



# forum

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## The SAFE System<sup>®</sup>: New Instrumentation and Methodology to Improve Follicular Unit Extraction (FUE)

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**T**he technique of follicular unit extraction (FUE) and the FOX<sup>®</sup> procedure and test as described by Drs. Rassman et al.<sup>1</sup> has added an additional technique to the armamentarium of the hair transplant surgeons. However, the technique as currently described is technically demanding and time-consuming, and there is the possibility of high rates of follicle transection. In the study by Rassman, 37.5% of patients were FOX<sup>®</sup> negative (not candidates for FUE) due to high rates of follicle damage. Even for FOX<sup>®</sup> positive patients (candidates for the procedure), the rate of follicle transection may be close to 20%. With transection rates this high, the efficiency of hair transfer to the scalp is low when compared to traditional strip excision with microscopic dissection.

The technique, as is currently described, may consume the better part of the day to extract and implant 500 grafts. The reasons for the long procedure time have to do with the nature of

the procedure, extracting a single graft at a time, and the frequent tethering of the follicular units to the subcutaneous tissue requiring tedious dissection for removal. Some clinics have resorted to using non-physician staff members in an effort to increase the rate of graft extraction.

Newcomers to this technique have found multiple sources of difficulty in performing FUE. In my own experience, the frequent lack of association between the exit angle of the hair and the subcutaneous course of the

follicle is particularly problematic. When this is coupled with frequent changes in follicle direction, transection is frequent. Another problematic area in FUE is the tethering of the follicle to dermal components requiring either time consuming dissection or shearing of the follicles as extraction is attempted. All of these factors contribute to the relative lack of physicians performing FUE and account for the lack of research into the refinement,

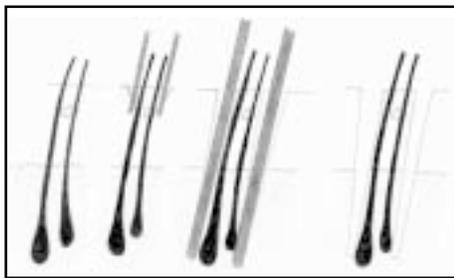


Figure 1. Illustration of the SAFE System<sup>®</sup>

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**The BIG One, Down Under**



**ISHRS 13<sup>th</sup> Annual Meeting  
Sydney, NSW, Australia  
August 24-28, 2005**

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improvement of instrumentation, and efficacy of this technique.

An analysis of the surgical causes of transection or shearing leads to the following elucidation of the surgical dilemma: as the depth of sharp dissection increased, the transection rate increased; as the depth of the sharp dissection decreased, tethering and subsequent shearing increased. The solution is rooted in classic surgical training; that is, when there is an anatomic entity that needs to be preserved adjacent to tissue that needs to be removed, **blunt** dissection is the method of choice. The application of blunt dissection and the answer to the surgical dilemma described above resulted in the following solution for FUE:

**Limit the depth of sharp punch dissection to limit transection, and utilize blunt dissection to relieve tethering.**

The methodology has been named the SAFE System® for Surgically Advanced Follicular Extraction. The surgical process involves two steps. The first is the utilization of a sharp 1mm punch (Miltex, for example) inserted to a depth of approximately 1.3 to 1.5mm. The second step is the insertion of a blunt punch to a depth of 4–5mm. Figure 1 illustrates the SAFE System®. The blunt punch utilized has a wider wall thickness than the sharp punch and has a taper at the tip allowing for gradual dilatation of the site and a large enough radius of the dull tip to minimize or prevent transection even if the tip comes in contact with the follicle shaft. This tip will be available from A to Z Surgical, Hauppauge, NY as the Harris Dissecting Punch. The dissecting punch can be inserted into the open end of a Miltex punch to provide an instrument integrated with the two types of punches (Figure 2).

The methodology and instrumentation was initially tested on a series of 22 patients undergoing standard strip excision, whereby approximately 25

grafts were extracted from the donor area prior to strip removal (typically from the mid-occipital area). The experience indicated that this technique was feasible as the transection rate was less than 10% in all patients. With these results, it was determined that larger cases could safely be tried and the results analyzed.

A total of 37 patients, including the 22 patients mentioned above, were

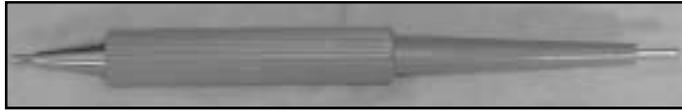


Figure 2. Instrument integrated with the two types of punches

enrolled in the study. The number of grafts ranged from 20 to 1,065. The total number of grafts examined for follicle transection was 6,947. The range of transection rates was 1.7% in a 504-graft case to 15% in a 125-graft case. Although not formally examined, there seemed to be a higher transection rate as the extraction sites moved from the occipital area to the parietal and temporal areas. The overall transection rate for all grafts was 5.6%. In two cases where the hair extracted was white and in another case from an African American, with approximately 20 grafts extracted, there was 0% transection. The rate of graft production varied, with a practical maximum rate of about 400 grafts/hour. Sustainable rates of 25 grafts in less than 3 minutes were common. The area of maximal graft production was consistently in the occipital area.

There may be several biases in favor of low transection rates and high rate of extraction. The most likely is that the majority of grafts were obtained from the occipital region, an area that has proved to allow easier extraction. The patients, although selected randomly, may have been mostly FOX® positive.

The author of this report has devised a methodology and surgical instrumentation to address some inherent problems associated with FUE that have resulted in a reduction of the transection rate, an increase in the speed of extraction, and an expansion of patient candidacy. The current plan for instrumentation is to produce a disposable

unit, called the “Scribe,” that has the depth limited, sharp “scoring” punch at one end, and a blunt “dissecting” punch at the opposite end. Work has begun on the “Scribe II,” which has both the scoring and dissecting punch housed on the same operating end of the instrument with thumb actuation of the device. Work has begun on a mechanized version that has the potential to increase extraction rates significantly, utilizing a modified dissecting tip to facilitate graft dissection.

The indications for FUE are a subject of some debate. If an assumption is made that the grafts obtained by FUE have a transection rate similar to grafts obtained by microscopic dissection and that graft survival is similar, then theoretically anyone is a candidate. Patients who may benefit to a greater degree by FUE are those with minimal or no laxity, excessive donor scarring, fear of pain, fear of linear scar, need for rapid recovery, or a need to utilize body hair.

FUE may confer certain benefits or advantages to patients. Less pain and a more rapid surgical recovery have been substantiated in nearly every patient. The potential donor area may be expanded to include body hair in certain circumstances. It may be possible to increase the scalp donor potential as the limitations imposed by scalp laxity may be decreased substantially; the degree of possible scalp donor expansion is unknown. The issue of scarring is controversial. The total amount of scarring due to FUE as compared to a standard strip excision for the same number of grafts is certainly not less. However, its diffuse nature may confer a decrease in detectability when the hair is closely cropped. A final possible advantage to patients is the ability to harvest follicular units with finer hairs from a slightly lower position on the neck or supra-auricular areas for use in the hairline or eyebrows.

With the state of the art of FUE, patients should also be aware of some disadvantages. With slower graft production rates, the patient will have to endure longer surgery times along with fewer grafts per session. This

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# Letter to the Editors

## *Please note the correction...*

Just a short note to thank Dr. Gillespie for his very kind review of the 4<sup>th</sup> edition of Hair Transplantation. Positive comments are particularly appreciated from somebody of his experience and skill.

On an aside, I wanted to point out a

small error in the review. There is, in fact, a section on FUE from pages 334 through 337. Also, I know the Donor Area chapter is a very dense chapter that would be difficult for anyone to get through, and that section could easily be missed when reading through the

text. For some reason it was not listed in the Index, so it's very understandable that it was overlooked. ♦

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## **SAFE® System**

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means that for cases requiring larger graft numbers, multiple sessions will be required. The price per graft for FUE cases is typically 50% to 100% higher than grafts produced with microscopic dissection. And finally, the patient should know that state-of-the-art strip excision typically results in minimal scarring if performed properly.

The SAFE System® for FUE compares favorably to traditional microscopic dissection in several respects. Transection rates are comparable to, or less than, microscopic dissection in most patients, and the rates are significantly less than traditional FUE. Graft production rates with this new technique are also significantly higher than traditional FUE methodology. This new technique has the capability to expand patient candidacy for FUE to virtually 100% of patients, including African Americans and those with gray hair.

*\*Disclosure: Owner of patent and trademark for the device and system described.*

Because of these enhancements to traditional FUE, the advantages to be gained by FUE may become available to the average practitioner and potentially more patients. ♦

## **REFERENCE**

1. Rassman W.R., Bernstein R.M., McClellan R., Jones R., Worton E., Uyttendaele H. Follicular Unit Extraction: Minimally Invasive Surgery for Hair Transplantation. *Dermatologic Surgery* 2002; 28: 720–728.