Robotic Follicular Unit Graft Selection

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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).

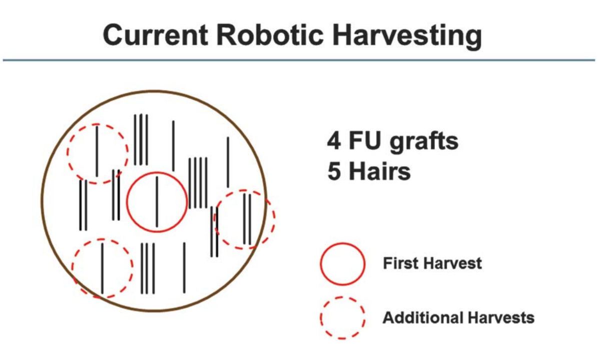

Figure 1. Random graft harvesting.

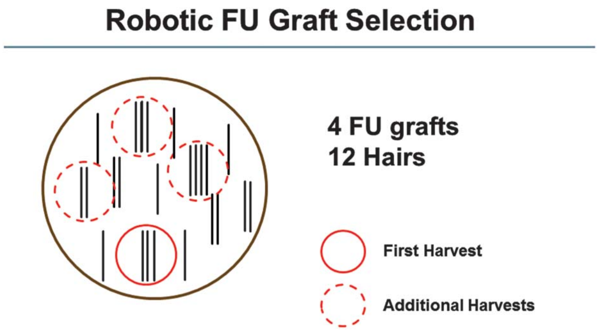

Figure 2. Selective graft harvesting.

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

Figure 3. Donor area showing experimental design.

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

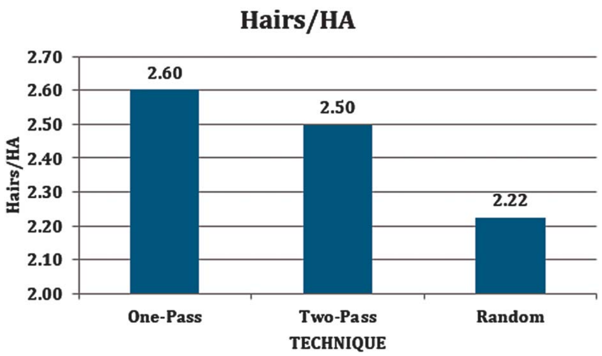

Figure 4. Hairs per HA.

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

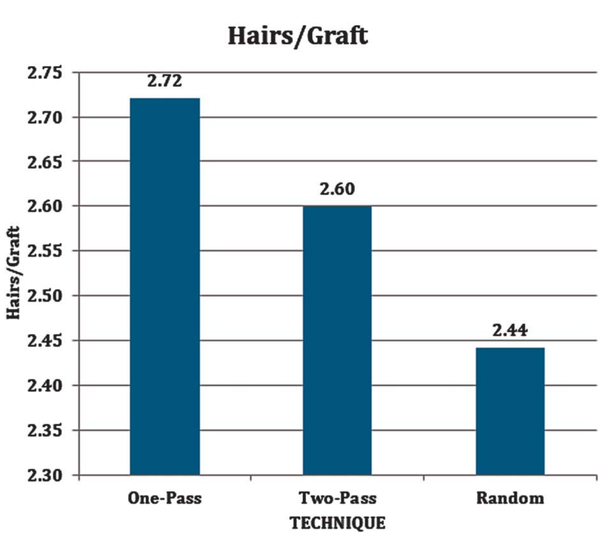

Figure 5. Hairs per graft.

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.

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