the incisions (i.e. into the fat layer right below the hair follicles) is the same. The difference is in the type of incision made.

Limitations of FUE

Follicular Unit Extraction harvesting requires a much larger area compared to strip harvesting (approximately 5x the area for the same number of grafts). This has two implications. The first is that, in order to perform large sessions of FUE, the entire donor area must be shaved. This can present a significant short-term cosmetic problem for many patients. In contrast, with FUT using strip harvesting, the donor incision can immediately be covered with hair – even in hair transplants that require very large sessions.

A second issue with the larger harvesting area in FUE is that with large sessions the doctor must often push the limit of what is actually "permanent" in order to get the desired number of grafts. This may present a long-term problem when transplanting a younger person in whom the extent of the permanent donor area cannot be precisely determined.

The method of graft harvesting also affects the quality of grafts and the fullness that may ultimately be achieved in the hair transplant. In FUT, follicular unit grafts are isolated with the aid of dissecting microscopes – a very precise method for preserving the integrity of follicular units. Although the Robotic FUE system appears to be the most accurate of the extraction devices, it is still not as accurate in generating intact follicular units as a surgical team that is skilled in the microscopic dissection process used in FUT.

Because the differences between FUE and FUT are significant and because there are distinct advantages and disadvantages to each, the needs of each person must be carefully considered when deciding which procedure to choose.

The Future of Robotic Hair Transplants

With the trend toward less invasive surgery and the preference of men for shorter hairstyles, the popularity of FUE will continue to increase. Although only a small number of cases of FUE were performed in the United States prior to 2002, FUE is rapidly becoming a mainstream procedure in many hair transplant surgeons' practices. There were three FUE Robots in the hands of physicians at the end of 2011, twenty-two by the end of 2012 and there will be an estimated seventy in operation worldwide by the end of 2013. The rapid adoption of robotic hair transplants speaks to the increasing interest in FUE by patients and the realization, by physicians, that this technology holds the key to improving the quality and consistency of a very demanding, labor intensive hair transplant procedure.

Robotic Recipient Site Creation in Hair Transplantation

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Editor's Perception on the Evolution of the Robot

I attended the Orlando Live Surgery Workshop in Orlando in April 2014 and saw a demonstration of robotic recipient site creation; however, it left me with a few concerns. I was very impressed with the sophistication of the mapping software and in particular the ability of the robot to recognize and adjust the pattern of incisions around existing hair in the recipient area.

As I watched the procedure, I noted that there was a lot of bleeding as the robot made sites. The robot had been set to make sites at 5mm depth. I asked why so deep. After discussion, during which there was a pause to extract a few test grafts to see their depth, the depth of insertion was reduced to 4mm. As the robot then proceeded, the bleeding of the recipient sites was much reduced.

In the below article, the sites were made at 5.5mm deep. As Dr. Francisco Jimenez reported, human scalp follicles average 4.2 ± 0.4mm long. In my practice, and, as so well described by Dr. Bradley Wolf in the March/April 2014 *Forum*, site depth and size is determined after measuring grafts and testing sample grafts for placement before proceeding with premade sites. The most common depth I use is 3.5-4mm, so sites at 5 and 5.5mm seem unusually deep to me. There are many potential problems with sites that are too deep, such as unnecessary vascular trauma, sunken grafts with pitting, and poor growth. One other potential problem with premade sites is that some patients just simply need slightly different sites because their grafts are slippery or because of the stiffness of their epidermis, or as a result of other characteristics that make their grafts more difficult to place. The only way to detect these patients and to avoid this problem is by testing each patient before making all of the sites.

The robot uses, I think, three sizes of needles to make sites. At the OLSW, I asked why needles were used and not custom-cut blades that can be made to any specific size, and I was told this is because eventually the robot will be used to place grafts through the needles. I don't know if this is the reason the manufacturer would give, but this does make sense. The consequence, however, is that the robot, as currently configured, will not be able to finesse recipient site size to the degree of surgeons customizing their site size to each specific patient.

I suspect that my concerns are unnecessary in the hands of experienced surgeons, however, some who will be using the robot will not be so experienced. My suggestion is that, if sites are being premade with the robot (or by hand for that matter), it should be routine practice to harvest some grafts first, and based on measurement and test placement adjust the robot to make the sites no deeper than necessary and to a size that optimally facilitates placement. I think this will avoid problems and promote the best results.

As it stands, at this point, in the battle between Ken Jennings and Watson, I pick Jennings. With further evolution of the robot, a day might come that the balance shifts. —RHT

The initial application of the ARTAS™ robotic system (robot), released in the fall of 2011, was the separation of follicular units from the surrounding scalp tissue, the first step in a follicular unit extraction (FUE) procedure.[1,2] Subsequent steps in FUE include removal of the follicular unit grafts from the donor scalp, site creation, and graft placement. With its new hardware and software capabilities, the robot can now perform one more step in this process, making recipient sites. Preliminary observations suggest that it can accomplish this function with greater precision and consistency than when performed manually.

For robotic recipient site creation, the doctor first draws a hairline and other markings directly onto the patient's scalp to delineate the recipient area. Next, multiple photographs are taken of the patient and, using new software called the ARTAS Hair Studio™ (AHS), the images and markings are converted into a 3D model of the patient. The robot uses the inter-pupillary distance (IPD) to match dimensions of the model with the actual dimensions of the patient.

To determine how the hair will ultimately grow, the physician uses the software to specify the angle of the recipient site incisions (relative to the plane of the scalp), incision direction, site depth, average density, and total number of incisions. The site spacing can then be easily modified to create variations in density in different parts of the scalp while the computer keeps the total number of sites constant.

An important feature of the ARTAS system is that the robot uses image-guided technology to avoid hairs of a specific diameter when making recipient sites. In this way, the distribution of sites that are created in the procedure can be made to complement the distribution of existing terminal hairs (or the hair from prior hair transplant procedures), while ignoring hair that is miniaturized or vellus. The physician can specify the cut-off diameter based upon the diameter of the patient's full terminal hairs. Partially miniaturized hair may also be included in the group of hairs to be avoided. Once this parameter is set, the robot will proceed to create sites at a minimum distance from the selected existing hair and do so randomly throughout the areas where the hair is finer or the scalp is bald.

The imaging software is currently used to translate the design the physician makes directly on the patient scalp into a computerized algorithm that directs the creation of recipient sites in the operating room. In the future, the system will also have the capability of simulating, in advance of the surgery, what the actual hair transplant will look like so that it can be used as tool to aid the physician during the consultation.

Case Study

The 44-year-old patient is a white male with straight, fine, brown hair and a Norwood Class VI-VII pattern of hair loss. His donor density is 70 FU/mm^2 and he has 20% donor miniaturization. After discussing the various surgical modalities for hair restoration, the patient chose FUE in order to wear his hair

⇨ page 96

Robotic Recipient Site Creation *from page 95*

relatively short. He understood that due to his extensive hair loss and limited donor supply, the goal was to restore light coverage to the front and top of his scalp. The ARTAS system would be used for both follicular unit dissection and recipient site creation. To minimize the time the grafts were outside the body, recipient site creation would be performed before graft harvesting.[3]

The morning of surgery the procedure was reviewed, consent was obtained, and five photos were taken; full-face front, top of scalp, back of scalp, and left and right sides. The photos were then loaded into the AHS. Using facial landmarks—eyes, nose, mouth, forehead, and chin—as a guide, a 3D model was built around the images and was displayed on a touch-screen monitor. The IPD measured 63.4mm. The recipient site parameters were then specified. The recipient site depth was programmed at 5.5mm with an angle of elevation from the scalp of 45 degrees. All of the sites were programmed to 0 degrees, meaning that they would point in a forward direction and be parallel to each other. The robot was programmed to avoid hairs with a diameter of 80u or greater (Figure 1).

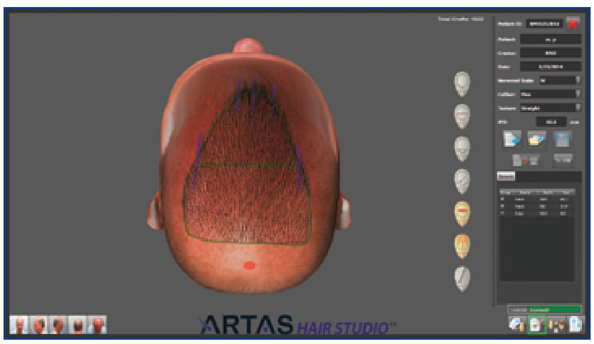

Figure 1. ARTAS Hair Studio showing the hair transplant design.

Vital signs were taken and a pulse oximeter was attached to the patient's left middle finger. The patient was sedated with oral Valium and IM versed. Local anesthesia was administered using a ring-block consisting of xylocaine 0.5%, bupivicane 0.25%, and epinephrine 1:200,000.

The robotic harvest and subsequent dissection yielded 2,256 grafts consisting of 228 1-hair, 1144 2-hair, and 884 3-hair grafts. All forty 4-hair grafts were dissected under a stereomicroscope into smaller grafts (3-hair and 1-hair) to generate enough 1-hair grafts for the frontal hairline and to ensure a natural appearance in a patient with low overall density.

Using a 19-gauge hypodermic needle to make the incision, the robot created 1,632 recipient sites. In Area 1, the frontal region of the scalp measuring 32 cm^2, 583 sites were created at a density of 18.2 grafts/cm^2. In Area 2, the mid-scalp measuring 61 cm^2, 1,049 sites were created at a density of 17.2 grafts/cm^2. The remaining 624 recipient sites were made by hand; 220 for the frontal hairline and the remaining 404 for the transition zone in the posterior aspect of the mid-scalp and to fill in gaps.

The current system uses a grid, measuring 2.5cm×13cm, that is placed vertically on the patient's scalp. This serves to orient the robotic optical system (Figure 2). After the grid is filled with recipient sites, it is moved to a new position adjacent to the first. In the current procedure, the robot created sites at 1,500/hour. With time for set-up and moving grids and creating the manual sites, the total time for site creation was 1.5 hours (Figures 3 and 4).

Discussion

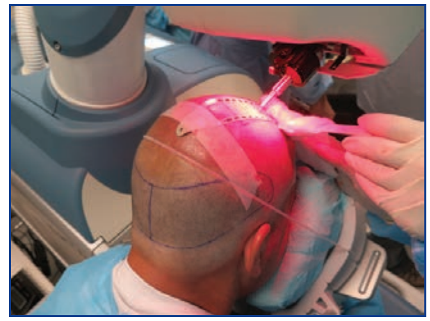

Figure 2. Creating recipient sites with the ARTAS robot.

As with the extraction process, the robot eliminates the inconsistencies inherent in creating large numbers of recipient sites by hand. The robot can create sites at a rate of up to 2,000 per hour, although there is more set-up time compared to sites made manually. The physician can specify punch depth (3.5 mm to 7mm), punch angle to the scalp (35 to 60 degrees), and site direction (forward, parallel, lateral, etc.). Once these parameters are set, site creation is precise and rapid.

Figure 3. Before, with marking for the procedure.

The case described above was the first time we used the robot to create recipient sites on the front and mid-scalp. Cases subsequent to this have shown that there is a rather quick learning curve that results in a reduction in the time needed for data input, set-up, and grid placement; and a shorter overall duration for this step of the hair transplant procedure.

Figure 4. Two days post-op.

One of the benefits of robotic site creation is that the distribution of grafts over a fixed area of the scalp can be exact. For example, if a physician wants to transplant 1,000 grafts evenly over 50cm^2 of area, this can be done with great precision and with uniform site spacing. In addition, the physician can vary the densities in select regions of the scalp and the robot will adjust the densities in other areas (in real time) so that the total number of sites remains the same. For example, if you have 2,500 FUs to cover 120cm^2 of scalp and you want to create a density of 25 sites/cm^2 in a 40cm^2 frontal forelock and use the remaining grafts to cover the other 80cm^2 of bald scalp, the robot will automatically calculate a second density of 18.75 sites/cm^2 for the remaining area.

Another benefit is that the robot can be programmed to avoid existing hair and select which specific hair diameters to avoid. The robot is programmed to keep a minimum distance from the existing hair of at least 250 microns (or greater with lower target densities) to ensure that the resident follicles will not be damaged and that the distribution of new hair is even and natural. This computerized mechanism appears to be more accurate than what can be done by hand and does not sacrifice speed in the process. This is an important benefit of the new technology.

Compared to manual FUE, the disadvantage of making sites with a robot is the additional set-up time and small additional cost (if one is already using the robot for extraction). The disadvantages of robotic site creation when performing FUT procedures include cost, the need for a dedicated room, additional staff training, and set-up time. Another issue involves the preparation for site creation. When creating recipient sites, the recipient area must be clipped to 1mm in length. In FUE, the patient often prefers this length to match the donor area, which has already been clipped. Since the donor clipping is not necessary in FUT, these patients generally prefer to keep any hair they have in the recipient area uncut. Therefore, only FUT patients who are already bald in the recipient area would choose to have their sites made by the robot. Because of these constraints, robotic site creation lends itself more to robotic FUE procedures and will probably be used less often in FUT procedures, even if there is a robot on the premises. A final issue is that using a robot for site creation may be impractical for very small sessions that can easily be accomplished by hand.

At this time, the robot is not capable of making the necessary directional changes needed to reproduce the natural swirl that occurs in the crown. In addition, although the robot can be programmed to create a hairline, the nuanced irregularity of the hairline lends itself to being done by hand. If the robot is used for this part of the procedure, a change to a smaller needle is required to accommodate the single-hair grafts.

For the physician who is skilled at follicular unit hair transplantation (either by FUE or FUT), robotic site creation adds modest value to the procedure, as recipient site creation is perhaps the easiest step to perform. A more significant benefit of the new technology is in the imaging tool that can assist the physician in showing the patient the outcome of the procedure in advance of the actual surgery. Of course, its greatest value is that automated site creation is a necessary precursor to the final step of a completely robotic hair transplant, automated graft insertion—a technology that is at least several years away.

Summary

In performing recipient site creation, the robot automates another part of the hair transplant process that can be prone to human error and variability. In addition, the new technology will soon give the physician a consultation tool to show what the hair restoration procedure can do and to help align the patient's expectations with anticipated results.

Probably the greatest significance of this new method of site creation is that it brings the technology one step closer to the goal of a totally automated hair transplant that can be performed with robotic precision, speed, and reproducibility. The physician can then focus on the critical, but more subjective, elements of the hair restoration process, namely, patient selection, patient education, and hair transplant design.

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ROBOTIC SURGERY REVOLUTIONISES THE TREATMENT OF HAIR LOSS

The ARTAS® Robotic System, the first and only FDA-cleared robotic hair transplant technology, is breaking new ground. **Wendy Lewis** spoke to three leading surgeons for insights into how this technology is transforming their approach to hair restoration

RESTORATION ROBOTICS, Inc., the company that developed the ARTAS Robotic System, is at the forefront in hair restoration. Follicular unit extraction (FUE) procedures have progressed from using labour-intensive handheld instruments to the computer-assisted, image-guided robot.

This innovative technology offers benefits in three key areas; precision, control, and reproducibility. It dissects follicular units accurately and consistently—hundreds to thousands of times in a single session. Visualising the surface in three dimensions, the ARTAS Robotic System uses programmed algorithms to select and extract the most robust follicles. Only what is necessary is harvested, physicians can adjust settings without interrupting the procedure, and the robot is able to compensate for patient movement.

A clinically-validated procedure

The ARTAS Robotic Hair Transplant is turning out to be a highly profitable clinically-validated procedure that can be incorporated into an existing aesthetic practice to attract a whole new segment of patients.

James A. Harris, MD, FACS, Medical Director, The Hair Sciences Center of Colorado in Greenwood Village, CO, has been using the system for over 7 years. 'The robot addresses patients' goals of what FUE offers, which is less pain, more predictable clinical results, no linear scar, and the latest new technology.'

By shortening the learning curve of FUE, the ARTAS Robotic System allows physicians to achieve a level of proficiency that would typically require years of practice with manual techniques. 'From the perspective of the physician, even if you perform FUE already, using the robot gives you superior quality grafts. It may take 6-12 months to become proficient at FUE by hand. The ARTAS System offers close to immediate ability to provide grafts at a reasonable speed, without the need for clinical skills and eye-hand coordination,' he continued.

Another advantage to the physician is that fewer personnel are needed as compared to a strip harvest technique. The robot is able to determine how hair grows in the donor area, and can then map out the locations of the hairs, including the angle of growth. According to Harris, 'The difference is really how the hair is extracted from the donor area. Traditionally, hair transplants involve the removal of a strip of skin and a team of technicians to remove grafts one by one. The ARTAS System removes the grafts one at a time directly from the donor area, which is less invasive.' As a result, patients also have a relatively quick recovery time.

According to Dr Marc R. Avram, clinical professor of dermatology at Weill Cornell Medical College in New

York City, 'The ARTAS System allows us to accurately and efficiently harvest individual follicular units. It has been particularly helpful for patients who like to wear their hair short where a visible donor scar would be of cosmetic concern, and also for patients who prefer not to have sutures following surgery.'

Paul T. Rose, MD, JD, a hair restoration surgeon in Miami, believes that for physicians who have difficulty mastering manual FUE, the robot is the best alternative. 'It has the ability to perform repetitive manoeuvres that would otherwise be very physically taxing on a person trying to do it day in and day out. Overall I think that the robotic device can out pace the manual technique,' he said.

This allows physicians to introduce a new procedure into their practices quickly. But Harris cautions that just having the machine and someone to operate it will not necessarily produce satisfactory results:

'Physicians still need to learn about hair disease, medical intervention, surgical technique, and aesthetic considerations.'

ARTAS Hair Studio™

The ARTAS Hair Studio™ 3-D modelling software is a new interactive consultation patient tool. With a viewable touchscreen, ARTAS Hair Studio allows patients to collaborate with their physician through the aesthetic hair pattern design process. The personalised design is transferred to the ARTAS Robotic System for precise recipient site creation on the patient's scalp.

Harris is part of the team that evaluated the development of ARTAS Hair Studio. 'One of the difficulties we have in hair restoration is how to describe the kind of result the patient may get with a certain number of grafts. Until now, they have had to imagine it on their head. With this new tool, we can look at the patient's head and determine how many grafts they may need, and be able to show them exactly what they are going to look like in 6 months if we do, for example, 1500 grafts in a specific area,' he said.

According to Harris, 'If someone is considering a procedure, as the surgeon I have to be honest about the realities of hair restoration. So, if they need 2000 grafts but they only want to pay for 1000, I may choose not do the surgery because the patient isn't going to get results that he wants. If they can only afford 1000 but they need 2000, I may suggest placing 1000 grafts in a smaller area so it looks decent. With the ARTAS Hair Studio, the patient can decide if they can accept the results of the 1000 grafts as they can get an accurate look at what the transplant may look like. It is an amazing tool for planning outcomes.' This innovative tool gives patients confidence because they can visualise simulated results.

> "The minimally-invasive procedure offers low downtime, is virtually pain-free, and there is no linear scar, tissue excision, or stitches needed."

There are numerous patient benefits for the ARTAS Procedure. The minimally-invasive procedure offers low downtime, is virtually pain-free, and there is no linear scar, tissue excision, or stitches needed. The ability to wear hair in any style, short or long, is a major plus. Results are natural-looking with faster recovery times. According to Harris, the procedure is comfortable and easily tolerated. 'Some patients watch movies on their iPhones. I normally sedate my patients so they can sleep for the whole procedure.'

Raising awareness of FUE

Restoration Robotics is raising consumer awareness of FUE, and they have expanded it so that more people are seeking treatment. 'Now that there is an option where patients don't have to take skin out of their scalp, they want FUE. I now do 12 to 16 cases with the robot per month,' said Harris, and he is seeing patients from all over the world. He describes the flow chart, as he calls it, of how patients find out about ARTAS. 'They start thinking about hair restoration and looking at treatments online. Then they look into surgical options, and find out about FUE. When they read up on FUE, they learn about the robot. The technology is grabbing a lot of people; 90% are interested in FUE and 80% or more are interested in the ARTAS Procedure.'

According to Avram, the majority of his hair transplant consultation patients are aware of the robot as an option. 'We discuss both the robot and elliptical donor harvesting with each of our patients. Many patients opt to pursue the ARTAS, while others continue to do the ellipse.'

'For patients averse to having a linear scar, the robotic approach is very comforting to them. The thought of having a linear scar on the posterior scalp discourages some patients from pursuing transplantation,' said Avram. 'If a patient chooses to shave their hair, after the procedure there will be no linear scar on the back of the scalp or any evidence of where hair was transplanted on the frontal scalp.'

Practice differentiator

The ARTAS Robotic System lets physicians take hair restoration technology to a new level, and is a real point of difference. It represents a new way to attract prospective patients who would not normally consider hair restoration surgery, owing to recovery time and visible scarring, among other factors.

'In large part the robotic procedure is meeting patient expectations,' according to Rose. 'Patients are pleased with the healing of the wounds and the ability to wear their hair shorter than they might be able to with a strip harvest. Patients are intrigued by the robotic approach and this alone brings potential patients into the office.'

'By having the robotic system I believe that patients have the sense that we are in the vanguard; offering the latest advances for hair replacement. It shows that we are willing to make the capital expenditure to offer patients all of the techniques that have been proven to work. It is a marketing advantage,' said Rose.

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Robotic Surgery: With New Technology Come New Opportunities?

Cosmetic practices can capture the male market if they move beyond facial rejuvenation to hair restoration. Robotic technology may enhance the practice opportunity.

BY PAUL WINNINGTON, EDITORIAL DIRECTOR

With all the press surrounding health care reimbursements and related topics, it's easy to forget that there are still new and exciting procedures to offer for the benefit of both your patients and your practice.

Robot-assisted hair restoration is one such procedure. The ARTAS System enables physicians to offer their patients a minimally invasive procedure that leverages image-guided robotics to deliver permanent, natural-looking results. Demand for a less-invasive hair restoration solution has seen a substantial increase over the past few years, and patients are willing to pay a premium price for the benefits.

EXTRACTION TECHNIQUES

Hair restoration has been the number one cosmetic procedure among men for several years, and it continues to grow in popularity.[1] Hair restoration procedures involve taking follicular units from "permanent" regions, such as the back and sides of the head, and transplanting them in the thin or bald areas on top of the head and hairline. Currently, strip harvesting represents the most common process for extracting follicles to be transplanted. Strip harvesting involves the use of a scalpel to remove a strip of hair-bearing tissue from the donor region and then the incision is closed with either staples or sutures. Using a microscope, the individual follicular units are then dissected from the tissue and transplanted to the area of hair loss.

Follicular unit extraction (FUE) presents an alternative to strip harvesting. Following surgical trends toward less-invasive procedures, single follicular units are extracted with small dermal punches so that the donor site does not require sutures or staples. Interestingly, while FUE seems like an obvious minimally invasive option for patients, practitioners have been slow to adopt the procedure. James Harris, MD, Medical Director of Hair Sciences Center of Colorado and an FUE pioneer, explains the reason behind this industry-wide reluctance. "If physicians want to become proficient at FUE, they need to undergo special training and along with this, there's a significant time commitment. Analysis of the angle, direction, and type of skin is a complex process requiring extensive experience. Until the surgeon has acquired this experience, the process is very tedious and slow."

Mark A. Bishara, MD, of Bishara Cosmetic Surgery & Hair Restoration, concurs. "Right now, strip harvesting is the most commonly used technique, and it's an efficient means of harvesting large quantities of follicles. But I stopped offering it as a primary modality for a number of reasons, including patient recovery time and wound morbidity. It took me six months of training to fully learn FUE, and for many surgeons, that acclamation period can serve as an entry barrier."

This less-invasive procedure is beneficial for both patient and surgeon. Patients require less post-operative pain medications; healthy grafts with ample protective tissue can be transplanted; and the procedure does not result in linear scaring so patients can wear their hair very short post-procedure. Furthermore, patients typically undergo a quick recovery, returning to normal activity in three days or less. "Following strip-based surgery, the donor site isn't healed for seven to 10 days or until sutures are removed. It's not uncommon for strip-based surgery patients to report a sense of tightness and some degree of numbness for two to three months after a strip harvest. There is a very real potential for discomfort. With FUE, pain is largely mitigated—or absent entirely—post-procedure," says Dr. Bishara.

BENEFITS OF THE ARTAS SYSTEM

Robotic technology is used in a variety of surgical and diagnostic procedures and is a good match for FUE. The ARTAS System is the first and only FDA-cleared technology that allows physician-controlled, image-guided, robotic-assisted

FUE. The ARTAS System utilizes specialized cameras and the latest in digital mapping to automatically assess the angle and direction of each follicular unit. Sophisticated algorithms then determine the hair density as well as the proper angle and depth of incision required to effectively harvest the units. The system can also determine a random extraction pattern.

The ARTAS System can harvest follicular units in a random pattern, according to distance limitations, or as a percentage of the total number of follicular units in a designated area. Under physician control and direction, targeted units are dissected at rates of over 500 grafts per hour. "I make minor adjustments to dissection depths and angles during the extraction process, to ensure the patient receives optimal results," says Dr. Bishara. "So there's still an element of physician interaction. But overall, the robotic technology alleviates much of the burden."

While in general FUE is less invasive, one drawback is its traditionally slow method for extracting hair follicles. "An average physician performing FUE may only be able to extract 200 to 300 grafts in an hour. This presents somewhat of a problem, as an average surgery requires 1,500 grafts. With the ARTAS System, we are able to extract 500 or more grafts per hour," says Dr. Harris.

"Initially, I was concerned that I would not be able to provide my patients the larger surgery session with the robot, but that concern was quickly shattered after we were able to extract 3,500 follicular units in one day," adds Craig Ziering, DO, FAOCD, Founder and Medical Director at Ziering Medical.

Additionally, comparisons of traditional FUE to robotic-assisted FUE also reveal the computer's ability to produce better grafts.[2] Newcomers to FUE often experience follicle transection rates of 20 to 30 percent when first learning the procedure. The ARTAS System, by comparison, consistently shows a follicle transection rate of about eight percent independent of operator experience. "The ARTAS System provides physicians a very safe method for consistently extracting a high volume of healthy, intact hair grafts in a short amount of time," reports Dr. Harris. "Follicular units require little or no trimming and are ready to implant immediately after harvesting. This bolsters graft success rates and reduces technician time, facilitating more efficient appointment scheduling."

PRACTICE GROWTH

According to the International Society of Hair Restoration Surgery (ISHRS), the total market size for hair restoration surgery has increased almost 50 percent since 2008, with a worldwide market close to $1.9 billion.[1] ISHRS members performed an average of 16 surgical hair restoration procedures per month, with 77.5 percent using the strip harvesting technique and only 22 percent using FUE. "When FUE first came out, doctors were obtaining bad grafts and giving their patients less than acceptable results, so a lot of potential patients rejected an FUE procedure," recalls Dr. Harris. "The beauty of the ATRAS System is that you can take a physician with very little experience and after a couple of hours of training, the doctor can produce grafts as good as those achieved with several years of experience. It's a remarkable achievement for the entire hair restoration industry."

This less-invasive method represents a new way to attract prospective patients who would not normally consider hair restoration surgery, due to its traditional recovery time and visible scarring, among other factors. Dr. Ziering further explains how the ARTAS System can be instrumental in growing and strengthening a practice. "Introducing new technology for the sake of just having the latest, greatest technology is not a reason for me to invest in something like the ARTAS robot. However, technology that improves my patients' overall hair restoration experience or meets a patient need, addresses a concern, or solves a problem—is worth it." Dr. Ziering says, "My Beverly Hills practice attracts patients from all over the world, and we're busier now than ever, because of my association with the ARTAS robotic-guided system that has already drawn in patients who would otherwise be apprehensive about the traditional drawbacks associated with FUE. My practice has always provided patients top-quality services, and ARTAS currently represents the state-of-the-art in less-invasive surgery. During the ARTAS procedure, I can devote more time to the artistry behind quality hair restoration, as the robotics eliminates a great deal of the operational tedium. There is a huge patient population waiting to be served."

Much like in other areas of medicine, such as all-custom laser eye surgery, patients are willing to pay more for value. The ARTAS System marks a significant investment for a practice, but patients will perceive the greater service and better results and be willing to pay it, specialists say. Dr. Bishara says, "Simply put, my patients—many of whom travel great distances to undergo this cutting-edge procedure—are willing to pay a premium for comfort and results. At a minimum, I'm doubling my business—largely because of how happy my patients are coupled with the impressive results I've been seeing. Through word of mouth alone, these satisfied patients are driving my business and establishing a global reputation for my practice."

"Hopefully, one day, I will have multiple systems doing robotic hair transplants," he adds. "I anticipate that robotics will lead the future of several medical fields outside of hair transplantation. The way I see it, I could embrace this technology early in my career, or wait ten years to hop on board. I chose to seize the opportunity to be one of this new technology's first adopters and subsequently become a world leader in my field. Without a doubt, I would encourage other practitioners to implement the ARTAS System. The benefits are too numerous and too important to ignore." ■

1. ISHRS 2011 Practice Census Results. http://www.ishrs.org/PDF/FinalPracticeCensusReport7_11_11.pdf.
2. Data on file. Restoration Robotics.

Robotic Technology Brings New Benefits to Patients and Practices

Can the new trend in robotic surgery benefit cosmetic dermatology practices?

BY HERBERT S. FEINBERG, MD

Androgenetic alopecia or common male pattern baldness (MPB) is extremely common. By the age of 35, two-thirds of American men experience some degree of appreciable hair loss, and by the age of 50 approximately 85 percent of men have significantly thinning hair.[1] The market has responded with a variety of different solutions over the years, with the most recent advance being a robotic system that achieves a very natural result in a minimally invasive procedure.

The surgical process of extracting and then grafting follicles of hair was originated by Japanese dermatologist Dr. Okud, in the 1930s. He discovered the process while helping burn victims. Dr. Norman Orentreich, a New York dermatologist, was the first to publish findings that hair from the sides and back of a man's scalp was more or less resistant to balding, and therefore extracting and grafting these hairs onto the front of the scalp solved the balding problem.[2] Although this discovery was well documented by the 1960s, it wasn't until the mid 1990s that hair transplantation surgery advanced enough to produce natural looking results. The practice of taking individual follicular units for transplantation, or micrografting, finally produced natural, virtually undetectable results in men seeking surgical hair restoration.

EXTRACTION METHODS

Today, hair follicle extraction is most commonly performed using the strip method. Single-strip extraction is the process of cutting a strip of the patient's scalp from the back of the head and then harvesting the hair follicles. It is possible to harvest 2,000-3,000 grafts in a session with this procedure. The process requires stitches or staples to close the wound site but with advanced skill, the surgeon can minimize the resulting linear scar at the donor site.

> "In today's world, almost any cosmetic procedure generates income. Procedural medicine in general tends to generate the greatest income, and that remains true in this case as well."

The alternative to strip harvesting is follicular unit extraction (FUE). FUE was pioneered by Bernstein and Rassman in 1995, and it fits in with the general trend in medicine over the last two decades towards less invasive procedures. Follicular units can be harvested one at a time using a dissection punch of one millimeter or less. The patient's hair has to be cut short so the scalp is clearly visible. A needle is used to score the skin above the follicular unit and a punch separates the follicular unit from the surrounding tissue. The follicular unit is then extracted using small forceps. The small holes left behind heal on their own and once healed are nearly undetectable. Benefits of FUE include a very quick recovery, less chance of numbness or paraesthesia, and an expanded donor area. With FUE there is no longer a problem of having to close a tight incision on the scalp or worry about reduced elasticity in the donor area, which often restricts further strip attempts.

Manual FUE, however, is extraordinarily slow and tedious and I, like many surgeons, do not find that this method presents results superior enough to merit the impracticality of the longer procedure time. Dr. Phillip Gildenberg, a brain surgeon, realized that just as robots are being used in other areas of medicine,

LEARN MORE AT DERMTUBE.COM: Learn more about how Dr. Feinberg incorporated robotic technology in practice and see the ARTAS Robotic System in action at DermTube.com: www.dermtube.com/ARTAS_Feinberg

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there was an opportunity to use a robotic approach with FUE that would cut down on surgery time and increase the precision and consistency of the procedure. The ARTAS Robotic System (Restoration Robotics, San Jose, CA) is an advanced robotic system for harvesting follicular hair units directly from the scalp. It consists of a precision robotic arm and advanced imaging technology that can map and track each follicular unit and determine the optimal angle and direction of each hair follicle for dissection. It then uses micro dermal punches to harvest individual follicles in a random pattern that is nearly undetectable after healing. This complex determination of angle and depth, as well as the repetitive motion of harvesting individual grafts, makes this a task particularly well-suited to a robotic aid.

The robotic approach basically combines the benefits of the less invasive FUE technique with the efficiency of the strip technique. With manual FUE, extraction of 1,600 grafts by hand could take six to eight hours of surgery, depending on the speed of the physician and the tolerance of the patient. But with the ARTAS Robotic System, this same number of follicles can be extracted in as little as three hours.

As a hair transplant specialist, I have always investigated new technology. I tested plugs when they originally came out and transitioned as they became smaller mini grafts, which were preferred over full grafts. When microscopes were used to cut grafts, my practice was the first in the New York area to use them. Yet, when FUE was developed as a new method of harvesting follicles, I was not interested. I could not justify taking the extra time required and experiencing the inconsistencies of manual FUE just to avoid a scar. The ARTAS Robotic Procedure, however, allows me to reap all of the benefits of FUE without the tediousness of performing it manually.

EFFICACY

FDA trials for the ARTAS System were prospective, blinded, controlled studies of 36 males at two separate sites.[3] Each patient served as his own control with half of the scalp dedicated to the ARTAS System and the other half reserved for manual FUE. The researchers analyzing the follicles were blinded to the extraction technique. The study established that the efficacy of the automated robotic system was not inferior to manual FUE and, perhaps most importantly, they have seen no adverse events or medical device malfunctions in any study.

My staff and I are finding that the quality of the graft with the robotic system is probably better than what we get with single strip extraction. Optimal growth occurs from six months to a year after the hair is grafted, and our very first patients are just now reaching that point, so we have not conducted a formal study. However, observation of new growth indicates that the yield is a little bit higher and overall, the procedure is better.

ADAPTING TO NEW TECHNOLOGY

Our practice first started using the ARTAS System in May 2012, and now, because I am extremely comfortable with the procedure, I introduce it to most of my patients. While some still choose to have the strip extraction method due to the higher cost of robotic FUE, there are three groups of patients for whom I suggest that the ARTAS Robotic System is their best option.

The first group consists of patients who wear their hair very short or wear it longer but do not have good hair quality, making it difficult to hide the linear scar. I recently saw a patient who had reasonably short hair and a fine linear donor scar from his initial transplant. But I felt that if he would have any future strip, he might have trouble hiding the scar. I recommended that in the future, he should consider switching to FUE with the robotic system.

The second group who are really attracted to the ARTAS Procedure consists of those patients who are drawn to techniques that are very hi-tech and new. They may not have difficulty camouflaging the scar, but they appreciate the benefits of the technology enough to pay the price difference.

The last group includes any patients with a very low pain tolerance. While using the ARTAS System makes the harvesting process longer than strip extraction, it is decidedly more comfortable for the patient and offers an easier recovery. My patients who have had both methods prefer robot-assisted FUE.

The ARTAS System is an innovative device that can produce excellent results, but it is important to remember that with any new technology, there is still a learning curve. While the system is automatic, various modalities, such as speed and angle of penetration of the needle and punch, skin turgor and the density of follicular units must be monitored. Previous transplant experience, especially understanding how to judge and handle hair grafts, makes for a smoother transition to robotic hair transplantation.

Now that my staff and I have worked with all types of hair texture and quality and received significant guidance from the manufacturing staff, we are very confident with the procedure and have no difficulty convincing patients to make the investment in it when we recommend it.

PRACTICE GROWTH

As a recognized hair restoration specialist with a busy practice, I have seen positive growth due to the adoption of the ARTAS System. Robotic technology is exciting, and we have received several new patients who have read about the ARTAS Robotic Procedure online and came in to ask more questions. Some have had a robotic follicular transplant and some have had strip extraction, but their initial impetus to call our practice was the new technology. The state-of-the-art technology captures interest, and I have been featured on local news outlets. Articles and television appearances not only attract new patients, they also impress current patients. Patients like to know that the practitioner they choose stays up-to-date with research and technology, and acquiring robotic technology generates very positive publicity in general.

Investing in new equipment is an ongoing endeavor in the medical field, and I have regularly purchased new lasers and other treatment and diagnostic equipment that were similar in price to the ARTAS System, but I've never had any machine that has paid back its initial investment so quickly. The initial investment for the machine was recovered in less than one year, an excellent return by any measure.

In today's world, almost any cosmetic procedure generates income. Procedural medicine in general tends to generate the greatest income, and that remains true in this case as well. In my practice, the greatest proportion of my earnings comes from hair transplantation, and the ARTAS Robotic System is the top earner in terms of specific overhead for this procedure. ■

Herbert S. Feinberg, MD is a world-renowned dermatologist and the founder of the Dermatology and Hair Transplant Center in Englewood, NJ. He is a pioneer in hair transplantation and has been performing transplants for over thirty years. He is the author of the frequently quoted book, "All About Hair," and can be reached at 201-568-6977.

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2. Orentreich N. Autografts in alopecias and other selected dermatological conditions. *Ann N Y Acad Sci.* 1959;83:463-479.
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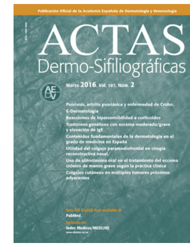

DERMATOLOGÍA PRÁCTICA

Actualización del método *Follicular Unit Extraction* (FUE) del trasplante de pelo

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PALABRAS CLAVE
Extracción de unidades foliculares;
Trasplante de pelo;
Trasplante de unidades foliculares

Resumen La *follicular unit extraction* (FUE) es una técnica de trasplante capilar que utiliza punches de pequeño diámetro (0,8-1 mm) para extraer las unidades foliculares. Aunque en sus primeros años tuvo escasa aceptación debido a la dificultad en extraer unidades foliculares intactas con un punch tan pequeño, la FUE se ha popularizado y es ya una alternativa a la técnica clásica de la tira (FUT). Entre los motivos, la cada vez mayor demanda por parte de los pacientes y la mayor habilidad de los cirujanos en las extracciones al contar con mejor instrumental y más experiencia. Entre las ventajas de la FUE destaca la reducción de molestias postoperatorias en la zona donante y el aspecto muy poco visible de las cicatrices puntiformes residuales. Sin embargo, la FUE requiere una mayor laboriosidad, aumentando el tiempo operatorio, y una larga curva de aprendizaje por parte del cirujano.

KEYWORDS
Follicular unit extraction;
Hair transplant;
Follicular unit hair transplantation

Follicular Unit Extraction for Hair Transplantation: An Update

Abstract Follicular unit extraction (FUE) is a hair transplantation technique that uses small punches (0.8-1 mm in diameter) to extract the follicular units (FUs). Though initially the technique was not widely accepted because of the difficulty of extracting intact follicular units with such small punches, it has since gained in popularity due mainly to rising patient demand, the availability of better instrumentation and greater surgical skill acquired from experience. It is now a recognised alternative to follicular unit transplantation (FUT), a technique based on harvesting the FUs from a strip of tissue. Among the advantages of FUE are less post-procedural discomfort in the donor zone and the barely visible scarring from the punches. However, FUE is a more laborious, time-consuming procedure that involves a long learning curve for the surgeon.

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Introducción

Hace 7 años los autores publicaron en esta revista una revisión sobre la técnica del trasplante de pelo con unidades foliculares (UF)[1]. Aunque los conceptos básicos del trasplante relativos al diseño de la línea frontal e implantación en la zona receptora expuestos en esa revisión siguen vigentes, se han producido cambios muy importantes en el método de extracción de las UF de la zona donante, conocido como *follicular unit extraction* (cuyo acrónimo es FUE) lo que justifica esta actualización.

En nuestros días la mayoría de los cirujanos de trasplante emplean de forma indistinta 2 técnicas, la clásica de la tira, también conocida como FUT o *strip harvesting* y la técnica FUE, si bien esta última ha crecido mucho más en popularidad y demanda, pues es percibida por el paciente, y en realidad lo es, como una técnica menos invasiva.

El objeto de esta actualización es describir los aspectos técnicos generales de la FUE y las ventajas que aporta, pero a la vez dar a conocer sus desventajas y controversias.

Concepto de *follicular unit extraction*

La FUE es una técnica de trasplante de UF en la cual la extracción de las mismas de la zona donante se realiza utilizando un punch de aproximadamente 1 mm de diámetro. Mientras que en la técnica FUT las UF son diseccionadas en un estereomicroscopio tras la extirpación de una larga tira de piel, en la FUE la extracción de las UF se realiza de forma directa y «ciega», con un punch cilíndrico, guiándonos solo por la dirección de salida del tallo del pelo por la superficie cutánea. Por tanto, lo primero que hay que comprender es que la FUE se diferencia del FUT únicamente en la manera de extraer las UF, si bien en ambos casos el proceso de implantación en la zona receptora se realiza de igual manera.

La FUE es similar a la técnica del *punch grafting* descrita por Okuda[2,3] en 1939 y Orentreich[4] en 1959, siendo la principal diferencia el tamaño del punch utilizado en la extracción. Mientras que Okuda empleaba punches de 2,5 a 3 mm y Orentreich punches de 4 mm (que contenían 10-20 pelos por injerto), en la FUE se emplean punches muchos más pequeños, con el objeto de extraer únicamente UF (1-4 pelos por injerto).

El primer artículo de FUE lo publicaron en el año 2002 Rassman et al.[5]. En los primeros años esta técnica tuvo escasa aceptación por parte de los cirujanos de trasplante, fundamentalmente debido a la dificultad en extraer UF intactas con un punch de diámetro tan pequeño, pero tras estos inicios complicados, en los que pocos cirujanos creían que fuera a consolidarse como una técnica alternativa a la tira, la FUE se ha ido popularizando en la década actual. Varios son los motivos: la mayor demanda por parte de los pacientes; la mayor habilidad de los cirujanos en las extracciones, que se consigue con la mejora del instrumental y con la práctica; los resultados, que en manos de cirujanos experimentados son comparables a los de la tira; y el mayor interés en aprender esta técnica por parte de médicos nuevos en este campo, al ser la FUE una técnica que no precisa de microscopios ni de técnicos entrenados en la disección de los injertos[6].

Tabla 1 Instrumental de FUE

Punches
Punches de punta afilada
Titanio (www.mediquipsurgical.com)
Cole serrated punch (www.coleinstruments.com)
Ertip punch turco (www.ertipmedical.com)
Ring Punch (Dr. Roberto Trivellini)
Punches punta roma
Hex punch (punta plana) (www.harrisfueinstruments.com)
Punch híbrido
Hybrid trumpet punch (www.devroyeinstruments.com)
Aparatos motorizados
SAFE System (www.harrisfueinstruments.com)
CDD-Vortex and PCID (www.coleinstruments.com)
WAW system (www.devroyeinstruments.com)
Mamba (Dr. Roberto Trivellini)
Ertip FUE micromotor (www.ertipmedical.com)
Dr. Jack's E-FUE device (Robbinsinstruments.com)
4D FUE (folliculartech.com)
Smartgraft
Neograft

Instrumental empleado en la *follicular unit extraction*

El proceso de extracción de la UF mediante la técnica FUE tiene 2 partes: 1) la incisión circular con el punch alrededor de la unidad folicular que la libera del tejido dérmico adyacente; y 2) la extracción de la unidad folicular, normalmente realizada con pinzas.

La incisión circular con punch es la parte más difícil y delicada de la extracción. El primer instrumento empleado en la FUE para hacer las incisiones fue el clásico punch de biopsia de piel de 1 mm de diámetro. El problema surgía en que al tener el cirujano que guiarse únicamente por la dirección del pelo que sale por la piel para introducir el punch, y dado que el punch debe cortar alrededor de cada UF, cuyos folículos (4-5 mm en profundidad) no son estructuras rígidas, sino que pueden cambiar ligeramente de ángulo, era muy frecuente la transección de los folículos y, por tanto, su daño irreversible. Por ello, se intentó en un principio extraer las unidades foliculares con punches de mayor tamaño (1,25; 1,5 y hasta 2 mm), pero entonces se perdía el concepto de trasplante de unidades foliculares natural e indetectable y además las cicatrices de la zona donante con estos punches de mayor tamaño se hacían visibles. Hoy en día la extracción de UF con FUE se realiza con punches de entre 0,8 y 1,15 mm de diámetro, siendo el del 0,9 mm el más empleado.

El instrumental empleado en la FUE se pueden dividir en 3 tipos: manual (fig. 1 a), motorizado (fig. 1 b) y brazo robotizado (tabla 1). Con el sistema manual la mano del cirujano introduce la punta del punch y hace el corte alrededor de la unidad folicular. Con los sistemas motorizados el punch se introduce en una pieza de mano manejada por el cirujano, la cual va acoplada a un motor que hace rotar u oscilar la cabeza del punch a un número de revoluciones determinada. Con el sistema robotizado el cirujano selecciona en una pantalla la UF a extraer y el brazo robótico

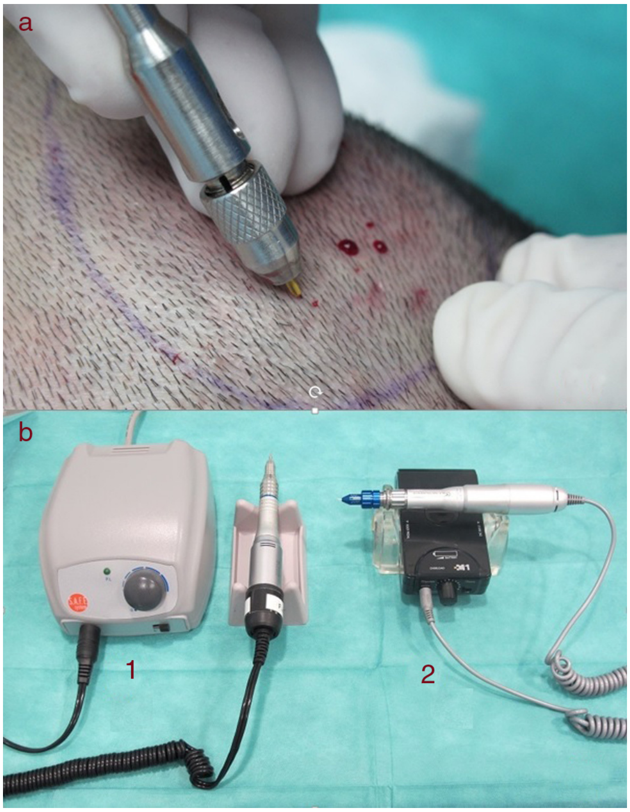

Figura 1 Sistemas de FUE.
a. Punch de uso manual. Para extraer la UF hay que alinear el punch con el ángulo y dirección de salida del pelo, y este debe quedar en el centro del punch.
b. Algunos sistemas motorizados: aparato SAFE de Harris (HSC-Development, Colorado, EE. UU.) (1) y aparato Vortex de Cole (Cole Instruments, Georgia, EE. UU.) (2).

realiza el corte circular alrededor de la unidad folicular. El Artas® (Restoration Robotics) es el único robot fabricado y comercializado exclusivamente para FUE[7,8].

Existe una gran variedad de punches comercializados que se diferencian en el diseño de la punta del punch. Se pueden clasificar en: punches de punta afilada *(sharp punches)*, de punta roma *(blunt punches)* y los punches híbridos (tabla 1). Los punches afilados tienen un mayor efecto de corte, mientras que los romos e híbridos actúan con un mayor efecto de disección del tejido[9–11]. La técnica de extracción es diferente según el tipo de punch empleado, como se comentará en la siguiente sección. En los próximos años irán apareciendo en el mercado nuevos punches con diferentes diseños cuyo objetivo no es otro que el de facilitar la extracción de la unidad folicular reduciendo el porcentaje de transección de folículos hasta mínimos aceptables y similares a los del método de tira (por debajo del 5-10%). El Artas® emplea un punch de punta roma que se desliza dentro de un punch afilado.

En opinión de los autores el instrumental es muy importante, pero también lo es la habilidad y la experiencia del cirujano. Hay cirujanos que utilizan exclusivamente punches afilados manuales y obtienen resultados tan excelentes como otros cirujanos que emplean sistemas motorizados con punches romos o híbridos. Los resultados, por tanto, no dependen solo del tipo de instrumental, sino del cirujano que hace uso del instrumento.

Figura 2 Cortes realizados con el punch alrededor de la unidad folicular y con el pelo en el centro de la superficie de corte.

Cómo extraer correctamente las unidades foliculares con *follicular unit extraction*

Para extraer las UF con FUE hay que alinear el punch con la dirección de salida del pelo, debiendo este quedar en el centro del punch (fig. 2). Utilizar lupas de gran aumento (4-5 ×) es importante porque permite una mayor precisión en la extracción. Con los punches actuales es necesario rasurar el pelo a 1-2 mm para ver su ángulo de salida, aunque se están desarrollando punches, aún no comercializados, que permitirán realizar extracciones con pelo largo. El ángulo de salida del pelo cambia según la zona de extracción. Las zonas donde el pelo sale en ángulo más agudo son las áreas temporales y los márgenes del cuero cabelludo. Una de las técnicas recomendadas para conseguir que el folículo se haga más vertical, y así facilitar la extracción es la infiltración con suero (tumescencia) inmediatamente antes del corte con el punch[12].

La profundidad a la que se debe introducir el punch varía según sea un punch de punta afilada, roma o híbrida. Los punches de punta afilada normalmente se introducen 2,5-3 mm, ya que a profundidades mayores (por debajo de la inserción del músculo erector del pelo) las porciones inferiores de los folículos en anágeno se separan y es cuando existe mayor riesgo de transección (figs. 3 y 4). Los punches romos e híbridos, por su mayor efecto de disección y menor de corte, se pueden introducir a mayor profundidad (> 4 mm) con menor riesgo de transección. Los punches romos, sin embargo, tienen mayor riesgo de introducir el injerto dentro de la dermis (injertos enterrados o *buried grafts*)[10].

Ventajas y desventajas de la *follicular unit extraction* (tabla 2)

Una de las innovaciones que ha traído la FUE ha sido la posibilidad de extraer UF de otras zonas corporales. Esto es útil

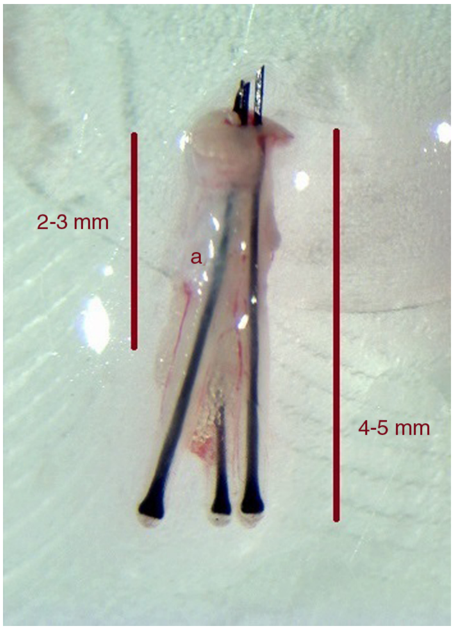

Figura 3 Los punches de punta afilada se deben introducir solo 2-3 mm en profundidad para reducir el riesgo de transección de los folículos. Los punch romos e híbridos se pueden introducir a mayor profundidad (> 4 mm).(a): Glándula sebácea.

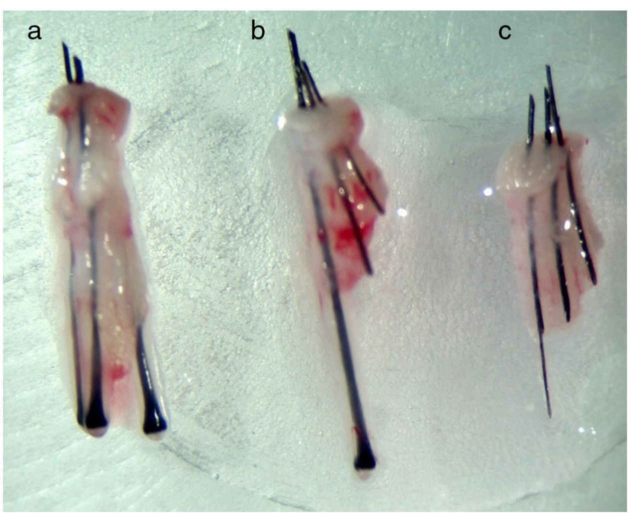

Figura 4 Unidades foliculares.
(a): Normal y sin daño; (b): con transección parcial de 2 folículos;
(c): con transección total de la unidad folicular.

en los casos en los que la zona donante del cuero cabelludo tiene baja densidad de UF, como suele ocurrir en pacientes con varias sesiones de trasplante previas. La zona de pelo corporal más empleada es la barba, sobre todo la zona submandibular (fig. 5). Otras zonas en las que se pueden extraer folículos son el tórax, el abdomen, el pubis, las piernas y las axilas[13,14].

Una indudable desventaja de la FUE es que resulta muy laboriosa y exigente para el cirujano. Dependiendo de la habilidad de este la obtención de 1.000 injertos con FUE puede durar de 1,5 a 3 horas, con lo cual es una técnica muy

Figura 5 Barba como zona donante; 1.100 extracciones realizadas con punch afilado de Cole de 0,9 mm en sistema motorizado Vortex® (Cole Instruments, Georgia, EE. UU.).

Tabla 2 Ventajas y desventajas de la técnica FUE

Ventajas de la FUE
Reducción de molestias postoperatorias y del tiempo de curación en la zona donante
Cicatrices puntiformes muy poco visibles
Desventajas de la FUE
Técnica más lenta, laboriosa y exigente para el cirujano
Se necesita rasurado de la zona donante para realizar la extracción
Unidades foliculares más finas y delicadas (mayor riesgo de daño durante la implantación)

«cirujano dependiente». La mayoría de los cirujanos limitan la sesión de FUE a un máximo de 1.500-2.000 UF por día para no extender mucho el tiempo operatorio[15]. En la experiencia de los autores, si hay que extraer 2.000 o más UF se prefiere hacerlo en 2 días consecutivos para no alargar el tiempo operatorio y minimizar el potencial daño de los injertos.

Cuándo es preferible *folicular unit extraction* o tira

Prácticamente cualquier paciente que es candidato a trasplante con tira lo puede ser igualmente a la técnica FUE (fig. 6). Sin embargo, hay situaciones en las que puede ser preferible emplear una u otra técnica (tabla 3). Por ejemplo, en pacientes jóvenes con áreas receptoras pequeñas la FUE da mucha más libertad a la hora de llevar en un futuro el pelo muy corto, y además permite hacer más sesiones si fuera deseable sin necesidad de comprometer al paciente a llevar el pelo más largo para tapar la cicatriz lineal de la tira. Sin embargo, pacientes que no desean raparse el pelo para realizar la intervención prefieren la tira, pues la cicatriz lineal quedaría tapada por el propio pelo.

También la FUE está especialmente indicada en pacientes con cicatrices por tiras previas en las que existe bastante tensión en la piel del cuero cabelludo. La FUE también es muy útil para corregir cicatrices engrosadas residuales por un trasplante previo hecho con tira[16].

Figura 6 Paciente buen candidato tanto para FUE como FUT. En este caso se trasplantaron 2.000 UF mediante FUE con punch afilado Cole de 0,95 mm en Vortex® (Cole Instruments, Georgia, EE. UU.).a. Antes del trasplante.
b. A las 24 horas tras el FUE.
c. Resultado al año de la intervención.

Tabla 3 Preferencia en el uso de la FUE o la tira

Preferencia de la FUE
Pacientes que llevan el pelo muy corto
Pacientes jóvenes con área receptora pequeña
Pacientes con mucha tensión en la piel del cuero cabelludo
Corrección de cicatrices residuales por un trasplante previo hecho con tira
Preferencia de la tira
Sesiones de más de 2.500 unidades foliculares en un solo día
Pacientes que no desean raparse el pelo para la intervención

Figura 7 Cicatrices puntiformes hipopigmentadas en la zona donante de un paciente operado con FUE con punch romo de 0,9 mm (sistema SAFE de Harris; HSCDevelopment, Colorado, EE. UU).

Controversias de la *follicular unit extraction*

Muchos pacientes tienen la idea equivocada de que la FUE es una técnica que no deja cicatriz, algo alentado en webs y foros de Internet. Nada más lejos de la realidad. Toda extracción realizada con un punch, por pequeño que este sea, deja una cicatriz puntiforme. Estas cicatrices suelen ser muy poco visibles, incluso llevando el pelo muy corto, aunque no en todos los pacientes (fig. 7). Uno de los temas más debatidos en la FUE es el daño que se produce en la zona donante cuando el número de extracciones es muy elevado. En otras palabras, ¿cuál es el límite máximo de extracciones que se pueden realizar en la zona donante sin que el daño se haga clínicamente visible? En teoría, teniendo en cuenta que la mayoría de las personas tienen una densidad de UF entre 70-80 por centímetro cuadrado, y que se pueden extraer hasta unas 15-20 UF por centímetro cuadrado por sesión, se estima que aproximadamente unas 3.000-4.000 UF es el límite máximo recomendable de extracciones por sesión[15]. Ahora bien, tras varias sesiones de FUE, cada una de ellas con miles de extracciones, la zona donante puede quedar con una densidad muy baja y adquirir un aspecto «apolillado» (fig. 8). También es importante realizar las extracciones de forma homogénea por toda la zona donante, para que no queden zonas con menos densidad que otras.

Por último, todavía hoy día algunos expertos cuestionan que el crecimiento de los injertos FUE sea igual al obtenido con la tira[17]. La controversia surge porque las UF extraídas con FUE suelen ser más finas («esqueletonizadas»), mientras que las diseccionadas al microscopio son más gruesas y con más tejido adiposo circundante. Quizás el pobre crecimiento observado en algunos casos de FUE sea debido a que al ser las UF más finas, su manejo durante la implantación debe ser más delicado, puesto que hay más riesgo de dañar la parte más sensible del folículo que es el bulbo

Figura 8 Zona donante hipodensa de aspecto «apolillado» por exceso de extracciones.

piloso con su papila dérmica. En cualquier caso, se necesita realizar estudios controlados comparando la supervivencia de los injertos extraídos con ambas técnicas para resolver esta controversia.

Cómo aprender e iniciarse en la *follicular unit extraction*

La irrupción de la FUE ha provocado un mayor interés en aprender las técnicas de trasplante de cabello. Sin embargo, la FUE tiene una curva de aprendizaje larga y no se pueden adquirir conocimientos suficientes en un taller de fin de semana. Por otro lado, dado que el tiempo requerido para que se vean los resultados es largo (entre los 6-12 meses) el cirujano tarda mucho tiempo, a veces años, en desarrollar las habilidades requeridas e implementar los controles de calidad adecuados para este proceso.

Una de las formas más rigurosas de aprender FUE es asistir a talleres y Congresos anuales organizados por la *International Society of Hair Restoration Surgery* (www.ISHRS.org). Esta sociedad ofrece también programas de especialización *(fellowships)* de uno o 2 años de duración en varias clínicas acreditadas.

Conclusiones

Sería lo ideal que el cirujano de trasplante conociera y practicara de forma habitual las 2 técnicas (FUE y tira) para emplear en cada caso la más conveniente para el paciente y no la más conveniente para el cirujano.

Como ventaja más interesante del FUE frente al FUT, destaca la reducción de las molestias postoperatorias en la zona donante y el que las cicatrices puntiformes pasan más desapercibidas. Como principal inconveniente, su mayor laboriosidad que se traduce en mayor tiempo operatorio y la larga curva de aprendizaje.

Conflicto de intereses

Los autores declaran no tener ningún conflicto de intereses

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