New Methodology and Instrumentation for Follicular Unit Extraction: Lower Follicle Transection Rates and Expanded Patient Candidacy

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BACKGROUND. Follicular unit extraction (FUE), as described in the literature for harvesting follicular units, is technically demanding, has limited patient candidacy, and can potentially result in high rates of follicle transection. Although FUE has potential advantages, such as faster surgical recovery, less postoperative pain, less noticeable scarring, and possible expansion of the donor area, the acceptance of the technique is limited by the problems noted above. The proposed methodology and instrumentation may allow widespread adoption of FUE.

OBJECTIVE. To present the SAFE (Surgically Advanced Follicular Extraction) System , a new methodology and novel instrumentation for FUE. This article presents the efficacy of this methodology and addresses patient candidacy.

METHODS. Twenty-two patients undergoing standard strip excision were enrolled in a pilot study to assess follicle transection rates using the SAFE System. Based on the success of the pilot study, an additional 37 patients receiving a total of 6,947 grafts were examined. Transection rates were recorded, and patients were examined for complications or adverse reactions.

RESULTS. The average follicle transection rate was 6.14%, with a range of 1.7 to 15%. The only adverse reaction was the occurrence of two buried grafts, resulting in inflammatory subcutaneous cysts requiring excision.

CONCLUSION. It appears that the SAFE System provides the methodology and instrumentation to enhance current FUE techniques and expand patient candidacy. The transection rate of this method compares favorably with traditional microscope graft dissection. Physicians with a modicum of technical skills can use the technique, and there does not appear to be a significant adverse reaction rate.

DR HARRIS HAS APPLIED FOR A PATENT ON THE BLUNT PUNCH USED IN THIS STUDY. HE HAS ALSO APPLIED FOR A TRADEMARK ON THE SAFE SYSTEM.

ONE OF the most recent advances in hair transplantation is a method of graft production called follicular unit extraction (FUE), described by Rassman and colleagues[1] and called the FOX procedure. In this technique, follicular units are isolated and dissected from the skin, primarily using a 1 mm sharp punch. The proposed benefits of this technique to patients are less postoperative pain, more rapid surgical recovery, expansion of the potential donor area to include body hair, a possible increase in scalp donor potential (limitations imposed by scalp laxity may be decreased), and less noticeable scarring.

Although hailed as a significant advancement when initially published, adoption of the technique by most hair transplant surgeons has been limited in spite of the proposed benefits. The main reasons for this are related to potentially high rates of follicle transection, the requirement of a high degree of technical skill, and

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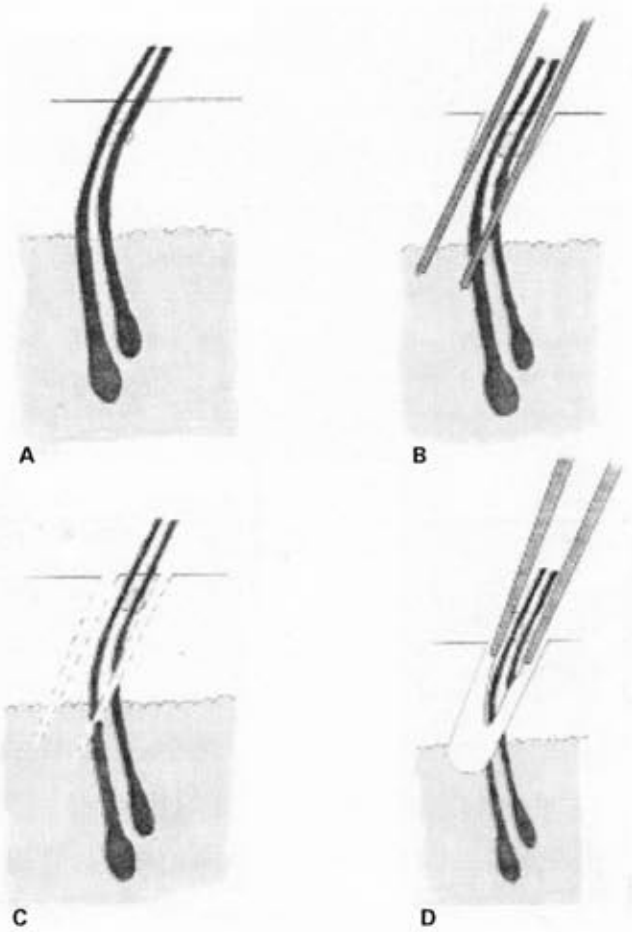
 • Published by BC Decker Inc •
DOI: 10.111/j.1524–4725.2006.32006

limited patient candidacy. Rassman and colleagues felt that approximately 60% of patients were candidates for the FOX procedure.[1]

In my experience in performing FUE as described by Rassman and colleagues, I have found that their claim that this procedure is technically demanding is highly accurate. Multiple attempts at this procedure were met with high rates of transection, usually in excess of 20% during the initial attempts and usually greater than 15% even after some experience. My conclusion from this experience is that factors beyond technical skill and histologic differences between patients contributed to the unpredictable transection rates.

After performing FUE on several patients, there were some consistent observations. The two factors that seemed to correspond to higher transection rates were follicles whose exit angle of hair did not match the subcutaneous course of the follicle and a higher degree of tethering of the follicle to the subcutaneous tissues. Compensation for these factors by changing the depth of the punch insertion resulted in several outcomes. To decrease the "tethering" effect, attempts to increase the depth of punch insertion increased the risk of sharply transecting the follicle (Figure 1). In a second scenario, to decrease the risk of deep sharp transection of the follicle, a shallow-depth punch insertion resulted in less separation of the follicle from the subcutaneous tissue, which increased the risk of shearing the follicle during the extraction process.

In my analysis of the dilemma described above, it became apparent that the answer might require two surgical steps with two separate instruments. A critical component was the classic surgical solution to the problem of a fragile or critical anatomic structure that needs to be separated from a second structure, in this case, the follicle from dermal tissue. It was postulated that a sharp 1 mm punch could be inserted to a "limited depth" to avoid sharp transection of the distal follicle followed by a blunt "punch" inserted into the limited depth incision and advanced to the distal end of the follicle to "dissect" the distal follicle from the investing dermis. The leading



{12}**Figure 1.** (A) The subcutaneous course of the follicles does not follow the angle of hair emergence. (B and C) Sharp dissection with the punch results in transection of the follicular unit). (D) The effect of follicle curvature results in a high proportion of transected follicles. Q12

edge of the blunt punch is fashioned in such a way that even when encountering a follicle at angle, it will facilitate the entry of the follicle into the lumen of the punch rather than transect it.

Purpose

The purpose of this study was to assess the efficacy of the SAFE (Surgically Advanced Follicular Extraction) System, as described below. The intent was to ascertain whether this new methodology would result in lower rates of follicle transection compared with standard FUE. In the process of evaluating this new methodology, an attempt was made to identify those patients, based on transection rates, who would not be candidates for FUE by the SAFE System.

Materials and Methods

The instruments used to evaluate the SAFE System were a 1 mm punch (Miltex Inc., Bethpage, NY, USA) designated as the scoring punch and a 1 mm dissecting punch. This punch has no sharp edges and a slightly tapered leading edge. The methodology for all patients involved the insertion of the scoring punch around the follicular unit to a depth of 1.3 to 1.5 mm at an angle that approximated the exit angle of the hair shafts. This depth corresponds approximately to a point on the punch where the bevel of the sharpened tip ends or becomes confluent with the punch shaft. This was followed by the insertion of the dissecting punch at approximately the same angle to a depth of 4 mm. The graft was then visualized, grasped at the region of the sebaceous glands with forceps, and removed with slow, constant traction. Figure 2 illustrates the concept of the SAFE System for FUE.

If bleeding was problematic after several grafts were obtained, a 1:100,000 epinephrine solution was injected intradermally for vasoconstriction. Injection of a solution into the deep dermis and subdermal plane to attain tumescence is not routinely performed because it typically resulted in a "mushy" dermis, impeding the FUE process.

Patients undergoing strip excision follicular unit transplantation were enrolled in the initial evaluation. These patients had between 10 and 20 grafts extracted and analyzed for follicular transection rates by examination using a Meiji stereomicroscope at ×20 power. Additional patients were enrolled to receive grafts obtained exclusively by the SAFE System, and the grafts were analyzed for follicle transection rates. The patients were observed postoperatively for any complications or adverse outcomes owing to this method of FUE.

Results

The initial testing phase, conducted on 22 patients undergoing standard strip excision, showed a

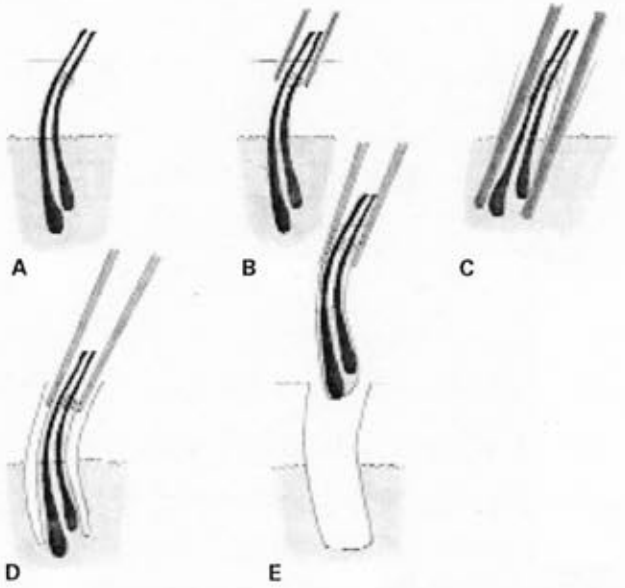


Figure 2. Illustration of the SAFE System. (A) The curved follicle in situ and (B) the insertion of the sharp "scoring" punch to a limited depth of approximately 1.3 mm. (C) Insertion of the dull "dissecting" punch to the distal end of the follicles and (D and E) the subsequent removal of the intact follicle with forceps.

transection rate less than 10%. This group included a black patient and a patient with white hair. It was felt that the methodology had technical merit and that it would be appropriate to commence with cases requiring substantially more grafts.

Thirty-seven patients were enrolled, and the total number of grafts examined for transection was 6,947. The range of grafts extracted was between 20 and 1,065. The average rate of follicle transection was 6.14%, with a range of 1.7 (504 graft cases) to 15 (125 graft cases). Combining all grafts for all patients resulted in an overall transection rate of 5.6%. The occipital area seemed to have a lesser degree of tethering of the distal follicle to the dermal tissue compared with the temporal or parietal areas. This tethering required longer applications of extraction force or dissection at the base, resulting in slower extraction rates in the parietal and temporal areas. A phenomenon called "capping," the separation of the epidermis from the dermis, occurred more frequently in the parietal and temporal areas compared with the occiput. When capping occurred, the graft was left in situ or further dissection was employed to remove the graft.

This technique, although reducing the incidence of graft transection, may result in a higher incidence of follicular unit burial in the dermis. The reason for this is probably mechanical in nature, that is, related to the dull punch traveling through the dermis in a pushing fashion. When there appeared to be a higher degree of follicular unit tethering to the dermal tissue, there seemed to be an increase in the incidence of graft burial. This phenomenon is seen more frequently in the temporal or parietal areas compared with the occiput.

The exact rate of graft burial is unknown; however, in one set of 500 graft extractions from the occipital and temporal areas, there were 36 buried grafts (7.2%), with 29 of those recovered, leaving 7 buried grafts (1.4% of total graft attempts). In a series of 40 patients and approximately 10,000 grafts, there were 2 instances of buried grafts that resulted in hair-bearing inflammatory cysts that required removal.

When a buried graft was noted, pressure was applied to the surrounding area in an attempt to "force" the graft to the surface. This was followed by direct examination of the surgical site, where often either the epidermal portion or the distal portion of the follicle was identified, allowing direct removal. If the graft was not visible, small curved forceps with the tip directed toward the more "superior" (where the hair exit angle is obtuse) aspect of the incision were used to blindly grasp for the buried graft. This is where the depth of the incision made by the scoring punch will have been shallower owing to the angle of insertion. If the graft could not be located, a small incision was created toward the superior aspect to enlarge the opening for exploration. If the graft could not be located, the graft was left buried.

Figure 3 illustrates the donor site 1 day and 14 days following a SAFE System FUE. When extracting 1,000 grafts or less, small strips of the scalp measuring 3 to 5 mm may be shaved rather than shaving large areas or even the entire scalp. Figure 4 is a close-up of a superior crown transplantation and frontal hairline using the SAFE System.

Discussion

FUE, as presented by Rassman and colleagues,[1] provided an exciting new method for obtaining follicular unit grafts. Unfortunately, the procedure was difficult to learn, time consuming, limited in terms of patient candidacy, and potentially harmful to the follicular unit grafts. The SAFE System, as described, has the potential to bring the technique of FUE into the hands of the average hair restoration surgeon for the average patient while at the same time providing follicle integrity.

The SAFE System has significantly expanded patient candidacy, including blacks and those classified as FOX negative using

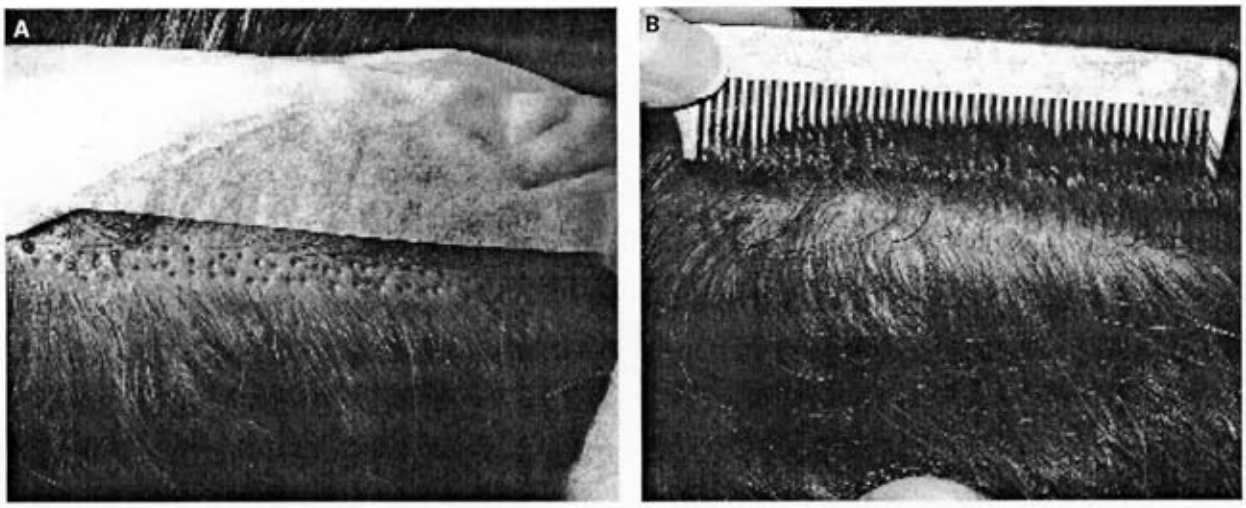


Figure 3. The donor area following SAFE System follicular unit extraction at (A) 1 day and (B) 14 days.

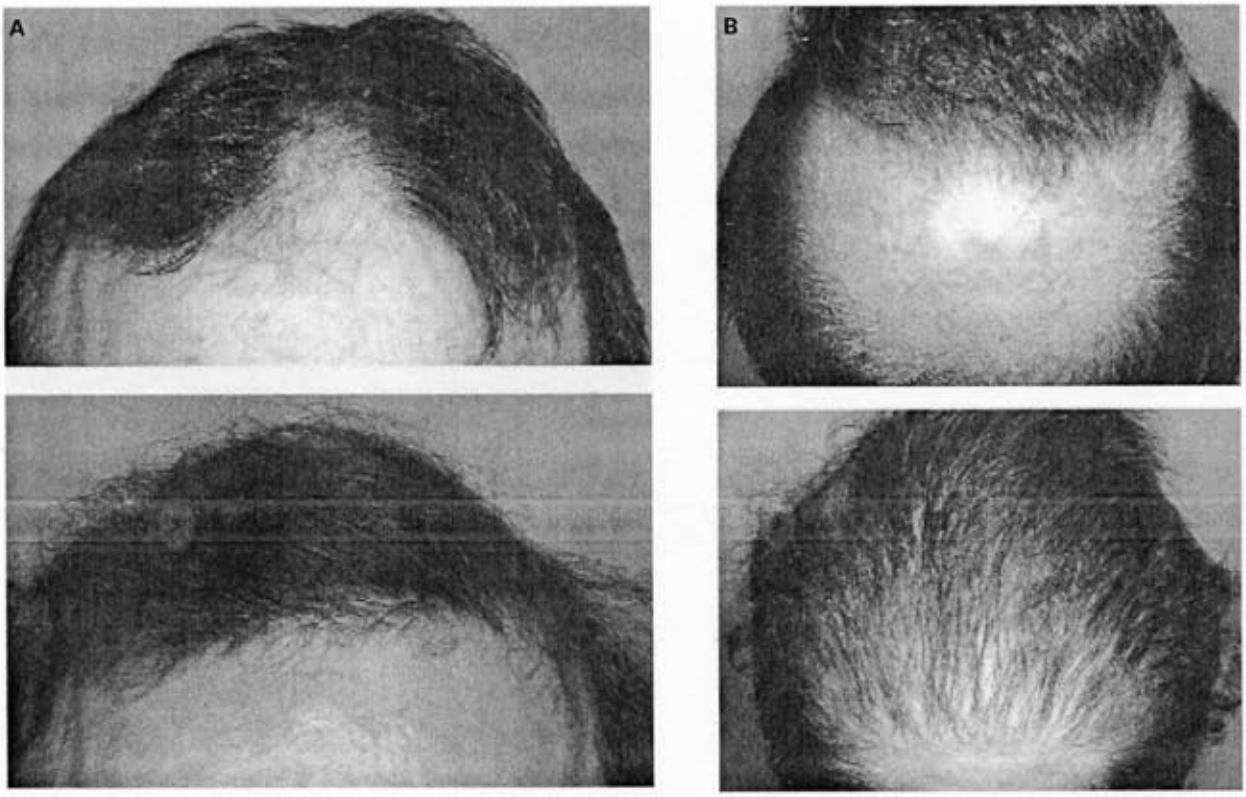


Figure 4. Frontal and upper crown reconstruction using the SAFE System. The frontal area (A) used approximately 400 follicular units, whereas the upper crown (B) had approximately 900 grafts. The "after" photographs are 10 months post-surgery.

the criteria set forth by Rassman and colleagues.[1] Another advantage may be the use of this technique in patients with white or gray hair. Patients with this hair characteristic present a unique challenge to those performing microscopic dissection because it is extremely difficult to visualize the follicles; therefore, the risk of transection is high. Because the SAFE System uses blind dissec-

tion, the follicles do not need to be visualized but are inherently protected by the "blunt" dissection.

Although there are possible benefits to the patients, such as absence of a linear scar, virtually pain-free surgery, faster recovery, and increased donor capacity, there are some advantages that accrue to the surgeon. Because the SAFE System is easily learned, physicians who do not employ highly skilled staff trained in microscopic dissection techniques may offer follicular unit transplantation. It may also allow physicians not currently providing follicular unit transplantation to expand their offerings. As the technique evolves, the use of physician extenders, such as physician assistants and nurse practitioners, may allow leverage of resources and therefore cost savings and price reductions to the patient without sacrificing the quality of the grafts provided.

FUE is a valuable addition to the hair restoration surgeon's armamentarium. With the introduction of the SAFE System, more surgeons will be using this technique for FUE, allowing more experience globally and, eventually, refinements of the technique. With this broader experience, we will achieve a clearer definition of the indications and contraindications of this procedure. Additionally we may be able to answer the questions regarding the optimal timing of procedures, extraction sequences, and maximal donor area yield.

Reference

1. Rassman WR, Bernstein RM, McClellan, et al. Follicular unit extraction: minimally invasive surgery for hair transplantation. Dermatol Surg 2002;28:720–8.

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COMMENTARY

The purpose of Dr. Harris's article is to describe a mechanism for increasing the number of patients who may safely be considered for follicular unit extraction (FUE). Given the figures that he presents, there is no doubt that it would significantly reduce the 40% of individuals who Rassman and colleagues described as not being suitable for FUE using their technique.[1] However, Harris goes too far when he states that after his studies were completed, it was his opinion that "all patients were candidates for the SAFE System." With at least one patient showing a 15% follicle transection rate with the described technique, a small percentage of patients would still appear not to be candidates. Most of us would find a 15% rate of transection or even a 10% rate of transection too much. In the same vein, a designation of the "SAFER technique" would be less misleading than a designation of the "SAFE System." It is too easy for the reader who is scanning an article to come to the conclusion that this approach is entirely safe or for laymen reading such a designation to believe that it is entirely safe for the follicular unit, which it is not. What it is is much SAFER.

In my commentary on Rassman and colleagues' article, I also took exception to the designation of FUE as being "minimally invasive surgery."[2] A review of that article and my commentary gives the rationale and details of why I objected to it. In brief, if one were extracting 500 follicular units via FUE, 500 incisions with a 1 mm diameter punch would produce at least 1,560 mm of skin incision. In contrast, the perimeter of a strip that was 6 × 83 mm long (containing 500 mm surface area) could be expected to produce 500 follicular units, with only approximately 200 mm of total incision being made into the skin. A designation such as "minimally invasive surgery" was completely out of place

in that first article and is also completely out of place in this one. Lastly, it has now been more than 3 years since Rassman and colleagues started experimenting with and using FUE. Although they, Dr. Harris, and others have all postulated that it may be possible to obtain more follicular units out of any given donor area using this technique—when compared with strip harvesting—and that it might be useful for transferring body hair to the scalp, both of these potential advantages have not materialized, either in medical articles or at meetings. In particular, on two occasions, speakers at the annual meetings of the International Society of Hair Restoration Surgery were scheduled to discuss both of these theoretic benefits and bring patients to demonstrate them. On both occasions, the speakers failed to show up for their presentation. The longer we have to wait to see these benefits, the more reasonable it becomes for us to conclude that we are unlikely to ever see them.

There is also a growing suspicion among hair restoration surgeons that, at a certain point, and at least in certain individuals, removal of thousands of follicular units using the FUE technique may result in a moth-eaten or Swiss cheese appearance in the donor area if the patient ever decides to shave the hair in that area. The ability to do this without revealing noticeable scarring was another of the advantages proposed by proponents of FUE, yet, once again, we have yet to see a shaved donor area after the removal of 4,000 to 6,000 follicular units via FUE, in publications or at meetings. At what point should we conclude that the suggested potential benefits are not realistic? Having said the foregoing, there are, in fact, definite advantages to FUE in some situations. They have been described not only by Dr. Harris but also by Rassman and colleagues and this commentator.[1,2] I believe still, however, that its role will be limited to specific patients who have specific needs or goals. For individuals within that group, the technique described by Harris would seem to be a very good one, especially for novices in the technique, who might otherwise have higher transection rates.

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1. Rassman W, Bernstein R, McClellan, et al. Follicular unit extraction: minimally invasive surgery for hair transplantation. Dermatol Surg 2002;28:720–7. Q14

2. Unger W. Commentary. Dermatol Surg 2002,28:727–8.