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.

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.

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 $3.5 \times 3.5\ cm^2$. 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.

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

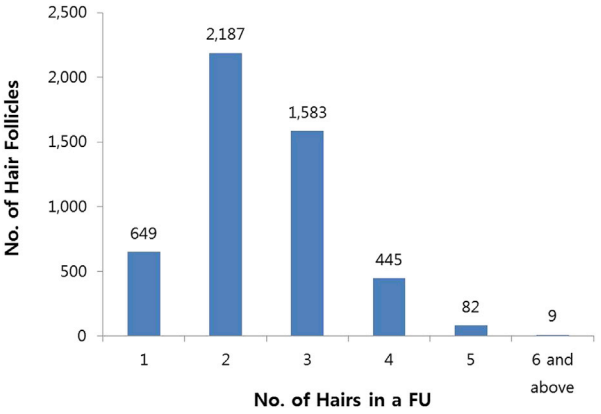

Fig 2. The number of hairs in a robot-harvested follicular unit (*FU*).

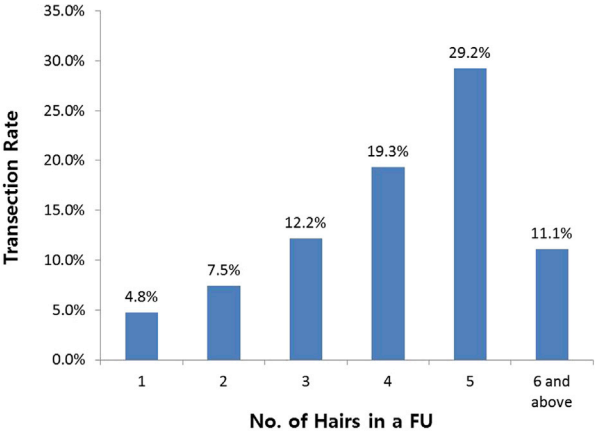

Fig 3. Transection rate according to the number of hairs in a follicular unit (*FU*).

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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