The SAFE System®: New Instrumentation and Methodology to Improve Follicular Unit Extraction (FUE)

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The technique of follicular unit extraction (FUE) and the FOX® procedure and test as described by Drs. Rassman et al. 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® negative (not candidates for FUE) due to high rates of follicle damage. Even for FOX® 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, continued on page 163
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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 dissec-
tion 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 dissec-
tion 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 1 mm
punch (Milex, for example) inserted to
a depth of approximately 0.3 to
0.5 mm. The second step is the inser-
tion of a blunt punch to a depth of 4–
5 mm. 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
dollicle 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 Milex 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
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 Ameri-
can, 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 instrumenta-
tion to address some inherent prob-
lems associated with FUE that have
resulted in a reduction of the transec-
tion rate, an increase in the speed of
extraction, and an expansion of patient
candidacy. The current plan for instru-
mentation 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 instru-
ment with thumb actuation of the
device. Work has begun on a mechan-
ized 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 transec-
tion 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,
and 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 substan-
tially; 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 cer-
tainly not less. However, its diffuse
nature may confer a decrease in detect-
ability 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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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.

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


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