Current Practices and Controversies in Cosmetic Hair Restoration

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BACKGROUND Hair restoration surgery has evolved into a scientifically based cosmetic surgical discipline over the last half century. A recent hair surgical technique to evolve, Follicular Unit Extraction (FUE), is a donor harvesting technique removing single "follicular units "one unit at a time" with a small round punch.

OBJECTIVE Describe the origins, current practices and controversies in hair restoration surgery; and challenges in adopting donor harvesting with the FUE technique.

MATERIALS AND METHODS The medical literature is reviewed in regards to the improvements in surgical hair restoration techniques. Publicly available direct marketing campaigns, promotional material, and Internet advertising of certain FUE devices are reviewed.

RESULTS After two decades of technique improvement cosmetic outcomes with hair restoration surgery are observed with FUE and Follicular Unit Transplantation (FUT) techniques. Although FUT remains the gold standard in hair restoration surgery, FUE has clinically demonstrated comparable patient outcomes and satisfaction. Certain FUE device manufacturers market the illegal concept of expanding the hair technicians role hair restoration surgery.

CONCLUSION FUE is a complementary and satisfactory donor harvesting method to FUT. The evolving trend for new or inexperienced surgeons to delegate partial or total surgical care and clinical oversight to non-licensed is discussed.

The author has indicated no significant interest with commercial supporters.

A Brief Historical Overview

Hair transplantation was first recognized in the 19th century with the surgical use of scalp flaps for male pattern balding. Japanese physicians described modern hair transplantation with intact hair follicles to repair scarred scalps, eyelashes, and eyebrows during the 1930s and World War II. Twenty years later, the science of hair transplantation was advanced with Orentreich's donor dominance theory, which stated that transplanted hair in the new recipient site expresses characteristics similar to those of the donor hair follicles original growth characteristics.

Carlos Uebel in Brazil subsequently furthered modern hair transplant surgery for male pattern baldness in the late 20th century by advocating excision of a linear donor strip with subsequent creation and implantation of follicular grafts containing three to four hairs into surgically created incisions in the scalp. 4 In 1994, Limmer 5 recognized that natural follicular groupings of hair follicles consistently produced predictable cosmetic and natural-appearing outcomes. He described single-strip harvesting using stereomicroscopic dissection of individual follicular units, known today as follicular unit transplantation (FUT) or the strip procedure. Bernstein and Rassman^{6,7} contributed to the refinement of the FUT technique exclusively using follicular units as the only element in hair transplantation. In 1994, Unger advanced Orentreich's donor dominance principle and knowledge of the limitations of the

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donor harvesting site by delineating the "safe" donor area (SDA).8

Numerous clinical and scientific contributions to hair transplant surgery are beyond the scope of this paper. Nonetheless, the medical literature reveals ample science-based evidence of the efficacy and reliable clinical outcomes of hair restoration surgery. Hair surgery techniques⁹ to redistribute hair to areas of alopecia include scalp reduction surgery; scalp and rotation flaps, advancement flaps, and free flaps; FUT by strip harvesting (FU); and FUT by follicular unit extraction (FUE).

In contrast to FUT, FUE is a method of obtaining individual follicular units from the donor harvesting site (body or scalp) one graft at a time using sharp circular punches. Punch hair grafting could be considered the forerunner of FUE, and Okuda first pioneered it in Japan before World War II. 10 In 1939, he published a seminal paper 11 on hair transplantation using self-made sharp circular punches with varying diameters from 1 to 4 mm. He preferred larger-caliber punches and believed that optimal punch size was 2-4 mm in diameter because such punches "collected many intact hairs." He found that the 1-mm punch could remove a cylinder of scalp containing two to three hairs, but the transection rate was unacceptably high, and he later abandoned the use of smaller-diameter punches.

In Western countries, mainly because of the original work published by Orentreich on donor dominance, the use of 4-mm punches for hair restoration surgery was a popular procedure in the 1970s and 1980s, 12 but the larger-diameter punches created the distinctive unnatural "doll" look or "plugs," and the technique was eventually discarded in favor of donor strip harvesting in the 1990s. Woods is widely known as the first surgeon to successfully harvest single follicular units using smaller circular punches (1 mm) in 1995, with an acceptable aesthetic appearance and low transection rate. He originally presented his surgical technique to an Australian medical association but failed to publish a medically

recognized paper describing his methods. Rassman and Bernstein¹³ later were the first to describe FUE as a surgical technique in the medical literature.

Follicular unit extraction (FUE) was originally performed manually using hand-held punches, and surgeons still perform manual FUE primarily in countries outside the United States. The procedure, though, failed to gain universal acceptance in the hair restoration field in the 1990s because: 1) the total number of hair follicles transplanted in a single surgical session was limited; 2) the procedure took longer to perform than FUT; 3) there were unacceptable and inconsistent technical harvesting problems; 4) it was considered laborious and slow for those learning the procedure; and 5) a higher than average transection rate was experienced.

With the recent introduction to the medical market place of motorized and robotic FUE devices, a larger number of hair follicles can be successfully harvested in a single surgical session, making this technique more attractive to patients and physicians. In the last decade, a handful of hair transplant surgeons 14–16 have advanced modern-day single-follicular-unit donor harvesting with FUE using motorized and robotic devices. Their work demonstrates a large number of harvested hair follicles (>2,000 follicular units) can be obtained in a single day with excellent patient tolerance, hair regrowth, and a low follicular transection rate comparable to FUT.

FUE involves using sharp or dull punches and various diameters ranging from 0.7 to 1.3 mm. It is unlike FUT because a linear donor strip is not excised, and postoperative wound healing is quicker and less traumatic for patients. Hair surgeons who perform both surgical techniques consider FUE to be less invasive than FUT. Advancing FUE donor harvesting has generated interest by patients and hair transplant surgeons.

Experience tells us that deceptive marketing and nonscientifically validated surgical techniques and devices have blemished the hair transplantation cosmetic specialty. An example is laser hair transplantation, which was eventually discarded as nonfunctional, offering no advancement in surgical technique and achieving poor outcomes. With numerous demonstrated clinical outcomes, validation of FUE as an established surgical hair restoration procedure has almost, if not already, been realized in the hair restoration specialty. Long-term validated scientific studies are forthcoming and expected with the newer motorized and robotic devices. ¹⁸

Six well-established motorized or robotic FUE devices are available for purchase in the market place: The Safe System, using a dull punch designed by Harris; Feller and True's motorized sharp punch systems; a computerized sharp punch system designed by Cole; an updated version of the Frenchmanufactured Omni system, marketed as NeoGraft in the United States and North America; and the newest FUE automated robotic device, called Artas.

FUT vs FUE

According to the 2011 Practice Census Results¹⁹ compiled by the International Society Hair Restoration Surgery, the hair restoration procedure that hair surgeons perform most is FUT, more commonly referred to as the donor strip method. With FUT, the surgeon excises a large piece from the scalp of the

TABLE 1. Indications for and Advantages of Follicular Unit Extraction

Short hairstyle preferred
Repair of donor linear scar
Inadequate laxity of donor site for FUT Procedure
Tendency to form hypertrophic scars
Emotional anxiety with FUT procedure
Body or beard as donor site
Minimal postprocedure limitations on strenuous
exercise

Presence of limited donor tissue for FUT Limited grafts for small repairs or surgery Desire for less-invasive procedure

FUT, follicular unit transplantation.

TABLE 2. Disadvantages of Follicular Unit Extraction

Long learning curve to acquire harvesting skills
Length of surgical cases longer than FUT
Excellent hand-eye coordination required
Risk of developing repetitive motion disorder and
other musculoskeletal disorders (not with Artas)
Harvesting outside of SDA
Higher transection rate initially when learning

Higher transection rate initially when learning technique

Hair must be short (1 mm) for surgery Tendency for capping (top of graft pulled off) Hypopigmentation in donor area Lost or buried grafts

Larger volume of donor scar (although scar is not linear)

FUT, follicular unit transplantation.

back of the head using a scalpel. Thousands of naturally occurring hair follicular groups are created, commonly referred to as grafts, from this strip of excised scalp. These grafts are then implanted into small incisions that the physician makes artistically in the balding regions of the scalp. When properly made, the incisions give the relocated follicular units hair growth direction, angle, spacing, and depth so that the surgeon can sculpture and create a natural-looking transitional frontal hairline.

Surgeons interested in introducing FUE into a surgical hair practice require understanding of the use and advantages (Table 1) and disadvantages (Table 2) of this surgical technique. A more-recent consideration for cosmetic hair surgeons who perform only FUT is whether to adopt FUE into their hair restoration practice. FUE enthusiasts claim that the advantages of FUE are that it is less invasive, with no linear scar left in the donor site. FUE antagonists proclaim its potential for more total donor scar, especially with multiple procedures, higher follicular unit transection rates, risk of harvesting outside the "safe donor zone (SDA)," and extended learning curve.

For patients, other disadvantages associated with FUE is the greater expense of the procedure, that patients must cut their hair short to have a large procedure, and the procedure requires twice as long to complete the procedure as FUT. For the surgeon, the challenges are the procedure is physically demanding and the learning curve to acquire the skills necessary to perform FUE surgery is lengthy and challenging.

Acquiring FUE Skills: Difficulties Performing FUE for Hair Restoration Surgeons

Hair restoration training is traditionally taught in formal university or office-based residency and fellowship programs. For physicians beginning hair surgery who have outdated knowledge or have been trained in another specialty, it is more challenging to gain current surgical skill sets and competence. Surgical hair training in these circumstances is more similar to an apprenticeship than a formal postgraduate degree program. Acquiring new surgical skill sets occurs by completing hands-on postgraduate courses provided by private professional organizations and universities or in a mentoring relationship with an established hair surgeon.

For surgeons already proficient in hair restoration procedures who primary use FUT, the acquisition of FUE surgical skills can initially be difficult and frustrating. For the beginner, it is reasonable to expect low harvesting rates, high transection rates from injury to the follicle unit, buried grafts, tethering of grafts, long learning curve, and other untoward technical difficulties and challenges with the FUE device itself. Training can be obtained through numerous postgraduate training opportunities offered by the International Society of Hair Restoration Surgeons or individual one-on-one

| TABLE 3. Comparison of FUE and FUT | | |
|--|---------|-------|
| | FUE | FUT |
| Physical stamina | +++ | + |
| Learning curve | +++ | + |
| Hand-eye coordination | +++ | + |
| Potential for repetitive motion | | |
| Disorders | +++ | + |
| Length-time of case (hours) time start to finish-2000 grafts | 10–12 h | 5–6 h |

hands-on experience with professional colleagues already competent in FUE.

Follicular unit extraction (FUE) is not a straightforward or simple procedure to perform (Table 3). Mastering the procedure can be difficult because of the steep learning curve, requirements of physical stamina and endurance, patience, excellent hand—eye coordination, a delicate touch, excellent hand motor skills, and a substantial time commitment. The physician must also have a surgeon's diagnostic skills, aesthetic insight and sensitivity, and the expertise to deal with the rare unexpected surgical complication.

Current Controversies: Nonphysicians Performing Hair Surgery and Marketing FUE Devices

In the last few years, one manufacturer and distributor of a FUE device has openly promoted its apparatus as a "profitable turnkey" model for "new revenue stream(s)" to physician practices. In its "turnkey" model, it advocates that FUE hair surgery can be performed entirely by nonphysician hair technicians, just as nurses or physician assistants can be trained to perform cosmetic skin procedures using lasers, neuromodulators, and facial fillers. This business model is marketed and targeted to dermatologists, plastic and facial surgeons, and medical spas who are unaware of hair industry surgical standards.

The "turnkey" model raises concern for the future viability, practice, and art of hair restoration surgery. The concept of physicians with outdated, minimal, or even no knowledge of hair restoration to allow nonphysicians (hair technicians) to perform hair surgery from start to finish is unethical and potentially criminal. In the view of many surgeons in the hair restoration specialty, it is inappropriate to advocate these "new" hair technician responsibilities. These duties and skills include but are not limited to excising tissue, administering anesthesia, intraoperative management and monitoring of sedated patients, planning hairline designs, donor estimation, donor

harvesting of grafts, treatment of intraoperative complications, and creation of recipient sites.

Missing in the current dialogue about hair restoration surgery is the inconvenient truth that removing human tissue and performing hair surgery requires a physician and a surgeon's license. The novel innovation and concept of nonphysicians removing human tissue and primarily performing hair transplant surgery, in the author's opinion, is improper and illegal. It is not consistent with the standard of care in the medical community. It also potentially puts the physician and hair technician(s) in violation of state laws and subject to sanctions, malpractice insurance contract violations, license revocation, imprisonment, and fines. More importantly, omitted or forgotten in the conversation, patients are put at risk for poor outcomes. In the end, patients and the hair restoration cosmetic specialty are negatively affected by improperly and unlawfully performed hair restoration surgery.

Conclusion

Surgical hair restoration has made many gains in the last half century. Whereas in the past, plugs, scalp reductions, and flaps may have dominated the surgical discipline and resulted in consumer dissatisfaction, hair surgeons are now able to create natural fontal hairlines that are indistinguishable from native or original hairlines. Donor harvesting using FUE has made significant inroads with the automation of this surgical technique in the last several years. Studies comparing FUE with FUT are lacking, but surgeons currently practicing this technique observe clinical evidence of its success. Greater consumer acceptance of FUE and observed clinical outcomes comparable with those of FUT demonstrate the high likelihood of successful incorporation of FUE into hair restoration surgical practices.

Physician knowledge, training, and participation in the "critical to quality" steps of hair surgery is essential before implementing hair surgery in a cosmetic surgical practice. Caution is advised for physicians considering performing hair surgery with any FUE device based on a "turnkey" model. Physicians need to be aware that allowing nonphysicians to remove human tissue, monitor sedated patients, treat intraoperative complications, and exclusively perform hair transplant surgery without a physician's presence and direct oversight is unlawful and unethical. Allowing untrained or unlicensed personal or hair technicians to perform hair surgery is problematic and potentially involves state medical licensing boards initiating criminal investigations. Physicians are obligated, ethically and legally, to demonstrate satisfactory competence to the community standards of FUT or FUE surgical techniques and perform the surgical procedures themselves.

Hair transplantation using FUT or FUE requires training, cognitive and scientific knowledge, experience, and an extended learning curve. The hair surgery specialty is a rewarding, exciting segment of the cosmetic surgery practice. For physicians interested in pursuing FUE, "it is a procedure that requires dedication, devotion, enthusiasm, skills and appropriate instrumentation and technique." ¹⁰

Physicians are encouraged to contact and join the International Society of Hair Restoration Surgery (www.ishrs.org) for more information about hair restoration surgery training.

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