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Follicular Unit Extraction: Evolution of a Technology

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Abstract

Follicular Unit Extraction (FUE) hair transplantation began as a clinical offering in 2002. Since that time, this minimally invasive hair transplant surgery has grown to a market size of approximately $1.2 billion annually (48.5% of the total hair transplant business world-wide) and is continuing to grow rapidly. This growth is driven by a rapid expansion of the provider pool. New doctors, previous not in the business, have been entering the field and bringing with them, new patients from their own patient populations. The problems that they are encountering are similar to the historic challenges which are outlined in this article updated by the newer instrumentation that has evolved since 2002. Service organizations have arisen where non-professionals are performing the surgery for physicians unable to do so. This article summarizes the evolution of the FUE technology, which has not followed traditional new technological surgical procedures for training new doctors.

Physician innovation became critical in the dissemination of FUE and many doctors previously in the field have had difficulty keeping up. The idea of a minimally invasive FUE technology seems to take on a favorable 'aire' for potential patients and for those who heretofore would never have considered having a hair transplant is now coming forward. The authors believe that significant continued changes in the technology are an inevitable outcome of both the rise in the provider pool and the demand for these services. FUE has changed the labor pool as well. The authors have tried to outline the technical changes that impact both labor and the delivery of a better quality outcome provided that the doctors who rally to this opportunity get the proper training that they require. Proper training, unfortunately, seems to have taken a back seat as the financial incentives for the physician has put the cart before the horse.

Keywords: Follicular unit extraction (FUE); Minimally invasive hair transplantation; Ethics

Introduction

We are at the threshold of a revolution in the field of surgical hair restoration. This has been driven by the increasing demand for Follicular Unit Extraction (FUE), new enabling technologies, and new service organizations that can assist doctors in the surgery. These changes decrease the barrier to entry into the field that previously required surgical skills for strip removal, a real barrier to entry, so that an increasing number of physicians and most of the new physicians are now offering FUE. The world-wide market size for hair transplantation in 2014 was estimated at $2,472,332,531 (397,048 procedures, a 28% increase from 2012) of which 48.5% were FUE surgeries) [1]. There is greater awareness by the general public that permanent hair loss is something that one does not have to accept and that a 'minimally invasive hair transplant' is the way to do a hair transplant. As a result, patients who normally might not entertain having hair transplantation are now getting the procedure done and having surgery at alarmingly younger ages often driven by nefarious agendas of the doctors offering the service.

FUE seems to be driving the increase in hair transplant patients. Many of the new patients are coming from the private practices of dermatologist, cosmetic surgeons, ENT, gynecologists and even general practitioners with little or no specialty training in hair transplantation. These doctors have sought new revenue sources to expand their service offerings outside insurance driven medicine. The technology for FUE has evolved significantly since it was first introduced by this author and the quality of the service has substantially improved. The landscape of the providers are responding to the enabling technologies and new adjunctive services by non-professional technicians which give those, not skilled in the art of hair transplantation, the technical skills that otherwise would not easily be obtained.

With the field expanding so rapidly, more patients are seeking FUE surgeries and more physicians will have to develop competence in this evolving technical procedure. Of course expertise in the area of diagnosis and medical treatment must also be acquired and that will be the Achilles heel for those entering the business. Will these changes continue to induce alterations in the basic reach of the HT market? Will these new providers eventually produce the same quality results of the traditional hair transplant surgeons? Will these new providers continue to increase their market share? Will the drive to make money, dominate over the delivery of quality care? Let me outline my thoughts on the subject and provide background into the FUE technology and the unique way it has evolved.

The drive to FUE

The emergence of Follicular Unit Extraction (FUE) for hair transplant surgery has created a paradigm shift for the hair transplant industry, changing both the public's demand for what has been promoted as a minimally invasive surgery, and the need for service providers' to fulfill the demands for this process. Many patients were unwilling to undergo a hair transplant when it appeared to be an invasive surgery producing a visible linear donor scar and varying degrees of post-operative pain. Many providers wanting to enter the business could not put together the complex infrastructure to deliver a quality strip-harvesting procedure requiring teams of highly skilled nurses and/or technicians to dissect the grafts. Stylish young men wanted to wear their hair short without a visible linear scar. Doctor's applied the term 'minimally invasive' as a catch all phrase to recruit new patients and misrepresented the FUE being a 'scar-less' surgery. As a result, FUE became a good alternative to traditional strip surgery. The fast recovery time with minimal, if any, significant post-operative pain and no significant restrictions on exercise, more than offset the social problems seen with the shaved donor area which had to be managed for the first week of so after an FUE procedure was performed. A return to full normal function matched the lifestyle of many patients as they could resume their exercise program without any restrictions after the FUE surgery (Figure 1).

Figure 1: Healing wounds - seven days after follicular unit extraction surgery showing wounds which are slightly red (left) and nine months after strip surgery showing where hair accentuates a 3 mm scar from a short hair style (right).

For the physicians established in the field of strip harvesting hair transplantation, the FUE produced significant technical surgical challenges. Although FUE had not been performed routinely prior to the publication of this author's article "Follicular Unit Extraction: Minimally Invasive Surgery for Hair Transplantation" [2], the technique was quickly adopted by hair transplant surgeons across the globe. This was facilitated at the ISHRS meeting that same year, when the author handed out over 500 DVDs with a video that demonstrated 'how to perform an FUE'. What appeared to be a simple process shown in the video was quickly adopted by physicians across the globe. The FUE was inappropriately touted as a 'scar-less surgery' and heavily promoted to the public before the requisite skills were acquired.

Many doctors quickly adopted what they saw on the DVD and started offering the FUE to their patients. The result of these initial offerings produced 'Follicular Holocaust' and FUE failures were very common as transection and mishandling of the grafts dominated the physician landscape. Many of the surgeons with experience in traditional strip surgery tried to modify their techniques without appropriate reengineering of the fundamental processes that they learned with strip surgery. Special quality control systems for FUE were not developed and the doctors assumed, inappropriately, that they had succeeded in the extraction of the follicles without validating successful follicular extractions microscopically at the time they were done. With no quality control systems in place, process failures were not detected until these transplanted grafts failed to grow. In the original 2002 publication, the authors defined some of the problems they had seen over the preceding 6 year development period, but the authors suspect that few physicians initially appreciated the subtle nuances of the author's publications.

The FUE turned out to be more difficult than most doctors realized, nevertheless, many doctors were motivated to include this technology into their patient offerings. More and more patients wanted it and more and more physicians felt compelled to deliver it. It was immediately apparent that the large surgical staff required in the strip graft surgery, were unnecessary with FUE. New doctors entering the field and many of the existing hair transplant surgeons experienced a long learning curve at the expense of good quality care delivery. At one teaching seminar where James Harris, M.D. and I taught a course for FUE in 2004, one doctor who claimed skills in FUE and had a reputation of performing up to two FUE procedures/day of up to 3000 grafts each, demonstrated his skills before an audience of over 25 physicians. I took the initiative to examine the quality of this doctor's grafts under a microscope; over 90% of them were transected and would never grow.

There was a sense of urgency to solve the FUE technical problems and the individual ingenuity of doctors started to produce creative solutions. Much ad-hoc field research in each doctor's practice produced special tools to address the problems they thought were present. They produced alternative mechanical approaches for FUE and submitted multiple U.S. and foreign patent filings which exceeded medical publications. Initially, there were few insights into the mechanical, anatomic and physiologic causes of FUE failures. Experimentation was routinely performed on patients and this continued until the doctors performing the service developed the appropriate instruments and/or the requisite skills that produced the desired results; however, consistent replication of good results was not immediately apparent, since it generally it took 6-8 months to obtain graft growth, it would take a few years for doctors performing FUE, to make the appropriate adjustments to their techniques to understand their errors and get the desired results. Formal training took a few years before it became available and even today, training is very limited. Preceptor ships, the best way to master the FUE technique, were rarely available, as is the case today.

Hair transplant surgical procedures today

The donor area, a section of hair that is unaffected by genetic balding, is a segment of scalp measuring 2 ½ inches above the occipital notch (posteriorly) and extending around the head to the forward temple peaks at the hairline. This donor area is presently harvested by two techniques.

Strip surgery: Involves excising a strip of skin from the side and rear area of a scalp (in the center of the donor area, its inferior level at the occipital notch). This area is referred to as the 'sweet spot' because the hair density is highest and it is this area where the hair should last the lifetime of the patient. The surgical process itself requires some surgical skills and this often had become one of the barriers for entry into the hair transplant business. Once the strip is excised, the wound is then sutured or stapled closed. This excised strip of scalp is then moved to a dissection table where technicians cut the follicular units from the strip under stereo-microscopic dissection. The follicular units are isolated in their natural occurring groups (between 1-4 hairs each). Great care must be taken to keep the grafts moist through the entire period that the grafts are out of the body. The dissecting process is slow, tedious, exacting and labor intensive. The average cutting speed for graft dissection runs ~250 grafts/hour for a typical skilled technician. Grafts run the risk of desiccation in seconds, particularly when the grafts are exposed to air as they are moved from storage baths to the cutting area, back to the storage baths and finally into the recipient area. It is generally believed that exposure of the delicate grafts to air for as much as 10 seconds can cause death of the follicles which would not be detected until 4-7 months after the surgery). Scars may form in the donor wounds. Some of these wounds widen and become bothersome for the patients who keep their hair short. There is some post-operative discomfort for the first few days after the strip procedure is completed (Figure 2).

Figure 2: Viewing follicular units - microscopic view of the surface of a scalp showing follicular unit groupings of hairs (left) and view of cut grafts ready for implantation into the recipient area (right). Note that there is significant fat around these grafts that reflects an anatomic follicular capsule as well as a sub-follicular unit fat pad.

Follicular unit extraction (FUE): A harvesting technique which employs a hollow metal drill or punch and cores an intact follicular unit (FU) from its native donor scalp. The hair is cut to approximately 1 mm in length prior to the procedure. When extracting the graft with a hollow punch, the punch must be perfectly centered on the exiting follicular unit. The punch must be aligned within ~5 degrees of the proper angle below the epidermis which cannot be seen. The difference between the angle of the emergent hairs and the actual follicular units in the dermis is in the range of 15-25 degrees. The actual working angle can be confirmed in the first few FUE extractions. The angular offset varies at different parts of the scalp, so checking the grafts periodically is critical as the extraction process continues. Constant examination of the extracted grafts requires quality control processes to be implemented during the surgical procedure. Every graft extracted must be examined for integrity and recorded accordingly in the surgical record.

The punch is then advanced to a depth of approximately 3-4 mm from the skin level. Stopping the advance at between 3-4 mm is critical when sharp rotating punches are used as the follicles below this level start to splay apart. To remove the grafts from the scalp, constant gentle traction must be applied to the follicular unit at the skin level. Manual forceps are often used for this process but suction can also be used. The traction may cause the follicular unit still tethered at the base to break in half as traction is applied (capping).

Once the grafts are successfully removed, they are immediately placed in a liquid bath. One commercial system combines the coring with suction which draws the grafts directly into a fluid bath. The grafts are sorted by the number of hairs in each graft and by their quality, recorded as such and then placed in different holding 'buckets' sorted by the number of hairs per graft and held until implanted into a prepared recipient area. Graft placement can be performed with manual forceps, most often through pre-made sites, but at times, percutaneously with commercial implanters.

Compared to FUT, the FUE technique eliminates the need to excise a donor strip and can be performed by one or two technicians assisting the FUE surgeon. The strip procedure requires that the skin defect where the strip was removed to be closed. The removal of the individual follicular unit grafts from the harvested tissue is a manual, labor intensive processes that can require many staff members when large hair transplant sessions are performed.

History

Follicular Unit Extraction dates back to the Japanese literature. Okuda [3] reported that a follicle could be cored and plucked out of the donor area and freed at its upper attachment. Considering the date of the publication (1939), the war years limited the spread of the technology. It was ingenious that Okuda identified that only the upper third of the hair shaft needed to be cored however, he experienced failures on pulling some of the hair grafts from their original location. He felt it was therefore important to have the deeper parts of the hair follicle "nipped", indicating that he didn't realize that it was possible to pluck the hair completely out of the donor area in patients.

Pascal Boudjema pioneered mechanized punch grafting in the late 1980s, eventually coming up with a commercial system he called the Calvitron® and received US and world-wide patents on his instrument [4].

In 1996, this author started to perform follicular unit extraction (FUE) as a clinical research project and eventually realized that the various mechanical systems he developed did not produce consistently good follicular units extractions, in every patient, as traction to remove the grafts was applied. The variable results were not related to any of the any particular mechanical systems the authors had developed. The author completed a number of patients with FUE in the late 1990's. In 2002, Rassman et al., reported that there were histologic differences between the follicular units that could be plucked out easily and those that could not [2].

The authors identified different histologic elements that seemed to correlate with difficulty in 'plucking out follicular units' which included the presence of a thicker dermal sheath and a lesser amount of elastin content within the dermal sheath that possibly related to the resistance to coring of the follicular unit that was observed clinically. Those patients who were difficult to core were labeled FOX negative (FOX-) while those who were easy to core were labeled FOX positive (FOX+) and there were many patients that were clearly neither FOX+ of FOX-, just something in between the two. The authors suggested that each patient could have a set of test grafts to determine the ease of plucking the grafts. If there was to be a perfect design for a mechanical system, it would have to produce a consistent quality extracted graft independent upon the FOX status of the patient. The challenge quickly became apparent. In 2003, Rassman and Pak designed and patented a robotic system for automatic siting and extraction of the follicular unit. The patent was granted in 2006 [5] and may have addressed most, but not all, of the FOX- patients. This design was incorporated into today's ARTAS® Robotic System.

Follicular unit anatomy as it relates to the FUE process

The Follicular Unit (FU) is a complete organ system of ectodermal origin from epidermal and mesenchimal cells and contains glandular

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tissue, nerves, muscles, lymphatics and blood vessels. There are stem cells along the shafts of the hair follicles in the FU, with a heavy concentration at the bulb and near the attachment of the erector pili muscle and immediately below the sebaceous gland. The gross anatomy of a FU is not cylindrical in its normal undisturbed state, *in vivo*. The hairs of the FU grow, on average, in groups of one, two, three, and four hairs each and exit at the skin surface in close proximity to one another, often from what appears to be a single pore. The hairs of the FU diverge as they extend into the deeper dermis. This divergence varies between people and races. Harvesting of individual hair follicular units with various extraction instrument have problems which are addressed by many instruments that are used to align hair follicles within an FU so that the FU can be precisely extracted, one FU at a time with minimal damage. As previously discussed, the shaft angle of the upper 1/3rd of the FU does not match the angle of the hair exiting the skin, so adjustments have to be made to accommodate the varying angle from the hairs' below the skin to the hairs' exit angle. The coring process requires that the operator has good eyesight and proper magnification, but proper instrument alignment alone did not solve all of the problems encountered with FUE in the hands of many surgeons. The ARTAS robot seems to have solved many of these problems for the surgeon (Figure 3).

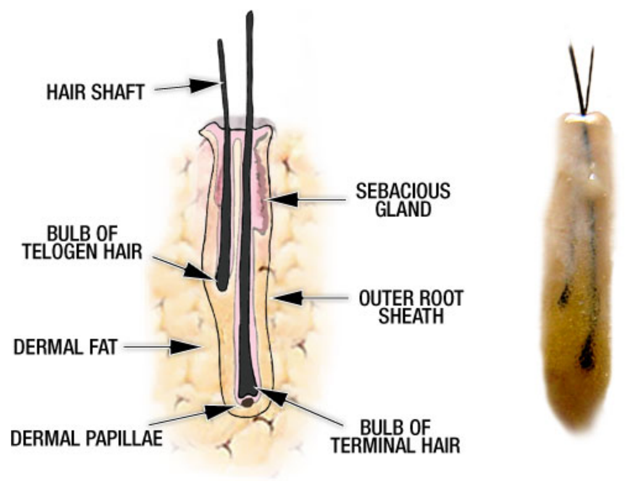

Figure 3: Follicular unit anatomy - graphic representation on left, actual, photo on right.

The Caucasian human scalp contains approximately 100,000 hairs in ~50,000 FUs (averaging 2 hairs/FU), the Asian about 80,000 hairs in about 50,000 FUs (averaging 1.6 hairs per FU). A 2.5–3 inch zone (as measured immediately superior to the occipital protuberance and wrapping around the side and back of the head to the frontal temple peaks) contains, on average, 10,000 follicular units in the Caucasian, which we in the industry call the permanent donor zone of hair (donor area). As documented by Orientrich the 1960s [5], the surgeon should be restricted to utilizing only this hair for donor hair as it is the only hair that is rarely involved in the typical genetic balding patterns of the adult male. There is some controversy on the size of this 'donor' area as some surgeons would like to define the area larger for economic reasons; however, when one observes many Class 7 patients over 50, years of all the measurements defined by Orientrich does measure 2 ½ inches superiorly above the occipital notch.

FUE surgeons, who adhere to harvesting only the donor area for FUE, may harvest as much as half of the 2 haired follicular units that were present before surgery in that zone. Assuming 10,000 FUs exist in the donor area in the Caucasian example, the maximal targetable harvest limit should be ~5,000 FUs. As the perimeter of this zone and the very frontal area should not be harvested, the actual numbers of harvestable FUs is probably less, unless more that 50% of the FUs are harvested. Harvesting above 50% of the FUs runs the risk of transplanting hairs that may not last the lifetime of the patient. It also runs the risk of making the FUE wounds noticeable if the donor hair should disappear as the person ages. In the Asian patient with an average of 1.6 hairs/FU, the number of FUs harvested with higher hair counts will be significantly less than the average so that the yield of hair (not FUs) in Asians is reflected by a lower FU count.

FUE produces punctate donor scars. These scars become visible over time, particularly if they extend beyond the donor area and measure approximately 1 mm in diameter. If every 4th follicular unit is harvested on a first pass surgery, this means that 2,500 grafts may be a reasonable limit for the first FUE session. A second harvest might reduce the available grafts as choice areas may have been harvested on the first pass and scarring almost certainly impacts the choice of FUE sites on a second pass surgery. Scarring below the skin from a first surgery increases the challenge of removing successful FU with subsequent extractions. Asians have a lower hair density (20% lower) when compared to Caucasians which means that an Asian donor area has ~8,000 FUs (not 10,000 FUs). The follicular units of a Caucasians average ~2 hairs per follicular unit while the Asian average 1.6 hairs per follicular unit implying that Asians who receive FUE will receive a lower hair count per graft from the same size donor area. This makes FUE grafting for Asians a more challenging procedure, especially when a second harvesting procedure is needed. FUE performed in excess of 5,000 Follicular Units, depletes the Caucasian donor area significantly. Imagine what it would do to a typical Asian when 5000 Follicular Units are excised, reflecting 2/3 of the permanent hair removed in a session of that size. This will almost certainly create a see-through donor area in most Asians who do not have coarse hair.

Changes in the practice of hair restoration

The changes that have occurred in the field of hair transplantation span the past 2 decades and they have been radical from both the physicians and the patient's point of view. Prior to the early 1990's, large grafts were used which created a classic 'plugy' look. In the early 1990's, small grafts in multiple small sessions became the general standard of care. Some doctors' hesitated to enter the field prior to the mid-1990s when they could not accept the large graft standard of care that was present at that time. These standards did change with advent of small grafts (Follicular Units) which were used in large sessions and appeared in publications from as early as 1993 [6-9].

The transition to small grafts in large quantities required re-engineering the surgical staff and the techniques that were used to manage the grafts. Longer surgeries, larger staffs and changes in the physical facilities were required for these large sessions of small grafts. With graft cutting speeds averaging 250 grafts per hour in reasonably experienced hands, a 3,000 graft strip surgery would take a staff of 4 cutting technicians, 3 hours to complete. The placing time for such a 3,000 graft surgery could also be clocked at 250 grafts per hour, but rarely would more than two technicians have the room to perform graft placing, by calculation another 6 hours of surgery added to the surgery. Without lunch breaks or rest periods, and assuming that all the staff were equally trained and skilled, the potential surgeries of 3,000 grafts would exceed 9 hours. The challenges of graft preservation for long periods of time as well as the vulnerability of these small grafts to air exposure which often killed the grafts before they were placed into the scalp were, initially, an unrecognized problem. Grafts out of the body for 9+ hours, had reduced survivals. As graft growth generally took 7-8 months, the re-engineering to manage these problems was slowly refined over years by those who were willing to 'take-on' these large sessions of small grafts. The evolution to large graft sessions via the strip method of harvesting took more than a decade. Public demand drove the process so it became a matter to adapt or quit. Some doctors just quit.

For the following 7-8 years after the doctors started to adapt to Follicular Units (FUs) in larger sessions, another technology emerged from this author, the technique of Follicular Unit Extraction. This again, required re-engineering the surgical staff and the techniques that were used. Different tools were required, special skills not easily acquired were needed and changes in the facilities were required again. The challenges were distinctly different than the challenges for strip surgeries with grafts in larger sessions and FUE required, again, re-engineering every element of the process, including physician retraining. Again, as before, this new FUE technology was driven by public demand and again, the doctors were left with the choice 'adapt or quit'.

The excision of a donor strip occurs in the center of the permanent zone of hair in the back and around the sides of the head. Repeated procedures rework this 'sweet spot' where the best and most permanent hair resides and the scars can be removed. Strips are never extended outside this 'sweet spot'. With FUE however, one removes only a small percentage of follicular units from the entire donor area and as only a subset of FUs can be removed, the donor area may not contain enough FUs to meet the demand of the bald area being transplanted when the extractions are distributed throughout the donor area. Some strong proponents of FUE are attempting to change the basic tenant that donor FUs can only be taken from the permanent zone. The justification for this amongst these proponents is that the permanent zone (what is left in the rim of hair of a Class 7 balding pattern patient) is only present in 7% of men so other balding men, who do not have a Class 7 balding pattern, have a different rule that can be applied. The next step in this new logic is that the FUs outside this zone can be harvested if the surgeon determines that the patient will never develop a Class 7 pattern of balding. As such, the donor area increases to the hairs seen in the Class 6 pattern patient by up to 50% of potentially harvestable FUs. This is presently an ongoing controversy that may never be resolved outside the courts when errors on patient selection occur and punctate scars start showing on patients who had their harvested hair outside the permanent zone as hair is lost from progressive balding that occurs in all men with genetic balding. The hard facts are that as patient's age, a doctor can't be certain to what degree of balding age will bring. Unfortunately, the motive to change the size of the predictable permanent zone to reflect the number of grafts charged to the patient alters the focus from good clinical science to physician greed.

These differences drive the market and they include (Table 1).

Strip Surgery may produce a visible linear scar	FUE Surgery will produce punctate scars
Strip Surgery (produce some post op pain)	FUE Surgery (minimal post op pain)
Strip Surgery do not shave the entire donor area	FUE has extensive shaving of donor area
Strip Surgery restricts some exercises a few weeks	FUE limitations are to just a few days
Strip Surgery wounds co-apt and take time to heal	FUE has only punctate wounds, heal fast
Strip Surgery produces a predictable graft quality	FUE doesn't produce consistent graft quality

Table 1: Real differences between patient experiences do occur when strip surgeries are compared with FUE surgeries.

For the person who is very young and may want to cut their hair very short, a linear scar, if it is of any significant width, will limit the patient's hair styling to a possibly longer hair length. For the professional athlete or very active exerciser, the FUE offers a fast, limit-free experience on activities in less than a week after the surgery. For the young person who does not have a significant balding pattern and can manage a shaved back of the head with a short hair style temporarily, the FUE is a reasonable choice. For the very bald patient in the Class 6 or 7 pattern of balding, the strip is a more efficient method of harvesting grafts allowing larger single procedures that would cover a greater balding area.

Follicular Unit Extraction: Anatomic and Mechanical Evolution of a Technology, Part 2

Follicular Unit Extraction (FUE) is a rapidly growing surgical procedure that, from its modern incarnation in 2002, had produced significant challenges for the doctors offering this technology to patients. The use of single, ~1 mm punch harvesting for follicular units (FUs) was presented by this author at the International Society for Hair Restoration Surgeon's meeting in 2002 and through a formal oral presentation. At the time of the oral presentation, DVDs were made available to everyone at the meeting. This inspired a 'see-one, do-one' mentality and doctors from across the globe who adopted the technique after viewing the DVD without any training and without understanding the nuances which was published in a detailed publication by this author at about the same time [2] embarked on aggressive marketing campaigns. Many doctors' immediately started to perform the FUE procedure. Most who tried produced Follicular Holocaust.

The challenges in learning the FUE techniques were many. Doctors wrongfully assumed that when a single punch cored a grafts, that all they had to do was implant the yield of the coring. With a 5-7 month initial growth period for most transplanted hair grafts, failures would only become apparent after the graft growth cycle would begin. Failure of the grafts to grow became the first realization that the doctor did not control the process. Re-engineering the surgical process became a priority as a result of the failures experienced by the many doctors attempting this new technique; however, like all new technologies, the absence of available training and the long learning curve stimulated doctors to 'invent' technologies on the fly to solve what was perceived to be simply, a mechanical 'instrument' problem. Many patients experienced failures while the doctors learned to adapt their techniques, one step and one patient at a time. Unlike other new technologies in medicine and surgery such as surgical staples and endoscopy where large companies became involved in the education and the dissemination of the technology, no such evolution occurred in the field of FUE hair transplantation. Doctors were left to figure out solutions to the problems of FUE failures on their own. Why was this technology so different than other hair transplant harvesting techniques? Did the physician have to develop new skills? If so, where would these new surgeons acquire the needed skills? Could they learn these skills on their own by repeated practice and accept initial poor results and a slow incremental improvement in their techniques?

The focus of Part 2 of this publication is to review the mechanical, anatomic, ergonomic and procedural challenges that had to be resolved in the evolving field of Follicular Unit Extraction (FUE). What is particularly significant is that the innovations by each doctor were not obvious in the hair transplant community. Instead of medical publication channels that are written to educate our colleagues; the first innovations were taken to the US and European patent offices where patent office submissions preceded medical publications. Secrecy, required in the initial phase of the patent process, was strictly adhered to until patent filings were complete. Rulings and/or issuances eventually emerged from the patent offices. Many doctors, feeling hubris in their visions of making money to become a successful FUE instrument entrepreneur, schemed to restrict their inventions. In-fighting between these physician inventors was common. This patent process in the United Sates usually took between 2-9 years, slowing down the propagation of the newer technologies and the newest insights in FUE for the hair transplant community. Profit through patent monopoly drove the process, not education of the innovator's peers for these wound-be inventors. As not all surgeons were innovators/inventors, the majority of doctors, continued on the laborious one patient at a time, one extraction at a time and one new instrument at a time - learning process. This slowed the emergence of significant competency in the field leaving too many damaged patients in the surgeon's wake. The authors will attempt to define the anatomic, ergonomic and mechanical challenges along with the innovations created by new surgeons who would eventually expand the FUE knowledgebase. Nowhere, to the authors' knowledge, has this information been fully documented prior to the publication of a thorough text book by Lam last year [10].

FUE challenges: A summary of the problems encountered with FUE include

Angle of attack for the FUE punch: The true angle of the Follicular Unit (FU) above the epidermis where it can be visualized when compared to the angle the hair as it exists below the skin, must be estimated. The correct angle must be calculated by determining the offset measured in each area of the scalp (it varies by area) and estimated as each follicular unit is extracted with good quality control systems in place for examining the results of each extraction. The variance angle of the hair below the skin when compared to the hairs exit angle above the skin ranges between 15-35%.

Vision: The human eye has limitations with visual accommodation as a person ages (around 44 years of age). The use of corrected optics is therefore critical as the 1mm punch must be aligned with the exiting hair. The exiting hair must be dead center in this punch alignment. The angular offset must be tested and estimated and re-evaluated constantly.

Eye fatigue: Eye fatigue eventually sets in, worse so for older operators. This fatigue factor limits the time the surgeon can focus on the FUE process. As the FUE process may take hours, eye fatigue plays a role in accuracy of the extractions. The longer the process takes, the more graft transection becomes a problem. The coring of the grafts, therefore, deteriorate over time.

Ergonomics: With lengthy FUE sessions, the surgeon frequently experiences back and neck problems. Adjustments of the patient's position at the onset of the FUE process may solve some of these problems. Placing the patient face down on the operating table allows the surgeon more freedom and it is easier to establish a correct and a consistent angle of attack. Well timed breaks are needed for the surgeon to keep performing efficient FUE extractions in a timely manner. An FUE extraction for 1000 FUE grafts, depending upon the skill and experience of the surgeon, can range between 30 minutes and 4 hours.

The challenge of hair follicle splay: Hairs in the follicular unit diverge as the hair follicles extend beyond 3m from the epidermal border. With all existing rigid extraction instruments, the splay produces potential for damage to the individual hairs. As all of the instruments used to core these follicular units are rigid and sized to surround the upper part of the follicular unit at its narrowest point, cutting the splayed follicles below that point easily occurs as the instrument advances deeper into the dermis. In the upper 1/3rd of the FU, the hairs are tightly bundle. For the upper 1/3rd, the prediction of the angular offset must be accurate within ~5- degrees of what is below the skin. All sharp instruments that are used for this purpose run the risk of transecting, not only the proximal upper 1/3rd of the follicular unit when the angle is off by more than 5 degrees, but more easily when a sharp instrument encounters the splayed hair within the lower 2/3rds of the FU. Sharp instruments increase the risk of hair shaft transection especially when rotation of the instrument is employed.

Anatomic anchoring: Follicular Units are tightly surrounded by a lattice work of collagen fibrils securing their position in the dermis. The hair follicles are also incorporated in a capsule in the dermis which is also connected to stroma (collagen fibrils) which supports the follicular capsule in place. This fibrous framework is made up of elastin and non-elastin collagen and the proportion of these two different types of collagen varies from person to person [2]. Some patients have collagen fibrils that are more elastic than others, while others have more inelastic fibril connections to the dermis. These inherent characteristics of the FU and its related collagen within the dermis impact the ability to 'cut-through'- the lattice of connective tissue and also to 'pluck' out the FU after it is cored to a depth of 3-4 mm. As the collagen make-up of any particular patient is unique for that patient, the FUE process also becomes variable and patient dependent. Since all mechanical instruments interact with the supporting structures of the follicular unit where it can't be visualized, they either tear or cut these connections during the extraction process. Every FU must be plucked out after it is cored from the surrounding dermis. As the grafts are anchored in the surrounding dermis, the FU is torn from its dermal position as pucking occurs.

Instrument variations – sharp vs. dull: Some doctors believe that blunt instruments may 'gather' the hair follicles as they are advanced deeper into the dermal fat beyond the 3-4 mm level where the splay begins but dull instruments cannot easily penetrate the epidermis. Many other surgeons use rotating drills that cut through the epidermis as they are advanced into the upper 3-4 mm within the dermis to the point where hair splay occurs. If these sharp instruments are advanced deeper than the upper 3-4 mm of dermis, the spayed follicles could be transected. Once the active coring is complete, the lower part of the FU is still attached to the surrounding dermis in its distal and inferior half. The extraction is performed at this point as the skin of the FU is then grasped by manual forceps or pulled upon by suction, plucking it out at the skin level. In people with high elastin content in their collagen fibrils, the cutting or breaking of these elastic fibrils occurs easily when it is pulled out. In many patients, even under the best of conditions (with the best technologies available), the grafts may be avulsed when traction is applied inappropriately. The tearing that occurs may leave part of the hair follicle in the patient's deeper dermis resulting in an avulsed upper partial graft with no lower half (a "capped" graft) and capped grafts can form foreign body reactions and may lead to localized infections. Patients with more inelastic fibril connections are more likely to have avulsed grafts when traction is applied. Remnants of the capsule can be left behind when inelastic collagen is present, even if the hairs within the graft are successfully removed.

Ethnic difference in patients: Africans are known to have unusually curly/kinky hair. In the coarse-haired African patient (as opposed to the finer-hair African patient, or Caucasian or Asian patient), the follicular unit hairs frequently have a very strong character below the skin and are not straight, but rather form a 'cork screw' shape when removed from their *in-vivo* location. These individuals may have many inelastic fibril connections (this has not been studied) and the tendency to avulse the grafts when traction is applied is greater than in other ethnic groups. Because of the 'cork-screw' shape of the follicles themselves, when the lattice of connective tissue is transected as the punch is advanced, the 'cork-screw' shape is probably intensified making it more difficult to fit the hair shafts within the advancing straight punch. This adds to an increasing risk of cutting the hair shafts during the early part of the extraction process in the upper third of the FU in these individuals. The hair splay in these patients in the distal 2/3rds is more irregularly than Caucasian and Asian patient within the follicular units and when the collagen fibrils are cut, the hair's' cork screw' shape most likely increases. This difference, in conjunction with the use of a rigid mechanical punch, makes consistent extractions more difficult in people with kinky African hair. When these follicular units are removed from their *in-vivo* state, the strong character of the hair shafts within the follicular unit often distorts the follicular unit visibly outside the body. Transection of the hairs in such patients is common and may not be easily overcome by traditional approaches to FUE.

Visualizing the follicular units: It is very difficult to visualize hairs that measures 40-70 microns with the naked eye. Younger surgeons have less problems visualization these hairs than older surgeons but visualization of the hairs and aligning it with a ~1 mm punch increases the challenge as the surgeon must manage a three dimensional process at this micro-level. There are two approaches to visualize and align the follicular units appropriately:

Seeing the exiting hairs with the naked eye: Either with or without magnification, and aligning the instrument manually at an appropriately adjusted angle that anticipates the change in the direction of the follicular unit below the skin is a problem for most doctors. Until this challenge can be overcome, the FU's are prone to follicular damage. The punch must be placed where the exited hair can be placed central in the punch and with the angular offset estimated between the exit angle of the hair above the skin and the angle of the FU below the skin. Once this angle is tested and known, the punch is then advanced downward through the epidermis and into the dermis. With a rigid sharp punch, angulation errors of 5% or more can transect the follicular unit in the first 3-4 mm, so proper alignment and angulation becomes both a science and an art form with a long learning curve for the surgeon. Add to this a 'feel' that the surgeon must develop as the punch is advanced and cuts the lattice of connection fibrils that secure the FU in place, particularly when advancing the punch in the first 3-4 mm of the FU. This becomes a skill that that takes tens of thousands of FUE attempts to master. Many operators learn to 'feel' the punch as it is pushed into the dermis and as it slides down the hair shafts. The feel, unfortunately, becomes instrument specific so the ability of the surgeon to change technology is not easy.

An optical system: Such as one used in the ARTAS® robotic system assures the alignment of the advancing punch with the upper 3-4 mm of the FU. This allows controlled alignment of the hollow punch as the operator estimates the angular offset between hair exiting the skin and the adjusted dermal angle of the upper part of the hair shaft below the skin. This offset is then programed into the robotic software which automatically aligns the sub-dermal hairs according to pre-programmed offset formulas. The internal optical system performs the alignment automatically, maps out the distribution and angle of the FUs. A two-punch system (a sharp and a dull punch sequentially entering the skin) is deplayed as each punch is advanced to a predetermined depth that can be adjusted in real-time, as the clinical situation demands. Periodic assessment to correct the angle of attack is necessary as extracted grafts must be examined routinely throughout the entire surgery.

Mechanical Forces

Mechanical forces are exerted throughout the FUE process

The epidermis is tough and often requires the use of a sharp (without or without rotation) cutting instrument to cut through this 0.5 mm thick surface. The sharper the punch, the less is the required force at the epidermal level. The mechanical dynamics of serrated punches are different as they require significantly more mechanical force to penetrate the skin but they do not require a very sharp edge to them, reducing the transection of the hair follicles in the dermis when the punch is advanced below the first 3-4 mm depth of the FU (Figure 4).

Skin stabilization

All of the forces applied at the epidermal level produce some degree of skin depression and trauma to the epidermis, the follicular capsule or the individual hairs within the capsule and this skin distoration impacts the position of the upper 1/3rd of the FU, thereby impacting the 'angle of attack' for the stiff punch. The same distortion is seen when traction is applied during the manual extraction process. Skin stabilization can be accomplished in three ways: (1) with the use of wide-spread dermal tumescence (most common modality used), (2) with the use of sub dermal tumescence (confined to one follicular unit with injection of small amount of fluid directly into or around the FU capsule) and (3) with a mechanical traction apparatus that spreads and tightens the skin (critical for use in the ARTAS robot). Without skin stabilization, the ability to control the dynamics between the extraction instrument and the follicular unit will be impaired making a consistent angle of attack for the advancing punch difficult.

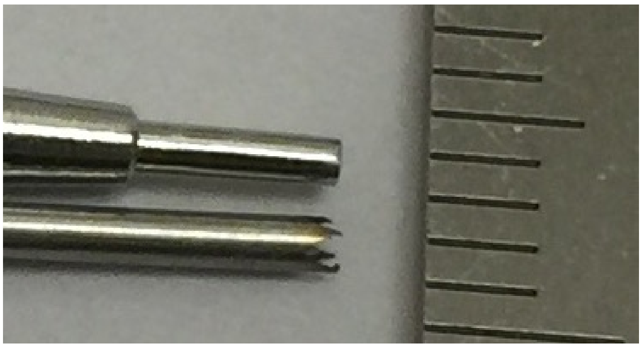

Figure 4: Two different types of surgical punches, one sharp (above) can be used with or without rotation and one serrated (mm scale).

Serrated punches and vibration

With serrated punches, resistance to the passage of the mechanical instrument is overcome by the application of a greater degree of force as the pointed part of the serrations more easily penetrate the skin. Greater direct forces are required in such instruments which do not employ rotation or vibration similar to what is seen when standard commercial punches are used for skin biopsies. A 'feel' is developed by skilled operators which sense the resistance as the punch is advanced through the epidermis and into the dermis with all mechanical punches. Serrated punches can be advanced deeper into the dermis than rotating sharp punches as it seems that these serrated punches allow the hairs to 'gather' inside the hollow punch. Sansui Umar developed vibration and an ultrasonic component to the punch to reduce the resistance as the punch is advanced and also includes a saline drip lubricating mechanism to further reduce the resistance seen [11].

Torque

Is a form of twisting force exerted by rotation. Twisting can tear tissue. Slow punch rotation may not overcome the initial inertia of the surrounding tissues and may produce more tearing. Dull rotating instruments create more torque. Very sharp instruments offset this problem. In some of the mechanical applications, high speed drills are used which minimize the initial twisting inertial forces on the FU and reduce the force required to advance the punch. With a rotating sharp punch, inaccurately assessing the correct angle below the skin increases the risk of graft transection.

Methods to Address Mechanical Factors Include

(i) Use of sharp needle dissections aligned along the estimated direction of the shafts below the skin of the hair follicles, can partly cut through the epidermis along with the fibrous attachments of the follicular units prior to an extraction, especially when used in conjunction with traction. This is a tedious process as the needles are utilized in parallel to the follicles in multiple passes and the risk of direct FU damage is statistically low. With this technique, traction on the grafts is applied after repeated needle dissections. In patients with follicular units that have a high elastin collagen, this technique reportedly works well, but Alan Feller (inventor of this technique) reports that he abandons the attempted FUE in patients who apparently have low elastin contents in the fibrous stroma around the FU and resorts to a standard strip harvest when his FUE attempt fails [12].

(ii) Vibrating punches was defined by Sansui Umar. It utilized vibrating punches and works similar to a dull punch, possibly requiring more force as the coring occurs. He utilizes lubrication as well to reduce the required force [11].

(iii) Use of a serrated punch (non-rotating) with sub-tumescence seems to overcome many of the problems for most collagen types as the sub-dermal fluid works its way into and around the follicular capsule helping break up the fibrous connections as the stiffened follicular capsule guides the punch as it is advanced into the dermis [12].

(iv) Use of dull, rotating punches below the epidermis which 'gathers' the splayed hair follicles as they are advanced with minimal cutting of the spayed follicles [13]. The epidermis in this situation is scored with a sharp punch and the rotating dull punch is used below the epidermis to cut/tear through the dermis. This is a two-step process performed in sequence [9,10] and is incorporated in the ARTAS robot.

(v) Use of high speed rotation with a sharp drill and a depth limiter. Without the depth limiter, the sharp punch will cut the splayed follicles as it is advanced below the 3-4 mm depth of the upper part of the FU [14].

Failures, Problems and Complications (recognized and unrecognized)

Damage to the FU

Probably the most significant short-term failure with FUE is seen with an inability to align the grafts as the punch advances at the correct angle. Although this problem is easily recognized with good quality control systems in place, many doctors do not routinely examine their FUE extraction quality during the surgery. Microscopic examination of each extracted graft will identify every anatomic element of the follicular unit and if these elements are damaged, the doctor needs to know this to modify, in real-time, how the process is being performed. Manual FUE requires a special skill that takes time to learn and where a three-day course without considerable hands on training does not impart the requisite skills needed to become competent in delivering manual FUE skills. Many doctors, even those who have taken courses, use their patients to learn the FUE technique, often at great cost to the patients in terms of outcomes. Doctors who apply good quality control systems to analyze each extracted graft will know their success/failure in achieving good, non-transected, non-damaged FU extracted grafts; however such quality control systems are often bypassed by many surgeons. With a 5-7 months growth cycle for the average hair transplanted graft, feedback loops for surgeons may requires years before they can develop adequate skills and build adequate quality control systems for this process.

Desiccation

Is a problem as there are more steps in moving grafts from (a) the scalp, (b) to the sorting area, (c) to the holding solution and (d) eventually to the person who implants the grafts manually or with implanters, and (e) finally placing them into the recipient area. Great care must be taken to minimize these 'out-of-solution' periods to avoid graft death from desiccation.

What are quality grafts

FUE graft quality is an area poorly understood. We know, for example, the grafts that are excised with FUE are frequently stripped from their capsule and the inferior fat pad when compared with strip harvested grafts, but the anatomical yield from FUE which often produces extractions that are not on 'dead-center' may have other effects related to some critical anatomy of the FU relative to the sebaceous gland and the area where the erector pili muscle attaches. Also, what does 'dead center' mean when the FU is not cylindrical when *in-vivo*. Some reports are already circulating suggesting that in some FUE surgeon's hands, anagen cycles may not repeat 2-3 years after the surgery.

Vascular problems

In the donor area vascular damage may appear as graft numbers increase in the limited space of the donor area. Doctors' drive the number of FUE grafts often for financial reasons, so that the percentage of grafts extracted reflects a greater proportion of the FUs in any given donor area, pushing the number of grafts with the FUs closer and closer together, I believe, may produce a significant vascular impact on the donor area. The vascular risks have been poorly documented and I believe that many doctors 'hide' complications with regard to vascular problems as related to wound healing such as (a) the appearance of focal areas of necrosis, (b) increased miniaturization in the remaining hairs within the donor area after FUE. Consider that the number of FUs extracted could be as high as 1 out of 2 of the FUs present in the donor area; such high extraction ratios logically should produce more micro vascular damage. Reports of necrosis appear spontaneously at hair medical meetings but I believe that this complication is far more common than reports indicate.

Scarring is inevitable

Scarring in the donor area as a result of all FUE and strip procedures. The scarring produces traction on the adjacent follicular units and influence the FUE process on all subsequent procedures. The follicle direction in a scarred scalp below the skin may be significantly different than the usual angular offset calculated in an unscarred, virgin FUE donor area. This may be a problem for the ARTAS robot, which uses mathematical formulae established from estimated follicular unit offset calculations which depend upon a consistent direction for the follicle below the skin in any given area. It is also a problem for motorized systems that use a rapidly rotating sharp punch, where it is difficult for the operator "feel" the tissue during FUE. For some mechanical hand driven systems, experienced operators can develop a feel for the direction of the follicular unit and partially mitigate this problem especially with serrated punches when sub dermal tumescence is used.

FUE mega sessions

For the purposes of this section, FUE Mega sessions will be defined as FUE graft numbers that exceed 2000 grafts in s Caucasian with average hair density. That means that for an Asian, a FUE mega session would be, on average, 1600 grafts and for an African it would be 1200 grafts. As the numbers of extractions go up, many doctors find themselves working into the 'non-permanent zone' of the donor area to get the number of grafts that the recipient area requires. The justification for this is that so few patients actually visibly exceed the Norwood Class 7 zone of permanent hair, the area heretofore that had been considered an unsafe harvesting area. By changing the definition of the safe donor area to the area corresponding to a Class 6 balding pattern, the donor area can easily be doubled. As age causes donor area alopecia (undeniable to the knowledgeable hair transplant surgeon with years of experience), such changes become more an issue of economics than good medicine. The results of extending the donor area beyond the Norwood Class 7 zone may cause loss of some or all of the transplanted hair as the donor area develops signs of aging alopecia.

Hardware Associated Methodologies

Adjuncts for most FUE surgeries include tumescence and/or mechanical traction to stabilize the skin. This is often applied by assistants with manual instruments. An example of a mechanical, spring loaded skin stabilizer instrument routinely used with the ARTAS robot was invented and patented by this author [15]. With any mechanical force applied to the skin, a reduction of skin movement works to facilitate the stabilization of the skin, no matter what instrument are used.

A summary of the systems presently in use include

Harris 'safe' system® and the ARTAS® robot: A combined, sequential two punch system with a sharp and a dull punch. The sharp punch is limited to scoring/cutting the epidermis and then a rotating dull punch is advanced below the epidermis to complete the dissection bluntly. Conceptually, the dull punch dissection gathers the splayed hair follicles in the deeper dermis and tears the lattice of connective tissue connecting the follicular capsule to the surrounding dermis, however, this punch is not advanced beyond 3-4 mm depth in the dermis as the sheering factors from the rotating dull punch can tear the distal follicles. The goal is to avoid cutting follicles particularly at the point where they splay, but inevitably there are cuts/tears to the follicular unit or the fibrous connections of the unit to the surrounding dermis and some follicles are torn apart in the process in the advancement goes too deep. The use of rotation is critically important to this two-step process.

ARTAS robot's scalp tensioner and working area: The ARTAS® robotic system uses a skin stabilization system called the 'Scalp Tensioner' [16]. As with all FUE technologies, the scalp is shaved to a 1mm hair length. The Scalp tensioner is used in the ARTAS® Robot System not only to stabilize the skin by stretching the skin tightly, it also keeps the robot oriented to the field it is working in (usually a 5 by 6 cm square) and establishes fiducials by which the computer working with the robot orients itself in the active working field. The robot navigates its way around this square during the graft identification and extraction process. The square Scalp Tensioner is then moved to another location in the shaved donor area. The ARTAS robot uses a combination of hardware and software to identify every follicular unit in this field and also measures the number of hairs in each follicular unit (identifying them with a green lighted dot). It can select the size of the FUs that the surgeon wants to extract. The angle of the hair's exit seen above the skin is also measured. The computer calculates an angular offset for the hair shaft below the skin and then the grafts are cored from their existing donor bed. The proper angular offset is initially an estimate of about 15-20 degrees and it is confirmed once the robot commences the FUE process as the surgeon performs 'test extractions'. At the time of this writing, the ARTAS Robotic System only performs two functions: (a) coring the grafts and (b) placing the recipient sites in the scalp. The grafts are removed manually, usually with forceps.

Very sharp punches: Must limit the dissection to just the first 3-4 mm of the upper part of the FU before the graft splay becomes a factor and the angle must be less than at least 5% off the true upper 3-4 mm graft shaft angle for a successful extraction without damage to the follicular capsule or hairs within the capsule. If a sharp punch is moved below the upper 3-4 mm of the follicular unit, it will cut some of the splayed follicles. Gentle traction is used to extract the lower part of the follicular unit and, as traction is applied, the lower hairs tend to gather closer together [17]. At times, instruments (needles) can be used for further dissection as traction is applied to the follicular unit to facilitate further dissection without the risk of significant follicle transection or capping. Capping (transection of the hair shaft at about mid-shaft level caused by the wrong angle of attack or by tearing the graft when traction is applied are problems seen with doctors who have not mastered the manual FUE process and the 'feel' of the punch as it is advanced forward. John Cole defined the use of a depth limiter to limit the depth the punch can go in a patent 3-4 mm [18].

Neograft® and the Calvitron® technology: The technology uses a rotating sharp punch with suction applied as the punches are advanced. This instrument was first described by Pascal Boudjema in the early 1990s that resulted in a commercial system called the Caliviton®. The suction produces traction which supposedly causes the splayed hairs to be gathered together as the punch is advanced deeper into the tissue, thereby reducing damage to the individual hair follicles. The follicular unit is pulled out of the wound by suction to avoid some of the potential damage caused by forceps, but adds additional risk as the shearing force caused by the suction which can separate or avulse follicles from their surrounding support tissue. In spite of the mechanized action, the Neograft still requires great skill to perform properly [4].

Other Technologies: Manual twisting in a back and forth motion with traction on the graft while using a sharp punch with limited depth is thought to minimize transection and is a technique deployed by many surgeons.

Vibration instead of rotation, with or without a sharp punch for cutting the skin and possibly followed by a dull punch below the skin is another alternative, presently not in commercial use.

The use a semi-sharp four-pronged serrated punch without rotation is introduced into the skin so that the forward protrusions of the serrations are placed laterally to the FU as the punch is advanced. The serrations have a length of approximately 2 mm. This avoids cutting most of the splayed hair follicles and allows advancement to a deeper depth, often the full length of the FU. Adding localized tumescence to this process further facilitates the dissection, a process which the author calls sub-dermal tumescence where the skin immediately surrounding the FU becomes tense and stiffens with the injecting fluid as the instrument is advanced. The stiffer erect follicular unit guides the punch as it is advanced and when it is combined with depth control in those patients with a low elastin collagen around the FU, it may become better candidates for this FUE extraction approach.

Feller system: Uses a fixed 1-3 needle system for scoring the skin and follows the dissection deep into the dermis. Dr. Feller reported that when he encounters a patient with low elastin collagen, he abandon's the surgery in favor of a strip harvest [15].

Ergonomics

The FUE procedure has produced considerable problems for the surgeon with regard to positioning and back problems, repetitive motion of the hand and eye strain. Most surgeons' place their patients face down and this gives the surgeon several advantages. The procedure can be done while the surgeon is sitting so the surgeon can 'fix' the angle of attack in a consistent and more ergonomic manner. Repetitive motions with the hand and wrist has created inflammatory wrist and hand problems for the surgeon to include various inflammatory conditions i.e. carpel tunnel syndrome and a 'golfer' elbow. A very cleaver innovation was recently presented at the 2015 ISHRS conference in Chicago by Shiao. He invented an automatic advancement of the punch once the punch touches the skin [19]. This relieves the surgeon of any wrist action as the punch is automatically advanced. This should replace the repetitive motions carried out by the hand and wrist and reduce many of the mechanical induced inflammatory processes experienced by the surgeon. This technology also has the advantage of producing a more consistent angle of attack during the FUE process.

Eye strain: Is a problem as the surgeon must maintain a close focus on the surgical field for an extended period of time. Good optical lenses help, but it does not ameliorate the accommodation strain that many surgeons experience. For surgeons above 45 years old, the challenges in this arena may not be simply fixed with optical lense corrections.

Skin scarring: There are always punctate scars created by the secondary intention healing associated with the FUE process as the wounds are left open at the time the FUE is performed. These scars reflect, to some degree, the size of the punch used. If the hair is shaved after healing has occurred for styling reasons, these punctate scars on the scalp are almost always evident unless the patient has an unusually high donor density, which hides these scars. It is generally believe that smaller punches produce smaller punctate scars. Some surgeons believe that there is a critical threshold on punch size and that is 0.9mm or less. Some doctors, for marketing purposes, misguidedly call this a 'scar-less surgery'.

Blood supply to the donor area: The donor area receives a rich blood supply from the greater and lesser occipital and posterior auricular arteries inferiorly. Anastomotic connections occur from the sides (temple vessels) and above from the anterior blood supply of the scalp; however, the main supply comes up inferiorly from the greater and lesser occipital arteries. There is a distinct difference between strip surgeries as it relates to blood supply which is a single transection of the blood supply at or near the occipital tuberosity. In this situation, blood, supply from above the incision comes from the temple collateral circulation and the rich anastomotic connections that are present with the inferior occipital collateral network. On secondary strip surgeries at the same location, re-collateralization occurs, so repeat surgeries do not impact the available blood supply to the scalp once healing is complete. Revascularization occurs after healing is complete and the collateral network is most likely enhanced from the 'stress' of the initial surgery.

FUE, which almost certainly transects the smaller arterioles diffusely in the donor area, produce more wound surface area and dermal scarring than traditional strip surgeries. By example, a 25 mm strip wound which might be used for harvesting 2000 grafts has a surface area of 500 mm, whereas a 2,000 FUE graft extraction would have a surface area of 1571 mm using a 1mm punch, a ~3 fold greater scar area when compared with strip surgery. With repeated strip surgeries taken at the same location within the donor area, the alteration of the scalp vasculature remains as it was after the first procedure, possibly with improved collateralization; however with the close proximity of each FUE graft to each other, there must be an effect on the microvasculature of the scalp, magnified with each subsequent FUE procedure. Normally, during a typical FU graft excision, every 4-5th follicular is harvested from the donor area. As the number of harvested FUs taken exceed a 4:1 or a 5:1 ratio, in one or more surgical FUE procedures, more subclinical vascular damage is impossible to avoid. I have seen a few FUE patients who had see-through donor areas when they have had multiple procedures totaling between 5,000 to 7,000 FUE grafts from other medical clinics. In the few cases I have seen, I have measured significant miniaturization of the donor hairs within the remaining follicular units suggesting that these observations could be caused by damage to the micro vascular supply. Although few reports have been presented related to necrosis from closely packed FUE grafts, there may be more problems than we are aware of. In Asian patients, with a 20% lower birth hair density than the average Caucasian and with African patients with a 40% lower birth hair density, these problems will almost certainly be magnified.

Partial FUEs: There is a movement, either intentionally or unintentionally to extract part of a Follicular Unit with a smaller punch, leaving some hair follicles remaining. There are unsubstantiated reports that some of the doctors, who do this, are getting either less graft growth, finer hair on those hairs that grow or failures of the FU to achieve a second hair cycle 2-3 years after the transplant has been completed. It is difficult to understand this pseudoscience and there is no objective scientific or clinical evidence that such a procedure matches the growth quality of a traditional FUE hair transplant that keep all of the anatomical components of the hair follicular unit intact. Until some of this pseudoscience evolves with more clinical science from the hype of the marketing arena and into the clinical space, spending much time on this tecniques is not warranted here.

Pants leg FUE extracted grafts: This is a term used to define a graft that is stripped of its distal follicular capsule and fat. The hairs separate from each other and may or may not have a thin layer of cell remnants from within the follicular capsule. This causes the distal hair follicles and bulbs to physically splay apart. Without sub-follicular fat or the capsule present, these grafts are difficult to place as they must be grasped at the bare bulb potentially producing considerable mechanical trauma during graft placement. These grafts also tend to dry out more easily as the protective fat and capsule is absent. Pants Leg grafts are common with FUE, particularly when there is a low elastin content in the collagen. In the paper by Rassman et al. [2], less than perfect grafts were more likely as the presence of elastin in the collagen decreased and more easily traumatized. The varying degrees of inelastic collagen would explain the appearance of Pants Leg. The various instruments discussed above may see a different frequency of Pants Legs, but there is presently no information on this in the literature. Logically, those grafts that have Pants Legs, which are subject to more damage from drying and the mechanical impact from placing them, may produce decreased growth and possibly a lesser quality of each hair in that particular FU (Figure 5).

Figure 5: Six FUE extracted grafts, three on the left have tissue remaining around the follicles, while the three on the right show that the lower parts of the hair follicles are stripped of their capsular fat showing 'pants legs'.

The process

During FUE, the grafts are removed from the donor area with one of the aforementioned systems and each graft should be examined with regard to the capping rate (when a graft is separated from its lower half), the degree to which they see Pants Legs, and as the number of transected hairs in each graft rises. Pants Leg and capped graft observations should be recorded in the medical record. Once the grafts are removed from the donor area, the grafts are placed into a holding solution until the surgeon is ready to place them in the recipient site. When placed into the holding solution, the grafts are sorted into 1-4 hair graft units, put back into a holding solution for temporary storage, and finally removed from the holding solution some minutes or hours later for placement into the recipient sites. The grafts with Pants Legs are very difficult to place and easily traumatized by forceps. The quality control process required for the management of the follicular units out of the body is identical to the quality control process used for traditional strip surgery except for the required inspection and recording process immediately after extraction for graft integrity. In the hands of some FUE surgeons, the skin edges of the grafts are trimmed as in my practice. By reducing the amount of skin on the surface of the graft, the visible skin disc is minimized when healing is complete. The grafts, once removed from the holding solution, must be placed quickly into the recipient skin area. Exposure to air for more than a few seconds can cause drying to the delicate structures within the hair graft, particularly more in those grafts with Pants Legs or those grafts without an intact follicular capsule with good fat located at the distal end near the bulbs The result of drying (desiccation) can kill the hair grafts so that they will no longer survive – something that may not be apparent for 6-8 months after the procedure is complete when growth failure is noted. Fat on the graft, reduces the risk of desiccation of the grafts and probably extends the 'safe' time to place the grafts by a few seconds.

Technology for the Future

Graft implantation instruments involved in implanting hair grafts into the recipient area

Forceps: The most common practice used in the United States is to create recipient sites and then transfer the hair grafts from a holding solution to a solution held in a small 'dental' cup on the finger that also contains the same holding solution. Pre-made sites can be made the day before the FUE to shorten the implantation and the total surgical time that the grafts are out of the body. This has an added benefit of facilitating the onset of healing prior to the placement of the grafts [13]. When forceps are used in skilled hands, this technique is very effective. The fat pad, inferior to the graft's bulbs, is grasped and the graft is dragged into the pre-made site with, hopefully, a single motion. The implanter can be modified to use suction to draw the grafts into the wounds. When FUE grafts are stripped of their inferior fat pad or have developed Pants Legs, placement with forceps requires the bulb to be grabbed, possibly crushed thereby adding potential trauma to the follicles. Multiple attempts to place the grafts increase the trauma and possibly damage the hairs within the grafts. This is a problem occasionally seen even in the hands of the most experienced surgeons or technicians as local changes in swelling of the 'sties' impacts the ease of placement. A common term 'graft popping' is used when swelling in the scalp envelope develops that causes grafts to extrude after they are placed.

Commercial tubular implanters (i.e. Choi or Lyon implanters): The use of tubular implanters that can receive a hair graft into the chambers. A hair that extends from the graft is dragged through a side slit in the tubular chamber to the appropriate distance. The hair must be long enough to grasp with a forceps as it is pulled into the open bottom of the tubular chamber through the side slit. It is advance away from the open needle until it is abutted against the piston end found within the hollow chamber. The implanter can be modified to use suction to draw the grafts into the wounds. Once the graft is in the appropriate position, this implanter uses a piston to drive the hair graft out of the chamber and into the recipient area after it is inserted into either pre-made wounds or directly through the skin. Great care must be taken that as the instrument is withdrawn in the same movement as the graft is left behind at the proper depth in the recipient site. If the piston is activated quicker than the withdrawal of the implanter, the grafts could be placed too deep or compressed in the wound. Insertions that are too deep will cause the graft to become a foreign body and eventually be rejected by the body, producing either a foreign body reaction or an infection risk.

Implanter for pre-made sites: The use of a tubular implanter that has no needle on it. It has a flat end which is placed directly over the pre-made recipient site. The implanter uses suction to draw a graft into its tubular chamber (it could use a side slit as well). By holding the graft loaded with implanter at the edge of the open wound, a piston drives the graft into the wound without entering the wound, just as a hammer would drive a nail into a piece of wood without entering the piece of wood [20]. If the alignment is correct, this instrument has the advantage of eliminating all extraneous forces on the graft which moves without obstruction to finally settle into the proper depth in the scalp wound, flush with the skin edge. This implanter is incorporated into the Neograft system.

Per-cutaneous implanter: A percutaneous method is deployed with the use of an implanter instruments similar to other commercial instruments. A hair that extends from the graft is dragged through a side slit in the tubular chamber to the appropriate distance. The hair must be long enough to grasp with a forceps as it is pulled into the open bottom of the tubular chamber through the side slit. The implanter can be modified to use suction to draw the grafts into the wounds. The graft is advanced away from the open needle until it is abutted against the piston end found within the hollow chamber. Hair grafts are placed directly through the skin without a pre-made wound (site) in one motion. This "percutaneous" instrument can be used to place hair grafts into pre-made sites as well, even with its sharp end but it is better to dull the sharp end if it is to be used in pre-made sites. The instrument includes a sliding piston within the housing but this instrument is different than the instruments defined in #2 above, as the piston does not move. When placed at the proper depth (various distances are marked on the side of the needle which reflects the length of the graft, a trigger on the implanter automatically withdraws the needle, leaving the graft behind at the desired location within the wound and flush with the skin. This has an advantage over the instruments defined in #2 above as the piston can't compress the grafts and the graft is always placed to its proper depth without the risk of burying or compressing the graft [21]. The graft may not stay where it is placed and can extrude from the wound if bleeding occurs from the percutaneous wound or pressure from the scalp envelope develops which can cause the grafts to be expelled. The sharper the needle, the less likely will be the impact from the pressure within the skin envelope. This instrument is not commercially available at the time of this writing.

These implanting instruments have several disadvantages. Graft depth can be difficult to control, a problem solved with above example, When the percutaneous instrument advances the graft into the scalp with the movement of the piston, the mechanics of this process may (a) compress the graft, (b) place the graft too deep, (c) dislodge previously implanted graft in the general vicinity of the implant site. The instrument, if sharp, will be less likely to force out adjacent grafts. As grafts are dislodged, great care must be taken to recover any dislodged grafts and either replace them immediately or return them to the holding solution. Grafts that remain on the surface of the skin from being dislodged, which are not replaced immediately, will die from desiccation.

These implanters offer a series of advantages which include (a) less graft handling and possibly less direct trauma to the individual grafts during the entire placement process, (b) faster placement of the grafts once a good cadence is established between the surgeon and his staff when placing grafts, (c) able to produce better graft placement for a less experienced operator and their teams (d) a reduction of labor, and (e) less time for overall graft placement.

Movements of hair grafts from the time they are created from either strip or FUE surgeries, produces challenges as they are (a) manipulated by humans, (b) squeezed or crushed by forceps, (c) forced into the premade sites with more than a single effort for each graft causing mechanical damage to the hair graft, (d) left open to the air, particularly when difficult placing occurs, (e) pop out as swelling in the skin envelop develops over time, (f) compressed as they are pushed into a wound by the piston of the implanter instruments, (g) not threaded into the implanter needle efficiently on a single pass where there is difficulty pulling the hair of the graft through the slit in the beveled needle (f) placed too deep in the recipient site. Since hair grafting as it is presently being performed is an open system, these aforementioned processes must be controlled by stringent quality control procedures and protocols. At the final step where implantation occurs, graft damage or death can occur for many of the above reasons. The time from graft removal from the donor site should be as short as possible, rarely exceeding 8 hours, preferably less.

A focus on labor and the evolution of close systems for FUE

Conversion from a purely open system (strip surgery plus forceps) with its incumbent high labor requirement for microscopic graft dissection, to a potentially more closed system with less labor with FUE using implantation instruments instead of forceps, offers the surgeon the ability to reduce the time and the cost of the hair transplant surgery for the patient. The ARTAS robot promises a more closed system sometime in the future, where FUE plus implantation may be done more seamlessly. The same could be true for manual implanters which are connected to a cartridge system for storage of the grafts during the surgery. Such systems were foreseen and one was built for commercial use by this author [22].

Future closed systems: The primary goal of any closed system is to maintain the grafts in a holding solution between the time the grafts are removed from the donor area and placed into the recipient area. For any closed system such as a robot with implanters connected to a cartridge, the patient must be in a different position for extracting grafts and when the grafts are implanted and for this reason, the seamlessness of extraction plus implantation may be impractical. Other critical goals of a closed system include: (i) not having forceps manipulate the graft, (ii) keeping the grafts from being handled or manipulated by humans and (iii) minimize the time the grafts may be exposed to air, (iv) reduce the time the grafts are out of the body. The placement of hair grafts into cartridge chambers that brings with it a small volume of the holding solution to keep the grafts alive and moist until the cartridge is discharged through the skin or the wound of the patient to its proper depth, is the ideal solution for a semi-closed system and such systems are presently being developed.

Discussion

Many dermatologist, cosmetic surgeons, family doctors, urologist, gynecologist, retired doctors from all sorts of specialties, etc. who have not previously considered delivering hair transplant FUE services, will enter the hair transplant field looking for a new source of revenue which is not tied to insurance reimbursement. As the industry is exploding, these new revenues will draw doctors to the hair transplant business. These new doctors have patient populations under management and this easily allows them to market FUE services directly to their patients. The availability of independent contractors who supply surgical and assistant services (legal or otherwise) seem to be available to do much of the work. Unfortunately, these doctors may look at a hair restoration more as an income stream than a valuable service for their patients.

Companies like Restoration Robotics, Inc., with their heavy investment in building a very sophisticated and expensive robot must expand their market beyond the traditional hair transplant surgeons which make up only a small fraction of the doctors in this business. Other companies such as Neograft have already established a business where 'rent a tech' services are available. Providing that these commercial companies comply with the laws in the various states where they are enticing doctors to enter the field, this may become the primary 'entrance point' for new doctors. The appearance of hair transplant mills in Turkey and Iran are great examples of efficient business organizations capable of delivering what appears to be a cost effective product with very low labor costs, but most do not meet the legal requirements imposed by medical laws in North America and Europe requiring licensed professionals and there is a question about the quality of the services they supply. With proper professionally driven, quality focused businesses, this could be a model outside the Middle East which would be augmented by new and creative tools that facilitate FUE and bring fees down. As FUE has been a challenging technology for many established doctors, opportunity abounds. With more and more providers reaching new patients in their daily interactions with balding people (50% of the male and female population over 50), the market will invariably expand. Today's market does not yet approach 1% of the balding population.

The incorporation of new technologies into the hair transplant field and the inevitable evolution to semi-closed systems will make the surgery simpler, easier to learn and more robust as the variables of today's open system must change to be competitive. These new technologies will allow a variety of doctors from various specialties to incorporate hair transplantation into their practices. The technological changes will require new providers, not presently offering hair transplant services, to seek out enabling technologies for FUE and 'hire a tech' services. Ethical questions are presently being brought to the forefront as these new doctors, unprepared with education and diagnostic skills that address hair loss, are taking a greater and greater share of the market.

What we have described are trends that are presently emerging as new, untrained doctors enter the business. I have not addressed the training that doctor need in the 'art' and clinical science of the hair transplant process. Diagnosis and strategic planning, as in any medical treatment, is at the heart any successful endeavor in entering this field. In the clinical science of diagnosis and treatment of the various forms of alopecia, the recognition that dermatological diseases often drive hair loss and understanding this is critical to the delivery of good quality services. Without the fundamental training in these areas, there will be a substantial harm for many people. Catastrophic problems may emerge as sub-optimal delivery of cosmetic and medical care will result. Over the past decade, two deaths have occurred during a hair transplant procedure in the United States showing the critical importance of good training. Everyone with hair loss, without the appropriate diagnostic workup, will, unfortunately, become candidates for an FUE hair transplant, too many times, often inappropriately.

Better training opportunities are needed for service to what I believe will be an increasing provider base. Many of the new doctors will not appreciate the nuances of design and planning for hair restoration and even less will have an understanding of the underlying diseases of the scalp which will bring inappropriate patients with hair loss to doctors. Societies like the ISHRS have the opportunity to empower these new doctors and teach the clinical science of diseases of the scalp including genetic balding and the art required to become a skilled and competent hair transplant surgeon but the effort seems to be falling short. Experienced HT surgeons developed these artistic, diagnostic and technical skills over many years but there is no route to empower these new doctors with that knowledge. Experienced doctor are not presently passing their skills to the new physicians entering the business, although the various societies are trying to make this happen. Doctors are fearful of creating more local competition and as such, do not open their offices.

The commercial companies selling hardware should engage experienced physicians and set up teaching seminars to teach the art and science of hair restorations by actively working and guiding new doctors into packaged training programs if these companies are going to profit and build ethical businesses. Companies such as Restoration Robotics, Neograft and others must not be treated as outsiders, because they are becoming more and more relevant but they have their own financial agenda and as long as they can sell services and their expensive systems, they may not be responsive to the ethical practices that should be the driving force for most good doctors entering the field. Technical hair transplant skills disassociated from the knowledge of scalp diseases will do much harm. If physicians skilled in the art, science, and delivery of FUE services do not embrace the expanding physician pool and offer new providers the teaching and training they need, in conjunction with the activities of commercial companies selling hardware into this market, the market will expand for the worse.

Conclusion

We are at the threshold of a revolution brought on by new and evolving hair transplant technologies and a shift in the type of providers who will exploit this technology. As the experience of new providers grows and as the technology continues to improve, the landscape of our industry will change. Commercial companies must take a stronger role in both the evolution of the technology and the training of new physicians. There is a great financial opportunity for new physicians entering this business and the 'old guard' must somehow embrace these new doctor and the new evolving tools that make these changes easier. With a 28% increase in the hair transplant business and evidence that this growth is continuing, we can already see the impact that FUE and commercial companies are having on the hair transplant industry. Those of us who have helped mold the radical changes from the old days of 'plug hair transplants', have a responsibility to become proactive in this revolution by providing quality teaching opportunities and by working with our societies and the commercial companies that are molding this industry.

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