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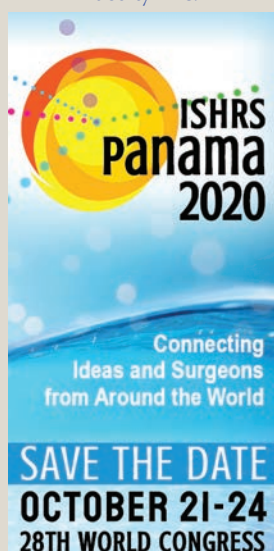
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Sharp and Hybrid Punches: A Detailed Comparison of Different Quality Control Markers

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Conflict of interest: Jean Devroye is CEO of Devroye Instruments, production of punches

This study was presented at the 2019 ISHRS meeting in Bangkok as a poster and was awarded "Best Tip".

ABSTRACT

Introduction: Low transection rate and high availability of usable grafts is very important for the surgeon performing FUE. Prior studies have shown a decrease in transection rate using the blunt over the sharp punch. The hybrid punch developed by Devroye with a flat cutting surface has clinically been shown to also improve the quality and yield of grafts compared to a sharp punch.

Objective: The goal of this study was to compare both the sharp and hybrid punch in terms of total grafts available and transection rate.

Study Design: This was a multi-center, side-by-side study looking at the same number of grafts removed via follicular unit excision (FUE) with the sharp and hybrid punches. Experienced physicians in both techniques removed grafts using the same-sized punch from similar areas of the scalp and recorded the number of graft extraction attempts, grafts obtained, and transection rates. From this information, a comparison of punches was undertaken looking at complete grafts available and the transection rates.

Conclusion: There was an overall higher yield of grafts obtained using the hybrid punch. Also, there was a nearly 50% reduction in the transection rate of the hybrid over the sharp punch. The selection of punch type is important for the physician desiring to maximize the total number of grafts and minimize transection in their patients.

INTRODUCTION

The hybrid punch was created by Dr. Jean Devroye in 2014 and introduced during the 2015 annual meeting of the ISHRS in Las Vegas.¹ It was inspired by the blunt punch invented by Dr. Jim Harris.² The hybrid punch has an external cutting edge along with a flat skin contacting inner surface and is designed to be less aggressive for the follicles, giving globally a better follicle yield.

OBJECTIVE

This multi-center study had two intentions: 1) to verify and compare the overall number of grafts available for hair transplanting with follicular unit excision (FUE), and 2) to verify the transection rate for both the sharp and hybrid punches and to demonstrate the variation of these two markers by comparing the grafts obtained with both punches.

STUDY DESIGN

A multi-center study was designed to draw a comparison between two quality control markers between the hybrid punch and the sharp punch: 1) the rate of grafts available for transplanting, and 2) the rate of transection of hairs per graft. We introduce two new terms, described in the next section, that permit a more accurate assessment of the quality of FUE grafts.

There were a total of 32 patients, the majority of whom were male. The procedure was carried out by extracting two sets of 100 grafts on each patient; one set was obtained by a hybrid punch and the other

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President's Message

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To Be or Not to Be in the ISHRS: A Question of Choice

It may sound funny, but I have to admit that the column I never used to read when I received a new issue of this journal was this one, the President's Message. Not because of a lack of esteem for my predecessors for whom I have enormous respect, but because as soon as I received the journal at home, what I wanted to read were the scientific papers that always taught me something practical and useful and that served as inspiration for me to make changes for the better in my practice. Although I am almost sure that most of you feel the same way, too, in view of my obligation to follow tradition and continue to write a President's Message in every 2020 issue, I promise at least to be as brief as possible.

One of the pillars of our ISHRS is education. Following the path of the founders of our society, from the beginning we adopted the principle of unselfishness with respect to the sharing of knowledge with other colleagues. Moreover, any doctor, no matter their specialty and formal training, has to date always been welcome in our society. However, circumstances have changed and we have had to adapt to the times in which we are living. As a result of the current hair transplant market, and with patient safety always foremost in our minds and satisfaction as our first objective, the ISHRS has found itself obliged to impose stricter rules for new doctors applying for membership. Henceforth, we will only accept doctors who accept and follow the ISHRS's policy of "only doctors doing hair transplant surgery." We believe in our principles, and as the leading society in hair restoration surgery, the ISHRS has to be a model to follow regarding ethical conduct. We have great faith in our beliefs, and other medical societies support our policy. It is as simple as this: if we consider that taking a punch biopsy is a minimally invasive surgical procedure, then the excision of thousands of follicular units with a circular trephine (punch) must also be considered a surgical procedure, and therefore should not be done by non-medical professionals.

We all know that there are excellent hair surgeons using technicians to harvest their FU grafts from the donor area, and I realize that if those surgeons are in perfect control of the surgery at all times and the technicians have been adequately trained and are continuously evaluated, the manual skill required in the excision process can be performed equally well by the technicians as the doctors. But we must also acknowledge that they are allowing technicians to make medical decisions with each square centimeter they harvest (in order to avoid complications such as overharvesting or necrosis) for which they have no legal authorization or formal training. We, as a society, cannot support such a

paradigm because if we do so we also open the door to numerous unethical doctors with minimal-to-zero knowledge in this field who have no expertise in providing appropriate supervision and are only looking for an easy way to increase their profits by hiring technicians to do part, if not all, of the surgery. When a lack of expertise results in improper patient selection or surgical complications, the victim is always the same: the patient.

For this reason, if you prefer to follow the paradigm of hiring techs to perform hair transplant surgery instead of doing it yourself, please do not apply for ISHRS membership. There are other societies who will be happy to accept you as a member. Furthermore, if you are an ISHRS doctor who uses techs to perform surgery for you, please embrace your values and leave our society. We prefer not to kick anyone out of the ISHRS since we are doctors and not policemen, but this is a question of choice that you, as a doctor with honesty and integrity, have to make. I really see no other option or change in ISHRS policy—which is consistent with our principle of putting patients before profits—any time soon, at least not in 2020. Of course, we never know what will happen in a few years. Only time will tell if our medical ethics are able to stand strong in the face of big business challenging the privileges that medical licensure provides. ■

Please join the ISHRS Annual Giving Fund and help in our Fight the FIGHT campaign with a donation! It is crucial that we have member support. Please make your donation to help support the battle against the unlicensed practice of medicine. To donate to the Fight the FIGHT campaign, go to:

<https://ishrs.org/make-a-donation/>

Co-Editors' Messages



Jeffrey S. Epstein, MD, FISHRS
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A welcome from your new *Forum* editors. Since 1994, my first year in hair restoration surgery, I have been a regular reader of what was O'Tar Norwood's labor of love for this emerging specialty. Its purpose as stated in the inaugural issue—"the rapid dissemination of ideas, questions, concepts, views, and opinions"—is as relevant today as it was 30 years ago. While the politics may be a bit more complex, the reality is we are all colleagues in this wonderful field.

It thrills me to think that I, along with Aditya, will be at the helm for the next three years, a time that promises to be one of continuing scientific advances that we will bring in a timely manner to the entire HRS community. We are committed to working diligently and creatively to not just continue the path of excellence and accessibility set by the editors before us, but also to more actively solicit contributions from our membership—that means you—all of whom have something to teach or to provoke in thought or controversy.

It feels great to be published in the *Forum*, and the new FORUM ePUB (see Robert True's article) means wider audience exposure. In 1996 I published my first *Forum* article, and it was affirming to think that a young surgeon like me could not just learn but also teach through this publication. This affirmation set me on the course to where I am today, not only with a portfolio of publications, but something more substantial—a feeling of being part of the hair restoration community. There are no invitations handed out to "join," rather just encouragement to submit articles, present lectures, and get involved with educating the public on what our specialty is about.

With all the regular columns to be continued, including two of my favorites for their thought-provoking content (Greg William's *Ethics* and Russell Knudsen's *Controversies*), there will be several new columns. We look forward to publishing opinion pieces that encourage debate like William Rassman's letter to the editors with Paul McAndrews' reply, as well as providing coverage of efforts by our members that include *pro bono* work to repair the poor outcomes from turn-key or other unqualified clinics.

Some articles in this issue may be familiar to those who attended the 2019 World Congress in Bangkok, including Igor Bottura's on a case presented at the M&M conference, Jean Devroye's multi-center study that took home the "Best Practical Tip" award, Vlad Ratushny's column on exosomes, and Scientific Chair Robin Unger's impressions of the meeting. As always, the literature review by Aditya Gupta is succinct and worth a read. One particular asset of working with Aditya is the experience in scientific writing he and his team of researchers bring. I feel fortunate to share our editorship, and like any successful marriage, I feel I got the better bargain. Speaking of marriages, I want to thank my wonderfully supportive wife Gorana for encouraging me to take on this role, and for allowing me to see, through her eyes, more than ever just how wonderful a specialty this is. ■



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There are many great articles in this issue touching on a variety of topics. Gregory Williams's *Spotlight* highlights an important topic not often discussed: the vulnerable patient. This article is a salient reminder that we need to keep the best interest of the patients at the

forefront, and identifying vulnerable patients should be a priority. Russell Knudsen's *Controversies* also touches on this topic, describing the pressure patients can put on hair restoration surgeons for surgery that may not be the best option for them. With the increasing trend of unscrupulous clinics luring patients with promises of miraculous results at a fraction of the price, we need to stand united and fight the urge to give in to patient requests that are not in their best interest.

In *Letters to the Editors*, William Rassman and Paul McAndrews explore the debate about black market vs delegating in hair transplant procedures, highlighting the differences between legal delegation of certain parts of the hair transplant surgery and the illegal practice by unlicensed practitioners/technicians. This is an important discussion to continue with the goal of defining the best moral practice. This debate brings to light that the ISHRS's "Fight the FIGHT" campaign is not about restricting robotic devices or the delegation of certain procedures to a technician, but rather it is about promoting public awareness of the safety implications of illegal practices by unlicensed medical hair transplant technicians.

Vlad Ratushny's *Hair Sciences* discusses the topic of exosomes. Recently, there has been excitement over the potential of exosomes as a novel therapy for hair restoration. Exosomes appear to promote hair follicle stem cell proliferation and growth and may present a game-changer to the field of hair restoration; however, we need to keep in mind this therapy is in its infancy and much work is required to determine where exosomes fit in hair restoration. Efficacy and safety have yet to be evaluated, as detailed by the warning issued by the FDA regarding the general use of exosome therapy (reprinted on page 18).

A case report by Igor Bottura discusses the phenomenon of kinky hair after FUE and provides some insight into the causes. Excessive and careless graft handling with forceps during graft placement in the recipient area is suspected in the case presented. Although this phenomenon has been known for 25 years, not a lot of research has gone into determining why it happens, and thus, how to prevent it.

The new FORUM ePUB journal site is up and running! In his article, Robert True gives a detailed breakdown on how to use the site, which facilitates the search for past *Forum* articles. This site is a great step forward for the ISHRS enhancing the visibility of the *Forum* and the ISHRS to the public and to the medical community at large.

I look forward to working with Jeffrey, who has a wealth of clinical and academic experience; I know I will benefit from his unique perspective and wisdom. I can see that there are definite advantages to having him as my co-editor. ■

set by a sharp punch. This extraction was always performed in the best donor area, and the occipital scalp was preferable to the parietal portion of the scalp. The two donor areas on each patient were of the same size and had the same surface appearance.

The same punch size, corresponding to the measure of the diameter of the cutting edge, of the sharp and hybrid punch was used on each patient. Most commonly, this diameter was 0.9mm. The sharp punch was either serrated or not, with an external or internal sharp edge.

The calculations were obtained following the definitions established by the ISHRS FUE Committee in 2014 and 2015.³

Follow-up parameters

Our method of quality control was to calculate two entities, which came from four sets of data numbers:

1. The **rate of grafts unavailable for transplanting**. This is the difference between the number of attempts (in this study it was 100 attempts) and the number of grafts available for transplanting (intact or having some transections). This difference is the sum of the capped grafts, the completely transected grafts, the missing grafts, and the buried grafts. This number is important because with unrefined techniques, the rate of unavailable grafts could be 10–15% or even higher.
2. The **follicle transection rate**, also called the “**rate of transection**.” To calculate the rate of transection, it’s elegant to refer to two complementary numbers:
 - a. First is the calculated **number of follicles (hairs) per graft expected (CFGE)**, and second,
 - b. the calculated **number of follicles (hairs) per graft achieved (CFGA)**.

The difference of the CFGE and CFGA, divided by the CFGE, is the **follicle transection rate (FTR)**. It’s important to understand these two concepts, CFGE and CFGA.

For example, on the same patient, achieving 2.4 follicles per graft from the 2.6 follicles per graft expected with a 0.9mm punch (an FTR of 8%) is more efficient (in terms of the total number of hairs that can be transplanted) than achieving 2.1 follicles per graft from the 2.3 follicles expected with a 1mm punch (even if the FTR is also 8%).

STUDY RESULTS

The following table and charts summarize our results.

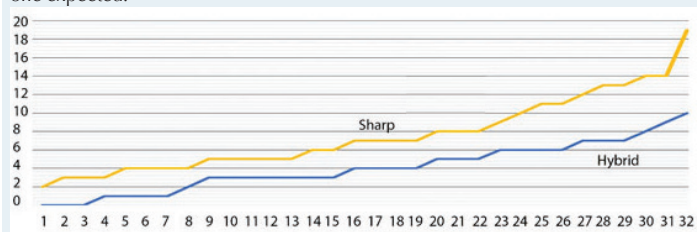
The follicle transection rate of sharp vs. hybrid punches was 17.7% vs. 9.2%, respectively, as shown in Table 1.

TABLE 1. Follicle Transection Rate of Sharp vs. Hybrid Punch

	Rate of Grafts Unavailable	CFGE	CFGA	Follicle Transection Rate
Sharp	7.7%	2.37	1.95	17.7%
Hybrid	3.5%	2.37	2.15	9.2%

As shown in Figure 1, the influence of FTR on the number of grafts unavailable for transplanting, where patient study number is on the x-axis and rate of grafts unavailable is on the y-axis, was 7.7% for the sharp punch and 3.5% for the hybrid punch.

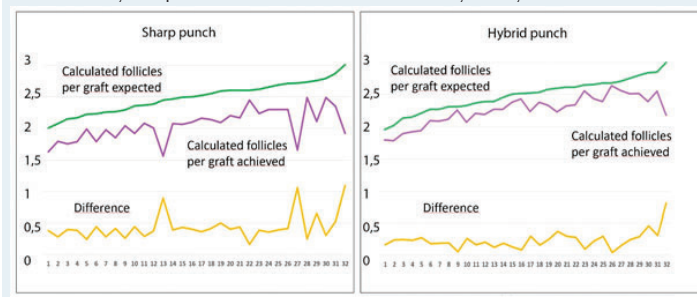
FIGURE 1. Influence on calculated number of hairs achieved in comparison with the one expected.



The CFGE had a value of between 2.01 and 3.01 follicles per FU, with a mean of 2.37. This does not vary between the sharp and hybrid punch because of the similar donor area. The CFGA with the sharp punch had a value of between 1.56 and 2.49, with a mean of 1.95. The CFGA with the hybrid punch had a value between 1.59 and 2.64, with a mean of 2.15.

This means that the rate of transection is reduced by approximately one-half when using a hybrid punch (from 17.7% to 9.2%). (See Figure 2.)

FIGURE 2. Hybrid punch reduces rate of transection by nearly one-half.



DISCUSSION

The yield obtained with the hybrid punch showed a global improvement in terms of reduction of grafts unavailable for the surgery, as well as an almost 50% lower rate of transection. Both factors combined yielded an 11% improvement in terms of hairs.

This study corroborates the previous results obtained by Drs. Shapiro and Josephitis in which, for example, the CFGA was, respectively, 1.9 (sharp) and 2.2 (blunt).⁴ In our study, the CFGA was 1.95 (sharp) and 2.15 (hybrid).

It’s important to note that when we are honest about the calculation of the rate of FUE transection, this rate is still relevant when determining which FUE method is considered the best. This rate is approximately 9% with the hybrid punch and approximately 18% with the sharp punch.

The large variability of our yield in terms of CFGA ranging from 1.56 to 2.64 is interesting to note. This stresses the relevance of documenting a case by counting not only the graft number but also the hair number achieved.

It should be noted that all of the surgeons who participated in this study mainly utilize hybrid punches as part of the WAW system, but all have extensive experience in the use of sharp punches for FUE. This level of experience and familiarity may have played a part in the superior results achieved in this study with the hybrid punch. There is agreement that it is easier to become “skilled” with hybrid punches, because the learning curve is not as steep as it is with

sharp punches, and that transection rates would be particularly lower with hybrid than sharp punches in challenging cases, such as patients with more curl or splay or those with a more acute angle of exit. Two surgeons, one experienced in sharp punches the other in hybrid punches, can get good results in their cases, but it is our perception that in general the incidence of these good results across the board is less with sharp punch technology.

There is a place for further research on figuring how to achieve an FUE rate of transection similar to the 1–2% rate achieved with FUT. It all starts with simple quality control in any practice to verify what we are claiming.

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Comparing Follicular Transection Rate in Revision FUE Cases Who Previously Underwent Various Types of Hair Restoration Surgery: An Exploratory Study

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ABSTRACT

Background: Follicular unit excision (FUE) has come a long way in establishing itself as an alternative technique for hair restoration. There exists a plethora of scholarly work on FUE, albeit there is a paucity of evidence on variables that affect the outcome of revision FUE. A successful hair restoration surgery is, among other things, predicated on the surgery's follicular transection rate (FTR).

Objective: The objective of this study was to determine whether there is an association between FTR and the type of hair restoration surgery patients had prior to their revision FUE; three surgical procedures were compared: strip harvesting (SH), FUE, and punch grafting (PG).

Material & Methods: The sample size for this exploratory study was 40 (i.e., $n=40$), and all the subjects were men with different grades of androgenetic alopecia. The subjects had undergone an FUE revision surgery from January to December 2014, and had their FTR and partial transection rate (PTR) calculated for each session. We compared patients' FTR and PTR among cases who had undergone various hair restoration techniques prior to their revision FUE. We defined FTR as complete transection of the graft, where all follicles in the graft are transected; PTR was defined as the incomplete transection of the graft, where at least one follicle in a graft is intact. Chi-square test of independence was conducted to compare FTR and PTR across revision FUE cases of patients who previously underwent SH, PG, or FUE.

Results: Out of a total of 40 cases, 52.5% (21) had undergone FUE surgery earlier, 35% (14) SH, and 12.5% (5) PG as the primary surgery. The average FTR in patients who had undergone strip surgery earlier was 3.22 per 100 grafts, while it was 3.33 per 100 grafts and 3.54 per 100 grafts in those who had undergone previous FUE and punch grafting, respectively. Chi-square test of independence showed that there was no significant relationship between the type of hair restoration procedure cases had prior to their revision FUE and the FTR and PTR. Nonetheless, our results support a trend where FTR and PTR are likely to be high if the prior surgery is FUE; moreover, post-hoc calculations for statistical power showed that the current study was underpowered.

Conclusion: Our findings suggest the type of hair restoration surgery men with androgenetic alopecia underwent prior to having a revision FUE might influence the success of the revision FUE. In addition, we noted revision FUE cases of male androgenetic alopecia are least likely to have high FTR if they had previously undergone strip harvesting. Furthermore, our calculations for statistical power from our exploratory study would be very useful for sample size determination in future studies.

Key words: follicular transection rate, partial transection rate, hair restoration

INTRODUCTION

The success of hair transplantation surgery is predicated on achieving optimal hair growth; successful growth of hair is dependent on maximising the graft uptake as well as the quality of transplanted hair.¹ Three methods of hair transplantation—follicular unit excision (FUE), strip harvesting (SH), and punch grafting (PG)—aim to achieve optimum graft growth. With technological advances and the surgeon's growing experience, the number of follicular units transplanted per session increases from a few hundred to a few thousand during the present giga sessions offered.² The limiting factor in any of these methods is the follicular transection rate (FTR), a factor that determines the success of any hair transplantation surgery. Follicular transection rate is likely to vary with the type of surgical technique, in general; other variables can also impact FTR, including surgeon expertise and donor scalp status.³ If FTR is high, then the chances of getting a higher yield of grafts is less, which, in turn, hampers the success of the surgery. The primary objective of our study was to determine whether FTR is significantly different among revision FUE cases of patients who had previously undergone different hair restoration procedures.

METHODS

The sample size for the exploratory study conducted at our hair transplant center was 40. All of the subjects were men with different grades of androgenetic alopecia who had undergone FUE between January and December of 2014; prior to the FUE, all subjects had various hair restoration procedures, such as SH, PG, or FUE. The FTR and partial transection rate (PTR) were calculated for each session by visual inspection method while extracting the grafts. We defined FTR as the complete transection of the entire follicular unit irrespective of the number of hair follicles, and PTR as transection of the follicles in the follicular unit leaving the follicular unit viable with at least one non-transected follicle. For example, if there are three hair follicles in a graft, and if one or two hair follicles are not transected, then it is a partially transected graft, with one or two viable hair follicles. All cases were photographed prior to the procedure and serially thereafter upon follow-up to assess the results.

For both FTR and PTR, we conducted a Chi-square test of independence. The explanatory variable was the type of hair restoration surgery that was conducted prior to the revision FUE. The outcome variable was categorical and the values of follicular transection rate values were grouped into

three categories: the “low,” “medium,” and “high” categories included FTR values between 1 to 3, 3 to 5, and 5 or greater, respectively. Similar categorization was done for PTR. We thought that FTR and PTR would be more meaningful outcome variables if they were categorical as opposed to continuous. Alpha was set to 0.05. (See Tables 1 and 2.)

TABLE 1. Comparison of FTR in Different Techniques

Primary Technique	Average FTR		
	Low (1-3)	Medium (3-5)	High (5 and above)
SH	8 (57%)	4 (29%)	2 (14%)
FUE	12 (57%)	4 (19%)	5 (24%)
PG	3 (60%)	1 (20%)	1 (20%)

TABLE 2. Comparison of PTR in Different Techniques

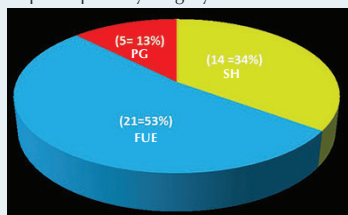
Primary Technique	Average PTR		
	Low (1-3)	Medium (3-5)	High (5 and above)
SH	4 (29%)	5 (36%)	5 (35%)
FUE	2 (10%)	11 (52%)	8 (38%)
PG	1 (20%)	3 (60%)	1 (20%)

RESULTS

Descriptive statistics

Of the 40 cases, 52.5% (21) had previously undergone FUE, 35% (14) had previously undergone SH, and 12.5% (5) had previously undergone PG (Figure 1).

FIGURE 1. Percentage of patients by technique of primary surgery



The FTR in revision cases with SH used for the primary surgery ranged from 1.25 in a case of 1,600 grafts to a maximum of 6.6 in a case of 1,000 grafts. A majority of the patients (57%) had an FTR < 3. The PTR ranged from 2.11 in a case of 1,700 grafts to 9.25 in a case of 800 grafts.

In cases where the primary surgery was FUE, the FTR ranged from 1 (a case of 1,500 grafts) to a maximum of 5.85 (a case of 2,000 grafts). A majority of the patients had an FTR < 3 (57%). The lowest PTR noted was 1.7 (a case of 2,100 grafts) and the highest was 7.71 (in a case of 1,400 grafts).

For cases with PG as the primary surgery, FTR ranged from a lowest of 2.11 (in a case of 900 grafts) to a maximum of 7.5 (in a case of 2,000 grafts). A majority of the patients had an FTR < 3 (60%). The lowest PTR was 3 (in a case of 900 grafts) and the highest was 8.9 (in a case of 2,000 grafts).

Statistical analyses

For FTR, our Chi-squared test of independence showed that the relationship between prior hair restoration procedure and follicular transection rate was not significant: X^2 (4, N=40) = 0.742, $p=0.9461$. For PTR, our Chi-squared test of independence showed that the relationship between prior hair restoration procedure and partial transection rate was not significant: X^2 (4, N=40) = 2.82, $p=0.59$.

Nonetheless, our results support a trend where high values of PTR and FTR are most likely with FUE as the primary technique; high values of FTR are least likely when SH is the prior surgical procedure, and high values of PTR are least likely when PG is the prior hair restoration technique.

Post-hoc calculation for statistical power for FTR showed that our study had a power of 6.9%; for PTR, the effect size for the Chi-square test of independence (i.e., Cramer's V) was 0.096. For an effect size of this value—and an alpha 0.05—the study would have needed a sample size of at least 1,288 subjects to be sufficiently powered (i.e., have statistical power of at least 80%). Furthermore, a post-hoc calculation for statistical power for PTR showed that our study had a power of 13.2%. For PTR, the effect size for the Chi-square test of independence (i.e., Cramer's V) was 0.19, and given this effect size (with alpha set to 0.05), the study would have had power of at least 80% had the sample size been at least 339.

DISCUSSION

The occurrence of follicular transection is expected in any transplant procedure; furthermore, follicular transection is reported to range from less than 2% to 20%.⁴⁻⁶ Once grafts are excised, there is perifollicular inflammation, perifollicular fibrosis, change in graft angulation, decreased density, extensive scarring, and reduced vascularity of the remaining hair follicles.⁷ Hence, the success of a repeat hair restoration procedure could be impacted by the prior surgery: the primary procedure could affect the harvesting of viable hair follicles and therefore result in increased transection while harvesting. The degree of transection could vary across different techniques.

In PG, the size of the punch used in the primary surgery is larger than typical FUE punches and the follicular transection in primary PG cases is also to the tune of 10% as suggested by Limmer.⁸ There is extensive perifollicular fibrosis in the donor area thereby leading to maximum difficulties in extraction of grafts (Figure 2).

FIGURE 2. Revision FUE in a previous punch grafting case



In primary FUE surgery, the FTR varies with motorized versus manual methods ranging from 5%-17.5%.^{9,10} When revision surgery is done with FUE technique, the FTR in our study was higher than when SH was the primary technique, and this could be explained by the fact that post-inflammatory changes affected the entire donor area.

In primary strip surgery, the follicular transection rates have also been found to be variable and more so with multi-blade knife, as reported by Shiell, up to 25%.⁹

However, in our study, FTR was found to be low in revision surgery in this subset. This can be explained by the fact that post-surgery inflammatory changes primarily occur along the suture line only and the rest of the donor area behaves like virgin area, which led to low FTR in the SH category of patients (Figure 3).

FIGURE 3. Revision FUE in a previous strip harvesting case



Regarding the partial transections, some authors feel that they may eventually grow hair.¹⁰ But our review of the literature has shown that the growth rate is not satisfactory in partial transection, and the quality of the hair that grows is less.¹¹ So, an experienced surgeon always tries to lower the FTR and PTR in FUE hair transplant surgery to improve the outcome of the surgery.

In order to achieve lower FTR and PTR, surgeons have devised the following ways of reducing the FTR by 1) using magnifying loupes, 2) determining the exit angle of the hair follicle, 3) infiltrating saline to decrease the exit angle of the hair, 4) using a flat instead of sharp punch, and 5) using the right amount of force while extracting the follicles.

CONCLUSION

The advent of newer techniques in hair restoration could be promising of low FTR. Findings from our study support a trend where type of hair surgery could affect FTR and PTR. Though our findings are not statistically significant, post-hoc power calculations from our study would be very useful for sample size determination in future studies whose objective is similar to ours.

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Kinky Hair after FUE Technique: Case Report

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I share this case that was presented during the M&M Session at the 2019 27th World Congress of the ISHRS held in Bangkok. A patient had persistent growth of tortuous hair in the recipient area after the follicular unit excision (FUE) technique.

INTRODUCTION

Kinky hair is an uncommon disorder characterized by flattened, twisted hair fibers at irregular intervals along the hair shaft axis; it can have a genetic etiology, but can also be an acquired condition (e.g., after hair transplantation, cicatricial alopecia, retinoids, repetitive trauma).¹⁻⁴ The etiology of kinked hairs noted in a subset of post-transplantation patients remains an enigma, although mechanical trauma to the hair bulb or hair bulge regions is hypothesized.⁴ This condition seems to be self-limited to 1 to 2 years.¹ Herein, I describe a case of kinky hair induced by hair transplantation, where the use of forceps during the placement of grafts may have been the main cause for this complication. This article discusses the possible factors involved in this abnormality and also ways to avoid this type of unsightly complication.

CASE REPORT

A 30-year-old man, Norwood-Hamilton Class III, presented

FIGURE 1. Donor area of 30-year-old male with Norwood Class III



with the intention to cover his receding temporal area. He was not using topical or systemic medications for hair loss. The evaluation of his donor area demonstrated dense, coarse, and straight hairs (Figure 1). The recipient

area was normal (Figure 2). Hair transplantation using the

FIGURE 2. Patient's normal recipient area



FUE technique was planned. Hairs were harvested from the parieto-occipital areas using a 0.85mm serrated punch, and approximately 1,500 follicular units were transplanted into the frontotemporal balding areas using forceps. The transplanted hair grew twisted, lusterless, and sparsely after 1 year post-surgery. Trichoscopic exam revealed an irregular, intermittent, flattened, and rotated hair shaft in the recipient area (Figure 3).

DISCUSSION

Kinky hair, also known as *pili torti*, is a congenital or

FIGURE 3. On trichoscopic exam, recipient area showed an irregular, intermittent, flattened, and rotated hair shaft.



acquired disorder of the hair shaft where the hair fiber is flattened at irregular intervals and twisted at 180 degrees along its axis.³ The hairs become dry, lusterless, and difficult to groom.^{2,3} This abnormality is best observed in dry trichoscopy and at high magnification.² There are many conditions associated with kinky hair, such as alopecia areata, cicatricial alopecia, hair transplantation, repetitive trauma, retinoid treatment, and systemic sclerosis.² According to Sadick et al, up to 25% of patients who undergo hair transplantation may develop kinked or wavy hair that appears different to their original non-transplanted hairs.¹ This was, however, an observation made in a paper written almost 25 years ago, when attention to proper graft handling was not nearly as recognized. The pathogenic mechanisms of kinky hair after transplantation remain inconclusive, but there are two possible theories. First, damage in the inner root sheath may induce an uneven molding of the hair shaft. Second, perifollicular fibrosis causes rotational forces, distorting the follicle.³ Problematic graft handling such as trauma to the hair bulb, desiccation, transection, or excessive trimming of the graft usually leads to poor graft quality, including kinky hair and poor growth.⁴

FUE grafts are more likely to acquire traumatic injuries because they are "skinny" (typically have less fat around the follicle) and more fragile compared to FUT grafts. When using forceps to place FUE grafts, three types of traumas can occur: bending with insertion, squeezing of grafts, and traumatic forcing of the grafts into the sites.⁴ Each of these mistakes can lead to kinky hair. In the present case, excessive and careless graft handling with forceps during placement might have imposed mechanical stress on the follicles, leading to this hair shaft disorder. To avoid the damage to the bulb region, the use of implanters has been recommended because they are able to safely place grafts with less trauma. Despite the fact that kinky hair is not considered a severe complication (most cases self-correct in 1-2 years), kinky hairs may lead to unaesthetic and unfavorable results.

CONCLUSION

We cannot conclude with certainty that the kinky hair observation in this patient was caused by trauma to the graft, but we suspect this is the reason as it is known that trauma at the bulb region can be responsible for the ap-

➤ BOTTOM OF PAGE 11



Controversies

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The Era of Instant Gratification

The Scene—The Consultation (in person or online)

Patient: Hi. I want a permanent solution to my balding. I don't want to take drugs and I only want to have one surgery. How many grafts can you do in a single session?

Doctor (or consultant): How old are you and how long have you been losing hair?

Patient: I am 27 and losing hair for 3 years. My dad lost all his hair by age 50.

Doctor/consultant: How are you going to prevent future hair loss, as surgery does not achieve this?

Patient: If I lose more hair in the future, I will just shave my head, but I don't want any scars to be visible. Otherwise, can't you just fill up the areas you think will be lost in the future at the same time as the balding area so I only have one surgery?

Doctor/consultant: We are happy to do 3,000-4,000 grafts in a single session but want to leave some in reserve for future needs.

Patient: How many donor grafts do I have?

Doctor/consultant: 7,000-8,000 probably.

Patient: I read online I can have 5,000-6,000 grafts in a single day if I go overseas. Why can't you do this?

These are real questions I get asked all the time during consultations, and it takes a while to explain my rationale for practicing as I do. The era of cosmetic tourism has amplified this as clinics outbid each other in what they perform in a single session to attract more clients. It is important for us to resist the notion of the "easy instant fix" that some of our patients expect.

I was reminded of this at our recent ISHRS meeting in Bangkok when I co-hosted a breakfast table about the long-term aspects of surgical planning. Not a single doctor attended the table! It could perhaps be argued that nobody wanted to hear me bang on about this, but I couldn't help notice that the table discussing body hair grafting was surrounded 3 deep in surgeons!

What are we to make of this? Body hair grafting to me is "donor of last resort" and should rarely come into play as only a small number of patients get to the Norwood VII that would make this a viable strategy. However, if we overuse our scalp hair resources with high-density, low-hairline surgeries, then perhaps all we will have left in the future is beard and body hair.

Our goal should be to provide adequate visual density while considering future needs rather than getting involved in a bidding war with other clinics, especially overseas ones, that only expect to see the client once and therefore use the "sky is the limit" approach to planning. ■

pearance of kinky hair after hair transplant. Risk of traumatic injuries to FUE grafts increases when forceps are used during their insertion. The use of implanters (sharp or dull) is recommended to minimize the trauma that can occur to FUE grafts during their placement in the recipient area. We recommend that surgeons and assistants follow a strict quality control protocol during the placement of grafts to avoid unfavorable results like kinky hair, poor regrowth, and other complications in the recipient area.

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Introduction to the New FORUM ePUB Site

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The electronic journal of the *Hair Transplant Forum International* went live at the end of October 2019. It can be reached at <https://www.ishrs-htforum.org>. I suggest you bookmark the site in your search engine for easy access in the future.

When you open the site, you will see the home page of the *Forum*—The Official Publication of the ISHRS (Figure 1). This site contains all of the content since the first issue in 1990. The opening banner tabs include Home, Content, Info, About Us, and More (in which you can ask for alerts and where you can give feedback) (Figure 2). There are also direct links on the right side to the ISHRS Twitter, Facebook, LinkedIn, Instagram, and YouTube.

In the upper right-hand corner is the login area (Figure 3). The ISHRS headquarters has emailed each member their individual login information. If you haven't seen that email, check again; if you need additional help logging in, please contact ISHRS's Project Manager, Sheri Valskis, at svalskis@ishrs.org, or the ISHRS Headquarters Office at info@ishrs.org.

Immediately below the login is the search bar (Figure 4). You can search by subject, content, or author, and you will discover that the richness of our *Forum*'s content is now at your fingertips.

When you click on the content tab, you will see Current and Archive (Figure 5), and when you select "Archive," the full archive opens up by year (Figure 6). When a year is selected, all of the issues for the year will be shown, and when an issue is selected, it will be fully shown.

When an article is selected, the title, author(s), and DOI designation will be shown (Figure 7). There will also be tabs at the top of the article for Figures and Data, Info and Metrics, and to select a PDF version. On the right-hand side, next to the article will be menus that show the content of the issue and buttons to print the article, download a PDF, get alerts on the article, email the article, or make an article citation (Figure 8). Below this is "Jump to section," which lets you move easily to different parts of the article. And, finally, related content will be shown.

When references are listed at the bottom of an article (Figure 9), they can be accessed directly (if open access) by clicking on the link.

In its current form, the FORUM ePUB is a big step forward to make all of the content available to our members. We are in the process of adding some missing content to the site and making every aspect fully functional such as the top articles, most cited, and most read (Figure 10). Also, this year, the new ePUB will be recognized on journal publishing platforms to further visibility and access.

Currently, only members are able to access full articles. However, the ISHRS Board of Governors believes that some of the articles are so important and foundational to the field that they should be open access and available to the broader medical community. To this end, a volunteer group of past *Forum* editors has reviewed the past 10 years of the *Forum*

and made recommendations on which articles should be open access. When approved by the Board of Governors, we will activate this feature.

Already, the content of the *Forum* is now much more recognizable through internet search engines. By submitting to platforms and providing some open access, the visibility of the *Forum* and the ISHRS to the public and to the medical community at large will be greatly enhanced.

It has been a pleasure and an honor to work on this project. It is rewarding to hear from members that they find the FORUM ePUB to be a significant benefit to the ISHRS membership. I hope you feel the same. ■

FIGURE 1. Home page of FORUM ePUB



FIGURE 2. Content of opening banner



FIGURE 3. Login in upper right corner

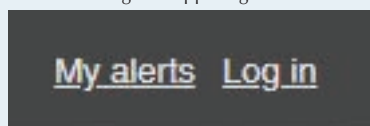


FIGURE 4. Search box upper right

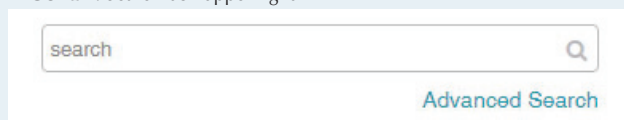


FIGURE 5. Content tab

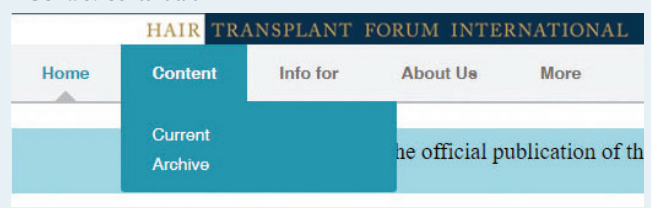


FIGURE 6. View of Archive menu

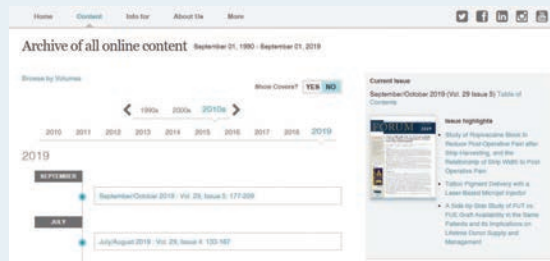


FIGURE 7. Opened article

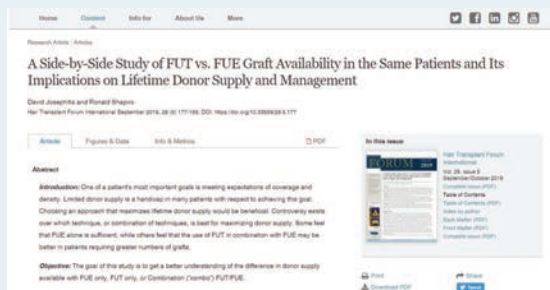


FIGURE 8. Content Bar next to article

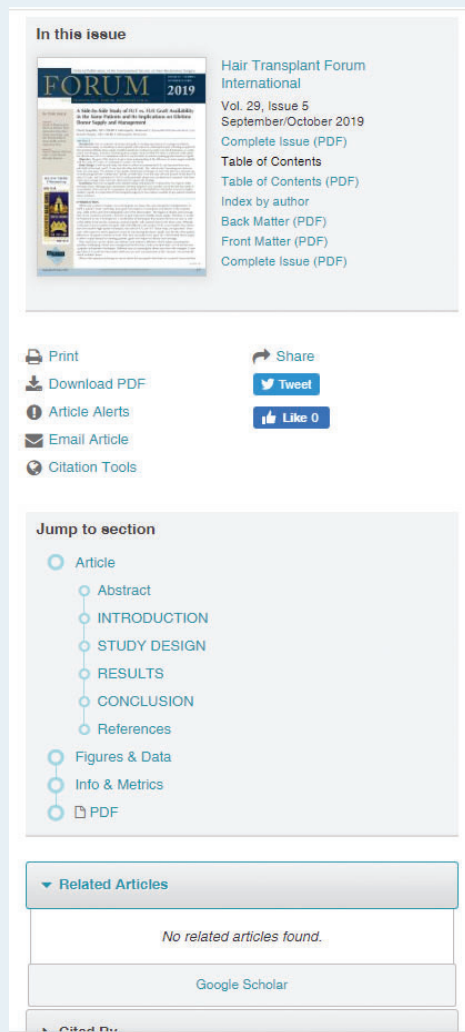


FIGURE 9. Article references with direct links

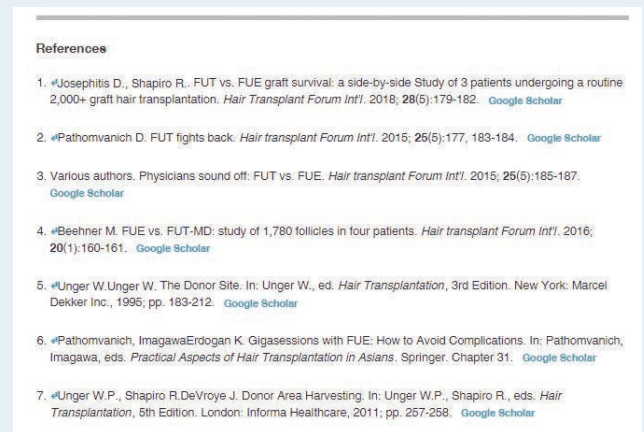
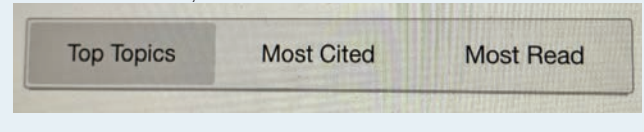


FIGURE 10. Tabs not yet functional





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- New featured articles section
- New! Some articles will be tagged for public viewing



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Medical and Professional Ethics

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Spotlight on the Vulnerable Patient

As hair transplant surgeons, we are in the privileged position of being able to transform the appearance of our patients by restoring their lost hair. In the private sector, fees are charged for doing this and there is therefore a crossover between healthcare and personal gain, between patients and consumers. People come to us asking for our assistance, but there are times when hair transplant surgery might not be in their best interest and their requests should be declined.

The first three paragraphs of the ISHRS Code of Ethics focus on not taking advantage of patients:

- I. The member recognizes that a greater moral responsibility is necessary in cosmetic surgery than in many other fields because of the often lack of oversight by government and/or peer review and the emotional involvement of the patient.
- II. The member acknowledges that he or she is in a position of trust and will not betray that trust.
- III. The member will not take emotional or financial advantage of patients.

Traditionally in medicine, the term “vulnerable patient” is defined as somebody who is permanently or temporarily unable to take care of him or herself and his or her interests, either because of a mental or a physical cause. Vulnerable adults are at risk of psychological and physical harm or being exploited for other people’s benefit.¹ Formally defining patients as vulnerable is contentious and care must be taken to avoid using it pejoratively or in ways that undermine fundamental rights, interests, or freedoms. A clear distinction must be drawn between adults who retain capacity to make decisions and those whose capacity has been lost or impaired.² Many patients seeking hair transplant surgery for genetic male and female pattern hair loss will have full capacity but are still “vulnerable” in the sense that they do not like their appearance, are seeking to change it, and might be susceptible to exploitation. The degree to which they are susceptible is likely to be proportionate to the level of distress felt as a result of their hair loss. This may vary from mild dissatisfaction to extreme dysfunction and social incapacitation.

All patients having a consultation for hair restoration surgery should be asked some basic screening questions to determine the degree of anxiety their hair loss causes and to identify those individuals who might be on the body dysmorphic disorder (BDD) spectrum and require more in-depth psychological assessment. Patients with BDD represent a special category of vulnerability and should not undergo surgery, but separating those high-anxiety patients with BDD from the high-anxiety patients without BDD can be difficult and requires specialist psychologist assistance.



Reflective Questions

- Have I ever suggested a hair transplant surgery procedure to a patient when a voice inside my head was saying, “I don’t think this patient is fully understanding what I am saying”?

It has been shown that pressure from the mass media to conform to the muscular “ideal” male body affects men’s self-image.³ The UK’s National Confidential Enquiry into Patient Outcome and Death (NCEPOD) publication “On the Face of It” concluded that “bulk emailing, pop-ups, social networking sites and web based advertisements may be more likely to influence groups of patients more vulnerable to suggestion,”⁴ but little research has been done on the impact of media images and advertising on men’s self-image to do with hair loss.

Many young men in their early twenties are very distraught about their maturing hairlines and temporal recedings, and they can be extremely insistent on addressing these with hair transplantation. I find assessing the risk of advanced hair loss and convincing this group of vulnerable patients to wait, consider topical and oral medication or other non-surgical options, and not have early surgery, is one of the most challenging aspects of being a hair transplant surgeon. Whilst we would hope that patient welfare would always be a doctor’s primary concern, more commercially centered clinics might take advantage of these young men by offering surgery in order to increase profits. Desperate patients may seek out these clinics if they have been turned down elsewhere.

Equally, women presenting with thinning hair at any age can be deeply affected emotionally, but the responsible hair transplant surgeon will adequately evaluate them for non-surgically treatable causes prior to quoting for a hair transplant surgery procedure and will decline those female patients who not suitable.

Language barriers can mean communication with patients may be compromised and in this sense, if you can’t explain the pros and cons of different surgical and non-surgical options, along with setting appropriate expectations, then a person who has full capacity in their native tongue might be vulnerable in a country where they don’t fully understand the language. This is true in the case of health tourism: patients travel seeking cheaper surgery, but when they get to their destination they find they cannot communicate adequately with the doctor or staff. This leads patients to make unwise decisions because they feel under pressure having traveled and spent money doing so.

What about special circumstances? I recently had a blind Norwood V patient who was seeking hair restoration. Whilst

I was confident that I could make a big difference in his appearance, what would be the parameters by which he would judge the result? I insisted that he bring an advocate with him to the consultation, and that the same advocate would come to all follow-up consultations and be the patient's nominated person to assess the result by proxy. But can one person really judge the "success" of a hair transplant for the person having it done? A mediocre technical result might exceed one patient's expectations whereas an above average aesthetic result might be disappointing to a patient who had higher expectations. This patient said he will judge the result by feel and will be happy just to be able to run his hands through hair on the top of his head again. He was gainfully employed and had full "capacity." What would you do in this situation?

What if an adult patient with learning difficulties presents to you requesting hair transplant surgery? Should they be discriminated against because they don't understand the nuances of your consenting process? Does the appearance of their hair matter any less to them than the appearance of how they dress? If they are otherwise well groomed and presented, then why shouldn't they have hair restoration if that is what they want? If they chipped a tooth, would they be denied cosmetic dental care?

Identifying vulnerable patients and not taking advantage of them should be a hallmark of all ISHRS members. As part of informed consent, the option of doing nothing should always be mentioned since, contrary to surgical patients with life-threatening conditions, no patient with hair loss "has to have surgery." Determining a patient's capacity to make decisions must always be assessed and if compromised, an appropriate responsible individual must be involved. Patients with capacity but whose understanding of the consent process is limited for any reason, whose ability to judge the outcome is impaired, or whose emotional state compromises rationale thought, should not be taken advantage of. To suggest delaying a decision for surgery whilst further evaluation is performed to determine vulnerability is always a wise ethical approach but may not be good for business!

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MEMBER SANCTIONS FOR ETHICAL VIOLATIONS

All ISHRS members agree to adhere to the Code of Ethics, Bylaws, and other ISHRS rules and regulations. When a violation occurs, the ISHRS follows its outlined due process. The ISHRS takes ethical violations seriously. The following sanctions were imposed in 2019:

1. Turkey: Membership suspended due to failure to deny inappropriate delegation.
2. Thailand: Membership terminated due to violation of the ISHRS's Ancillary Meetings Policy.
3. Turkey: Membership suspended due to misleading and inappropriate messaging.

All members are encouraged to be familiar with the Code of Ethics, Bylaws, Red Flags for Inappropriate Messaging, Qualifications for Scalp Surgery, and other ISHRS rules and regulations.

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Hair Sciences

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The Science Behind Using Exosomes as Treatment for Hair Loss: Review of Paper Showing That Exosomal Micro RNAs Induce Hair Follicle Stem Cell Proliferation and Differentiation

Based on the excitement at the recent Bangkok World Congress surrounding the use of exosomes as injectable therapy for hair loss, this month's column will review a paper discussing exosomes entitled, "Exosomal Micro RNAs Derived from Dermal Papilla Cells Mediate Hair Follicle Stem Cell Proliferation and Differentiation."¹ In this article, Yan and colleagues investigated how exosomes might regulate hair follicle growth using a model of Shaanbei White cashmere goats. More specifically, the authors employed micro RNA (miRNA) high-throughput sequencing to determine what kind of miRNA transcripts were expressed in dermal papilla cell-derived exosomes (DPC-Exos). The authors concluded that DPC-Exos regulate hair follicle stem cell (HFSC) growth and differentiation through genes involved in cellular signal transduction, fatty acid regulation, and cellular communication.

BACKGROUND

Exosomes are nano-sized extracellular vesicles that take part in cell-to-cell communication. Exosomes transport miRNA, messenger RNA (mRNA), and transcription factors to nearby cells, thereby influencing their function. DPC-Exos have been shown to promote anagen stage and delay catagen stage in hair follicle growth and to stimulate the proliferation and differentiation of outer root sheath cells.² Through mediation of gene silencing, miRNAs play a key role in regulating cellular functions including proliferation, differentiation, and even hair follicle development and periodic growth.³ This article aimed to examine the differences between miRNA expression profiles in DPC-Exos and DPCs in hair follicles (HFs) from Shaanbei White cashmere goats.

The key findings included the following:

1. HFSCs are located in the bulge area of HFs.⁴ Flow cytometry was used to isolate HFSCs from the bulge area of cashmere goat HFs. These HFSCs displayed the appropriate HFSC markers such as CD34, K15, and ITGβ1.
2. Exosomes were isolated from cashmere goat DP cells using a methodology of differential ultracentrifugation.⁵ Western blot showed that the DPC-derived extracellular vesicles (DPC-EVs) contained the exosome-specific marker CD63.
3. Nanoparticle tracking analysis with the Nanosight instrument demonstrated that the DPC-EV particle size was approximately 124nm. Transmission electron

micrography further verified the presence of DPC-EVs and determined that the EVs morphologically appeared to be exosomes.

4. Using an *in vitro* transwell system and Dil, a fluorescent dye used to label DPCs, the authors demonstrated the uptake of Dil-labeled DPC-Exos by HFSCs and that the exosomes produced by DPCs can be internalized by HFSCs.
5. Using H&E analysis, the authors showed that DP cells migrate closer to HFSC in the bulge area during telogen. The authors postulated that this critical and necessary interaction for new HF development may be mediated by DPC-Exos interaction with HFSC. However, there was no data to back up this claim other than the *in vitro* data noted above.
6. Using high-throughput sequencing, a technology that facilitates sequencing multiple miRNA molecules in parallel, the authors showed that 111 miRNAs were differentially regulated between DPCs and DPC-Exos.
7. Gene ontology analysis of genes targeted by the differentially expressed miRNAs between DPCs and DPC-Exos showed that these genes were involved in pathways of proliferation and differentiation of HFSCs and hair development.
8. Exosomal-enriched miRNAs targeted genes related to HF differentiation including *Dlx3*, *Foxn1*, *Hoxc13*, and the Wnt antagonist *Sostdc*. One miRNA enriched in DPC-exos, miR-22-5p, targets multiple genes that are important for HF and hair shaft formation. The proliferation of HFSC significantly decreased when transfected with miR-22-5p. Also, cell cycle distribution analysis showed that overexpression of miR-22-5p induced HFSC arrest in the S phase. Further analysis showed that the miR-22-5p targets the *LEF1* gene.

Collectively, the data presented in this article showed that exosomal miRNA may play a key role in targeting genes and cellular pathways that are essential for HFSC proliferation and differentiation. The authors likely used a cashmere goat model since one of their research goals might be to increase the yield and diameter of cashmere fibers produced by these goats. However, these study results may be applicable in the field of non-surgical treatment for alopecia using exosomes since similar mechanisms of exosomal regulation on HF and

HFSC may exist in humans. It would be important to try to replicate the findings in this study using a human HF and HFSC model. Also, changes in miRNA and gene expression should be verified to have an effect on protein expression and cellular functions in order to prove physiologic significance. As the clinical practice of using injection of exosomes for treatment of hair loss develops, it is important from the research standpoint to identify what components of the exosomes (miRNA, mRNA, or transcription factors) are responsible for the clinical benefit. Once that is discovered, these components can be further isolated with the goal of producing an even more targeted hair loss treatment.

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AtoZ has acquired the HARRIS instrument product line.



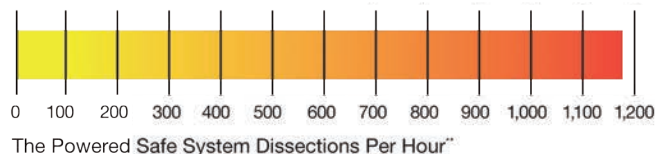
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Editors' note: While therapy using exosomes is generating a lot of interest, and is the subject of this issue's "Hair Sciences," it is important for physicians to be familiar with the FDA advisory on exosomes. —The Editors

The below is reprinted from the U.S. Food & Drug Administration website at <https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/public-safety-notification-exosome-products>. The content is current to December 6, 2019.

Public Safety Notification on Exosome Products

December 6, 2019

The Food and Drug Administration (FDA) is informing the public, especially patients, health care practitioners, and clinics, of multiple recent reports of serious adverse events experienced by patients in Nebraska who were treated with unapproved products marketed as containing exosomes. These reports were brought to the agency's attention by the Centers for Disease Control and Prevention, among others, and the agencies worked with the Nebraska Department of Health and Human Services. FDA is carefully assessing this situation along with our federal and state partners.

There are currently no FDA-approved exosome products. Certain clinics across the country, including some that manufacture or market violative "stem cell" products, are now also offering exosome products to patients. They deceive patients with unsubstantiated claims about the potential for these products to prevent, treat or cure various diseases or conditions. They may claim that they these products do not fall under the regulatory provisions for drugs and biological products – that is simply untrue. As a general matter, exosomes used to treat diseases and conditions in humans are regulated as drugs and biological products under the Public Health Service Act and the Federal Food Drug and Cosmetic Act and are subject to premarket review and approval requirements.

The clinics currently offering these products outside of FDA's review process are taking advantage of patients and flouting federal statutes and FDA regulations. This ultimately puts at risk the very patients that these clinics claim to want to help, by either delaying treatment with legitimate and scientifically sound treatment options, or worse, posing harm to patients, as evidenced by these recent reports of adverse events.

Health care professionals and consumers should report any adverse events related to exosome products or any other unapproved product to the FDA's MedWatch Adverse Event Reporting program. To file a report, use the MedWatch On-line Voluntary Reporting Form. The completed form can be submitted online or via fax to 1-800-FDA-0178. FDA monitors these reports and takes appropriate action necessary to ensure the safety of medical products in the marketplace.

Patients considering treatment with exosome products in the United States should:

- Ask if the FDA has reviewed the treatment. You also can ask the clinical investigator to give you the FDA-issued Investigational New Drug Application (IND) number and the chance to review the FDA communication acknowledging the IND. Ask for this information before getting treatment and follow up with your personal health care provider to confirm this information.
- Request the facts and ask questions if you don't understand. To participate in a clinical trial that requires an IND application, you must sign a consent form that explains the experimental procedure. The consent form also identifies the Institutional Review Board (IRB) that assures the protection of the rights and welfare of human subjects. Make sure you understand the entire process and known risks before you sign. You also can ask the study sponsor for the clinical investigator's brochure, which includes a short description of the product and information about its safety and effectiveness.

Patients considering treatment using an exosome product in another country should:

- Learn about regulations that cover products in that country.
- Know that FDA does not have oversight of treatments done in other countries. FDA typically has little information about foreign establishments or their products.
- Be cautious. If you're considering an exosome product in a country that may not require regulatory review of clinical studies, it may be hard to know if the experimental treatment is reasonably safe.

FDA remains committed to protecting patients. Our work to ensure compliance with the law does not take away from our firm commitment to advance an efficient path for the safe and effective development of novel regenerative medicine therapies and to help foster beneficial new innovations. We'll continue to work closely with investigators and firms legitimately working in this field and will do so in the most effective manner possible, while meeting the FDA's standards for safety and efficacy. We look forward to working with those who share our goal of bringing safe and effective products to market to benefit individuals in need.

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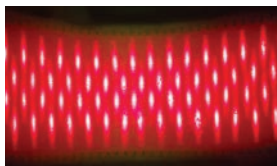
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A collection of white, cylindrical hair transplant tools with various colored caps (blue, green, red, black) lying on a light-colored, textured surface.

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Literature Review

Aditya K. Gupta, MD, PhD, FISHRS | London, Ontario, Canada | agupta@execulink.com

Oral Minoxidil for Female Pattern Hair Loss

Ramos, P.M., et al. Minoxidil 1mg oral versus minoxidil 5% topical solution for the treatment of female-pattern hair loss: a randomized clinical trial.

JAAD. 2019; 82(1):252-253.

There are limited options for women seeking therapy for female pattern hair loss (FPHL). Low-dose (0.25-1.25mg/d) topical minoxidil has limited efficacy and is associated with negative side effects such as altered hair texture. Thus, there is a need to identify new treatments for FPHL.

Ramos et al. investigated low dose oral minoxidil as a suitable alternative therapy for FPHL. Using a 24-week, randomized, open study design, the authors compared the efficacy of 1mg oral minoxidil to a 5% solution of topical minoxidil, each given once daily for 24 weeks. By evaluating hair density before and after treatment in 52 patients, the authors found that hair density increased with both treat-

ments and there was no statistically significant difference between the effectiveness of oral vs topical minoxidil. Oral minoxidil demonstrated a safe profile and was well-tolerated by the study participants. Adverse events reported were increased mean resting heart rate (6.5% increase without tachycardia), mild hypertrichosis (27% of participants), and pretibial edema (4% of participants).

Comment: This study demonstrates that oral minoxidil has potential to be a suitable alternative to topical minoxidil when treating FPHL, especially for women who do not wash their hair every day, making topical treatment compliance difficult. Most adverse events were well-tolerated, however, the possibility of serious cardiac side effects for those with preexisting cardiac disease should be noted.

Since this is a relatively small study, confirmation of the efficacy and safety of this treatment in a larger population is required. Additionally, since therapy would need to be continued indefinitely to maintain the effect, there needs to be an assessment of the long-term safety of oral minoxidil in women. ■

Topical Finasteride for Treatment of AGA

Lee, S.W., et al. A systematic review of topical finasteride in the treatment of androgenetic alopecia in men and women. *J Drugs Dermatol.* 2018; 17(4):457-463.

Oral finasteride is an FDA-approved treatment for AGA in men; however, this drug has several sexual side effects that can dissuade patients from taking it. Additionally, this therapy is not recommended for women of childbearing age due to its teratogenic potential. Thus, clinicians and researchers have been investigating whether topical finasteride is an effective and safe option for treating AGA in both men and women.

Lee et al. evaluate seven studies that explored the efficacy and safety of topical finasteride for the treatment of AGA in men and women. The concentrations of topical finasteride tested in these studies were 0.005%, 0.25%, and 1%, and all showed promising efficacy potential with limited systemic effects and no reported serious side effects. Topical finasteride 0.25% solution applied once daily appeared to

be the most effective preparation and frequency of application. Overall, the authors concluded that topical finasteride seems to be comparable to oral finasteride for promoting hair regrowth while minimizing unwanted adverse effects associated with the oral preparation.

Comment: There are only a small number of studies that have investigated the effectiveness of topical finasteride, but considering the promising results, larger, longer-term studies are warranted to confirm the efficacy and safety of this therapy. Although topical finasteride may avoid the more serious side effects of the oral preparation, participants of the studies did complain of scalp irritation, which is also a complaint of topical minoxidil therapy. Perhaps, larger randomized controlled trials could be performed with a view to getting topical finasteride FDA approved as a therapy for AGA. Adding topical finasteride to the therapeutic options available will provide more options for AGA treatment. ■

Sulfotransferase Activity Predicts Response to Minoxidil

Ramos, P.M., et al. Sulfotransferase activity in plucked hair follicles predicts response to topical minoxidil treatment in Brazilian female pattern hair loss patients. [Published online ahead of print, 2019 Dec 17.]

Dermatol Ther. 2019; 10.1111/dth.13195.

The only treatment approved by the U.S. Food and Drug Administration (FDA) for female pattern hair loss (FPHL) is topical minoxidil, which is successful in less than 40% of female patients. Minoxidil is converted to minoxidil sulfate by the sulfotransferase enzyme found in the outer root sheath of the hair follicle, the efficacy of which varies among individuals. Therefore, researchers have been investigating whether hair follicle sulfotransferase activity is predictive of response to minoxidil treatment in different populations.

Ramos et al. conducted an open label study with 8 female Brazilian participants with Sinclair Stage II-IV FPHL applying 5% topical minoxidil once daily for 24 weeks. An increase or

decrease in patient hair density determined responsiveness or non-responsiveness, respectively, to topical minoxidil treatment, while sulfotransferase activity was determined on participant anagen hair follicles. Low sulfotransferase activity was found to be directly correlated to non-responsiveness to minoxidil therapy. Therefore, the authors concluded that sulfotransferase activity is a predictive value of responsiveness to minoxidil therapy in Brazilian patients with FPHL.

Comments: This study contributes to the growing body of evidence that sulfotransferase activity is a vital factor in minoxidil treatment. These results support the utility of testing sulfotransferase activity in the clinic prior to topical minoxidil therapy, especially in females, to save time and cost of treatment of inherent non-responders. Moreover, this work highlights sulfotransferase as a novel target for hair loss therapies—enhancing sulfotransferase activity in non-responders could increase the efficacy of topical minoxidil in this population. ■

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Video is one of the biggest opportunities to market yourself in 2020. According to Social Media Week, check out some of these staggering statistics:

- ✓ By 2022, the number of videos crossing the internet per second will approach 1 million translating into 82 percent of all online traffic.
- ✓ Video consumption on mobile devices rises a whopping 100% each year.
- ✓ 78% of people report watching videos online each week while 55% of those watch on a daily basis.
- ✓ More than half (54%) demand more video content on top of what they already consume.

To help you get a jump start on video, Konstantinos Anasstasakis, MD, PHD, FISHRS, President of the Hellenic Academy of Hair Restoration Surgery, will be presenting a webinar on video marketing. His Greek YouTube channel has 179 videos with over 3 million views and he attributes much of his success to this platform and in this country of just 11 million people! Imagine what you can do in your own language or in English!

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Letter to the Editors

Re: Black Market vs good doctors using RNs and Physician Assistants (PAs) to do their surgery

William R. Rassman, MD | Los Angeles, California, USA | williamrassman@gmail.com

I believe we are blurring the lines between the issue of delegating components of the surgery, which are legal in some of the states or countries where we practice (Delegation), versus addressing the Black Market, which to me means anyone doing hair transplants who either is not licensed nor trained to do so. Given that there are many competent, knowledgeable doctors who choose to delegate FUE or direct percutaneous implantation, for example, we are tossing them into the same basket as the Black-Market operators who can actually harm their patients because of poor patient selection criteria or because they don't have the skills to manage the diagnostic and surgical process along with all of the possible risks during surgery. I have noted some examples below.

Example 1

The 40-year-old father of two small children died in California during a hair transplant a few years ago. The doctor was a licensed resident-in-training at a local residency training program (moonlighting to subsidize his income) who performed the surgery under the supervision of a chiropractor who hired him and whose technicians aided him step-by-step (including anesthesia) through the hair transplant process. The chiropractor's goal was to have a licensed doctor be responsible for the surgery (the chiropractor was previously admonished by the Medical Board of California for doing the surgery himself and forbidden to do so in the future). The doctor had no training in either the anesthesia required for the hair transplant or the surgery. I was told that the patient apparently died on the table, yet nobody knew he was dead until the end of the surgery when they tried to wake him up. I suspect he had overdosed on Marcaine. The California Medical Board took away the doctor's license but the clinic was still allowed to function. I call this a Black-Market example in California of an individual (a chiropractor) profiting from the practice of medicine with an untrained (yet licensed) doctor. This exact same scenario would be

comparable to a licensed MD who agreed to allow his patients to receive surgery from a hired team of technicians who would work in his office to do the entire surgery from design of the hairline, to administering analgesics and anesthesia, to FUE, to managing complications during the surgery, to completion of the surgery (the doctor may or may not be in the office at the time of the surgery). The use of the ARTAS® Robotic System, NeoGraft®, or SmartGraft technology does not change the logistics of this type of illegal process.

Example 2

Let me postulate a situation where a well-known hair transplant surgeon—with years of performing strip surgeries—can't adapt to the FUE technique (eyesight, tremor, too old to learn, doesn't like doing the FUE procedure), so he hires a well-trained and skilled RN or PA to perform the FUE for him (he may or may not be able to financially justify the purchase of an ARTAS robot). In this situation, the patient would be properly evaluated, be an appropriate candidate for the hair transplant, and have a number of grafts estimated that were determined based upon the surgeon's extensive experience performing strip surgeries. This surgeon would be present during the surgery and perform the anesthesia himself. His facilities would be up to the highest standards for modern surgical techniques, he would design the hairline and make the recipient sites. The use of the ARTAS robot can substitute for the RN or PA in this example. The ARTAS robot here, becomes the RN or PA substitute.

Comment

These stark examples are put forward for contrast. The Delegation situation (Example #2) is clearly on the opposite side of the spectrum as the Black-Market case (Example #1). I strongly believe that Example #1 falls into the Black-Market situation because 1) it is illegal, 2) it is amoral, and 3) it does not guarantee patient safety during the surgery, a natural hairline, good patient planning, or proper donor area management. Example #2 addresses the use of RNs, PAs (if this is legal in the state or country), and the ARTAS robot (an RN, PA, or skilled MD substitute). ■

IN REPLY...

Editors' note: Dr. Paul McAndrews, Vice President of the ISHRS, was asked to write a commentary on this letter to the editors.

Paul J. McAndrews, MD, FISHRS | Pasadena, California, USA | doctor@hairgrowthdoctor.com

There is a lot of intentional "blurring" being created in the field of hair transplantation today for nefarious reasons centered on financial gain. The two erroneous and egregious arguments are 1) FUE hair transplant is not even a surgery, and 2) the new FUE devices make it okay to delegate the procedure to individuals without a medical license.

The "Fight the FIGHT Campaign" (FTFC) is not about restricting any motorized FUE surgical drill device or about restricting the legal delegation of certain parts of the hair transplant surgery. The FTFC has always been about bringing

awareness to what is the illegal practice of medicine by unlicensed medical assistants/hair transplant technicians. These hair transplant technicians have **absolutely no medical license recognized by any governing medical board** throughout the world, even though they may have pretty certificates printed out for them by these medical device companies. These device companies have no authority to provide medical licenses to practice medicine. The FTFC was created to bring public awareness to the illegal practice of medicine that is being promoted by unlicensed technicians, unethical doctors, and unethical FUE medical device companies who are egregiously motivated by financial gain. When making

medical decisions that could affect the rest of a patient's life, financial gain should take a back seat to "doing what is in the best interest of the patient."

In California, as well as in the majority of the rest of the United States, a person practices medicine when he or she tries to diagnose or cure an illness or injury, prescribes drugs, or recommends/performs surgery. Practicing medicine requires a state medical license. A person that is not a licensed physician is in criminal violation of the law if he/she conducts surgery or any other procedure on another person that *punctures the skin* or harmfully invades the body. The practicing physician can delegate certain tasks under his/her direct supervision. The complexity of the medical evaluation/treatment allowed to be delegated is predicated by the level of medical training a certain office staff possesses. There are immense differences in the medical training between a Medical Assistant (MA) (i.e., a hair transplant technician), a Nurse Practitioner (NP), and a Physician Assistant (PA). An HT technician (MA) does not have to graduate from any school (even high school), doesn't have to pass any test, and is not licensed/certified by any medical governing body. On the other hand, NPs and PAs have ascending levels of training that enable them to practice medicine on more complex issues under the direct supervision of a physician who is practicing within his/her own scope of practice. These licensed medical personnel (NP and PA) have graduated with advanced graduate degrees and are licensed medical professionals with their own malpractice insurance.

The California Medical Board has classified the personnel in a medical office and defined what can be delegated to that type of personnel as noted below:

Medical Assistant (MA) (i.e., Hair Transplant Technician)

The classification of medical assistant (i.e., hair transplant technician) is defined under the provision of the Medical Practice Act as a person who may be unlicensed who performs basic "technical supportive services" under the supervision of a licensed physician. Under the law, "technical supportive services" are simple, routine medical tasks and procedures that may be safely performed by a medical assistant who has limited training and who functions upon authorized specific written instruction and under the supervision of a licensed physician.

An MA may not diagnose, treat, or perform any task that is invasive or requires assessment. It also states specifically MAs are not allowed to administer local anesthesia (i.e., lidocaine). The California Medical Board also specifically states it is illegal for MAs to perform "microdermabrasion" that goes into deeper layers of the epidermis (below the stratum corneum).

The cutting/excision of the donor scalp tissue used by every FUE tool used in hair transplant surgery not only cuts through the complete epidermis and dermis but goes into the subcutaneous (SQ) tissue to obtain a potentially viable transplantable hair follicle graft. This procedure inevitably severs blood vessels/nerves and creates scars each and every time the FUE motorized drill cuts through the scalp in order to obtain a hair graft. These FUE motorized drills leave thousands of full-thickness wounds on the scalp that each heal with a scar. The more times these motorized surgical drills cut out pieces of scalp, the more scar tissue is left in

donor region. An argument could be made that these sharp motorized surgical FUE drills are much more invasive than strip FUT HT surgery since more scalp tissue is exposed to a cutting blade with FUE, which creates more surface area of scar tissue. The thousands of recipient site incisions *also* cut all the way through the skin and into the SQ tissue, which inevitably severs vessels and nerves. These two segments of the hair transplant are by definition "**surgery**."

Nurse Practitioners (NPs) and Physician Assistants (PAs)

NPs and PAs are licensed allied health care providers. The scope of their practice is limited by their supervising physician. Whatever medical specialty a physician practices (e.g., general practice, cardiothoracic surgery, dermatology, etc.) limits the PA's/NP's scope of practice. A physician cannot supervise an allied health care professional when the surgery is outside his/her scope of practice. The written and signed **Delegation of Services Agreement** between the PA/NP and the supervising physician then further defines exactly what tasks and procedures a physician is delegating to the PA or NP. These tasks and procedures must be consistent with the supervising physician's specialty or **usual and customary practice** and with the patient's health and condition. Before authorizing a PA/NP to perform any medical procedure, the physician is responsible for evaluating the PA's/NP's education, experience, knowledge, and ability to perform the procedure safely and competently. PAs/NPs **cannot practice independently**. Every PA and NP must be supervised by a licensed physician (either MD or DO). The supervising physician is responsible for all medical services provided by a PA/NP under his/her supervision and for following each patient's progress.

Surgical Medical Devices

Surgical medical devices (motorized and robotics) are NOT considered unlicensed or licensed allied health care providers.

There are many different manufacturers of manual, motorized, and robotic devices used in FUE hair transplant surgery. These instruments are inanimate objects that have no capability to receive advanced medical degrees in order to substitute for an MD, NP, or PA in the practice medicine. I know of NO state or country's medical regulatory body that authorized a medical device to practice medicine. The motorized surgical drills used in FUE hair transplant surgery permanently cut out thousands of full-thickness, potentially viable hair-bearing skin grafts and replace them with scar tissue. For example:

1. The ARTAS Robotic System is an FUE device that is categorized as a Class 2 device and received a 510(k) clearance for the below:
 - **Indication of Use:** Harvesting hair follicles from the scalp of men diagnosed with androgenetic alopecia who have black or brown straight hair (**It is not indicated for or have clearance for females, other hair loss etiologies, white hair, red hair, curly hair, or hair on other parts of the body.**)
 - **Intent of Use:** To assist physicians in identifying and extracting hair follicular units from the scalp during hair transplantation, creating recipient sites, and implanting harvested hair follicles (**It does not state that it is a substitute for the physician, PA, or NP. It also does not state its intent of use is "to assist the unlicensed hair transplant technician."**)

2. The motorized surgical drills with suction devices and tissue storage containers used in FUE hair transplant surgeries, such as NeoGraft and SmartGraft, are categorized as a Class 1 device (e.g., a surgical scalpel is a Class 1 device). Class 1 devices have much less regulation and do not need to get 510(k) clearance describing the “Indication and Intent of Use.” These FUE surgical drills are probably misclassified and should have the additional clearances of a Class 2 device. A surgical scalpel is a Class 1 device, however, this does not make it okay for an unlicensed medical assistant (i.e., an HT technician) to cut out tissue from a live human; this is illegal and criminal in every state, and any doctor allowing this to happen in his/her office is “aiding and abetting the unlicensed practice of medicine”—the same goes for sharp motorized surgical drills used in FUE.

The motorized surgical drills used in FUE hair transplant surgery do not have the ability to reason or make educated medical decisions; it is just a motorized sharp rotational drill/scalpel that cuts through tissue. The person using the motorized drill should have the medical license, knowledge, surgical skills, and judgment. If the drill is slightly offline, the transplantable tissue can be destroyed. In the wrong hands, these motorized FUE drills could have grave consequences to the patients; there was a recent death involving FUE hair transplant surgery.

The making of surgical incisions in the recipient area is also vitally important for graft survival and naturalness of the procedure. These surgical incisions dictate 1) where the transplanted graft will go and potentially grow forever (placed in the wrong area, it will look unnatural as the patient ages and the hair loss progresses); 2) the angle and direction the transplanted graft will eventually grow, which is vital to the naturalness of the results; and 3) the allocation of what is a limited supply of donor hairs.

Considering the cosmetic and medical risks, these critical steps of the hair transplant surgery should not be delegated to an MA or licensed medical professional (PA or NP) practicing outside their scope of training or unsupervised.

Below are a few medical boards and societies and how they define hair transplant as a surgical procedure and their delegation policies:

The **American Medical Association (AMA)** states: “Hair restoration procedures, including surgical excisions, can only be performed by a licensed physician who meets appropriate professional standards and cannot be delegated to other health care professionals. It has been brought to the attention of the AMA by the International Society of Hair Restoration Surgery that some hair restoration companies have been advising physicians that hair restoration procedures, including surgical excisions, can be delegated to non-physician health care providers in their office. This is contrary to AMA policy. The AMA clearly defines surgery to include the incision or destruction of tissues, as well as the diagnostic or therapeutic treatment of conditions or disease processes by any instruments causing localized alteration or transposition of live human tissue, which include lasers, ultrasound, ionizing radiation, scalpels, probes and needles. Surgical procedures can only be performed by a licensed physician who meets appropriate professional standards and cannot be delegated to other health care professionals.”⁴¹

The **Medical Board of California** states: “Hair restoration surgery is the practice of medicine in California and may only be performed by properly-trained, licensed physicians and surgeons or licensed allied health care providers authorized to perform such procedures within their scope of practice. Companies may be marketing surgical devices to physicians indicating that hair restoration surgery is a delegable procedure, causing confusion about who may use such devices in California. Physicians may not delegate hair restoration surgery to medical assistants, who are unlicensed individuals with a very limited scope of practice pursuant to Business and Professions Code sections 2069 and 2070 and Title 16 of the California Code of Regulations section 1366. Medical assistants may not perform invasive procedures such as creating holes or slits in a patient’s scalp with a needle, scalpel, or other device. No unlicensed person may perform these procedures in California, including those using titles such as hair restoration technician, surgical technician, hair restoration assistant, or any other title. California’s Business and Professions Code section 2052 prohibits the practice of medicine by unlicensed individuals, as well as aiding and abetting the unlicensed practice of medicine. Violation can result in a fine of up to \$10,000, imprisonment, or imprisonment in county jail for up to a year or both the fine and either imprisonment.”⁴²

The **International Society of Hair Restoration Surgery (ISHRS)** states: “The position of the International Society of Hair Restoration Surgery is that any procedure involving a skin incision for the purpose of tissue removal from the scalp or body, or to prepare the scalp or body to receive tissue, (e.g., incising the FUE graft, excising the donor strip, creating recipient sites) by any means, including robotics, is a surgical procedure. Such procedures must be performed by a properly trained and licensed physician. All FUE harvesting tools, including robotic devices, are considered extensions of the hand of the operator, and as such, all operators of these devices must be physicians.

Physicians who perform hair restoration surgery must possess the education, training, and current competency in the field of hair restoration surgery. The ISHRS believes the following aspects of hair restoration surgery should only be performed by a licensed physician: 1) preoperative diagnostic evaluation; 2) surgery planning; 3) surgery execution including: donor hair harvesting, hairline design, recipient site creation, and management of other patient medical issues and possible adverse reactions; and 4) post-operative care

The ISHRS recognizes the delegation of the listed aspects of hair restoration procedures as follows: in some countries, accredited health professional groups, for example, Physician Assistants (U.S.), Physician Associates (U.K.), Nurse Practitioners (U.S. and U.K.), Surgical Care Practitioners (U.K.), are licensed to perform medical and surgical procedures under specific criteria. These health professionals are accountable to their licensing authority for unethical conduct. In these countries, the ISHRS recognizes that such professional groups are practicing legally, and the ISHRS approves of this as long as they are practicing within the scope of their license and under the supervision of a licensed physician who performs hair surgery and possesses the education, training, and current competency in the field of hair restoration surgery.

*The ISHRS believes it is unethical for an individual to travel to a state and/or country in which he or she is not licensed and perform the surgical aspects of hair restoration. The ISHRS also believes it is unethical for a doctor to train an individual to perform surgery who is not an accredited health professional licensed to do so. ISHRS members are required to agree to and abide by the ISHRS Code of Ethics and ISHRS Position Statement on Qualifications for Scalp Surgery. Violators will be subject to disciplinary actions.”*³

The ISHRS recently surveyed its members about this position statement. **Over 90% of the responding members either Strongly Agreed or Agreed with the Position Statement.** Only 7% Disagreed or Strongly Disagreed with the Position Statement. The ISHRS not only demands its members practice medicine within the law, it also desires its members to be at the forefront of the medical and surgical treatment of hair loss and to do what is in the best interest of their patients. The delegation of certain parts of the hair transplant surgery is very consistent with the ISHRS's Fight the FIGHT Campaign. What is being intentionally blurred for nefarious reasons is *which parts* of the hair transplant surgery can be delegated and *to whom* they can be delegated.

The state of California (along with other states and countries) has made it perfectly clear stating a hair transplant is a surgical procedure and cannot be delegated to unlicensed technicians. The provision of the Medical Practice Act (Business and Professions Code sections 2052) states:

- a. Any person that does not have a valid, unrevoked, or unsuspended “physician’s and surgeon’s certificate” issued by the state of California who diagnoses, treats, operates, or prescribes on a patient is in violation of

California law and is punishable to a fine not exceeding \$10,000, by imprisonment pursuant to subdivision (h) of Section 1170 of the Penal Code, by imprisonment in a county jail not exceeding one year, or both the fine and either imprisonment.

- b. Any person who conspires with or aids or abets another to commit any act described in subdivision (a) is guilty of a public offense, subject to the punishment described in that subdivision.

California and other states/countries are taking a stand against the unlicensed practice of medicine and doctors who are aiding and abetting the unlicensed practice of medicine. The ISHRS's “Fight the FIGHT Campaign” is taking the same ethical and legal stand.

References

1. American Medical Association Policy Finder. Surgical Assistants other than Licensed Physicians H-475.986 (2013). <https://policysearch.ama-assn.org/policyfinder/detail/h-475.986?uri=%2FAMADoc%2FHOD.xml-0-4320.xml>. See also: American Medical Association. Practicing Medicine by Non-Physicians H-160.949 (2014). <https://policysearch.ama-assn.org/policyfinder/detail/H-160.949?uri=%2FAMADoc%2FHOD.xml-0-763.xml>
2. Warning: Hair Restoration Surgery Requires a Medical License. *Medical Board of California News*. 2019(Summer), Vol. 151, p. 12. <https://www.mbc.ca.gov/Download/Newsletters/newsletter2019summer.pdf>
3. ISHRS Position Statement on Qualifications for Scalp Surgery. November 13, 2019. <https://ishrs.org/ishrs-position-statement-on-qualifications-for-scalp-surgery/> ■



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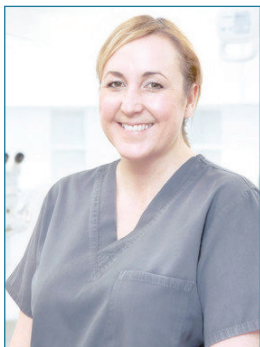
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Meeting Review

Rachael Kay, MBChB | Manchester, UK | rach.kay80@gmail.com

Summary of the Bangkok 2019 World Congress from the Scientific Chair

Robin Unger, MD | New York, New York, USA | drrobinunger@ungermedical.com

This meeting was ably summarized in the last edition of the *Forum*, but here I am happy to provide some additional thoughts and impressions. When ISHRS President Arthur Tykocinski asked me to be the Scientific Chair of the 2019 World Congress, I was far too honored to say anything but “yes.” First of all, it was surprising to me how many people are involved at every stage of the planning and execution of the meeting. I was so thankful to have the team in place, and for Victoria Ceh and Melanie Stancampiano’s handholding throughout the process. The Live Surgery portion led by Kapil Dua, Tim Carman, Damkerng Pathomvanich, and Ken Williams was a great success, and I was grateful to have them as part of my team. I was sorry that my father and mentor, Walter Unger, was unable to attend this conference—and I thank Sharon Keene for bringing his talk to life and his spirit to the World Congress.

The ISHRS World Congress in Bangkok was one of our most memorable. We arrived the day before the beautiful Loy Krathong Lantern Festival and were delighted to witness an incredibly beautiful display. Although the jetlag was fairly severe, this left me more time to get things done in the morning, before our packed days started! The triple crown concept (FUE, FUT, and SMP), which originated with Arthur over the past year, was carried through successfully.

The shorter program meant that the content was optimized and no time was left wasted. I also weaved FUE, SMP, and FUT/strip into the program in such a way that attendees were essentially unable to avoid learning about all three, and I think this really did help all doctors learn something new. As I stated at the start of the meeting, I wanted attendees to come away having learned something that they didn’t even realize they wanted to learn. Sometimes, as physicians in this day, we become so hyper-specialized in a particular technique that we are not even aware of how much we are missing... so everyone learned a bit about hairline lowering, gained strip harvesting pearls, learned about different techniques and approaches to FUE, and realized what could be achieved with good SMP. Top FUE devices were presented, dissected, and examined—and I was happy to have many experts in attendance to discuss their experiences with multiple systems.

The kickoff session set the tone with opening remarks, Fight the FIGHT campaign, and, of course, the inaugural Stough Lecture by Ohsang Kwon from South Korea.

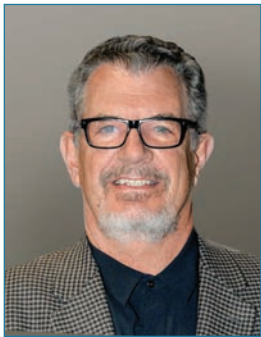
It is difficult to choose just a few invited speakers from the many wonderful specialists in our field, and I thank Victoria Ceh for her

help in advising me. Ohsang Kwon was a fairly easy choice. The possibility of Allogeneic Hair Transplantation in the future is especially exciting, given what we know about donor limitations that impact all hair restoration procedures—and the all too often overharvested donor areas that we are seeing from untrained technicians performing FUE.

Gillian Westgate has spoken at many of the hair research meetings and she always engages the audience, even one that is not super oriented towards basic research and science. She spoke about her experience with dermal adipose tissue being used in promoting hair follicle growth. Ramon Grimalt spoke about PRP and medical treatment for AGA, again highlighting the difficulty in assessing efficacy of hair loss treatments. This is something that I unfortunately learned firsthand after trying a novel technique (Optical Coherence Tomography) to assess the effects of PRP—and finding after over six months that it actually couldn’t be used for the purpose I had hoped! Tom Dawson, my fourth invited speaker in the field of hair restoration, gave another engaging and enlightening talk about hair care products and optimizing the appearance and health of the hair already in existence on our patients’ heads, helping physicians to understand the lay-public’s and consumer product manufacturers’ definition of “hair health.”

I have to say, my own small stroke of genius came with the invitation of Janet Nelson. I was trying to bring into the meeting a new perspective, one that hadn’t been extensively explored in prior meetings. Musculoskeletal disorders that can occur with repetitive motions and prolonged operating times are becoming all too common in many fields, and notably for hair restoration surgeons. I hope to be able to continue operating until I choose to stop, rather than to a time determined by my body breaking down! Janet helps me achieve this in New York City, and she brought her expertise to Bangkok to share with all of the attendees. Everyone got up and performed some of the stretches and exercises she recommends for micro-breaks throughout the day. These stretches are available on the ISHRS website, along with some of the sessions from the World Congress. This was a great new idea that Victoria and Melanie started, and I would encourage members to check out this new feature.

This is an exciting and fast moving time in hair restoration surgery. I think this last meeting helped cement the Congress as an event that presents a balanced view, introduces new concepts in a thoughtful way, and helps educate physicians in all aspects. ■



Message from the ISHRS 2020 World Congress Program Chair

Bradley R. Wolf, MD, FISHRS | Cincinnati, Ohio, USA | htwolf@wolfhair.com

Having attended the first ISHRS meeting in Dallas in 1993 and 22 of the subsequent 26 meetings, I am honored to be this year's Program Chair. The preparation for our 28th Annual Congress in Panama City, Panama, October 21-24, 2020, began prior to the Bangkok meeting. All chairs and co-chairs are in place and invitations have been sent to potential featured speakers. We are reviewing the Bangkok meeting member evaluations and comments to help better structure the Panama meeting.

Your feedback matters; we read every single comment. For example, there was a comment that the same speakers are at the podium every year. You can affect this complaint by submitting an abstract. Abstract submission opened in January. The "grading," or evaluation, of all abstracts is a



blind process. Abstract evaluators do not know the author prior to grading the abstract. We are always looking for new ideas and new presenters, so don't be shy, this is your chance.

Regenerative medicine, stem cells, and exosomes are popular topics. To that end, we are organizing a Hair Follicle Regeneration Symposium within the meeting. Ralf Paus, who will moderate, is a Professor at the Department of Dermatology and Cutaneous Surgery, University of Miami Miller School of Medicine, Miami, Florida. Dr. Paus's research explores the biology and pathology of the hair follicle, with emphasis on human hair follicle neuroendocrinology, immunopathology, and epithelial stem cell functions. I'll be profiling the meeting's featured speakers in this column over the course of 2020 to keep you updated. We hope to see you in Panama in October; it should be a great meeting. ■

CALL FOR ABSTRACTS NOW OPEN

We are now accepting abstracts for the 28th World Congress of the ISHRS to be held October 21-24, 2020, in Panama City, Panama.

Go to: <http://28thannual.org/faculty-info/>

**Abstract submission deadline is
March 16, 2020, at 9:00AM CDT.**



Important points:

1. All users must create or log into their existing account in the Catalyst system.
2. Limit of 2 abstract submissions per primary/presenting author.
3. Final results must be submitted with the abstracts. Abstracts will not be accepted that indicate "pending results" or "results will be presented at the meeting."
4. We are highly seeking abstracts in the following categories:
 - ⇒ Complications
 - ⇒ Consultation and Evaluation
 - ⇒ Graft Placement Including Implanters
 - ⇒ Non-surgical or Medical Therapies, Including Stem Cells
 - ⇒ Surgical Techniques
5. Please report on the number of hairs, and not only the number of grafts. Also include Hair Mass Index data, if available.
6. Proper, good-quality pre- and post-operative photographs are expected and should be included with the abstract.
7. All accepted presenters must be registered and paid-in-full for the World Congress by the indicated deadline for their name to be published in the program.

We hope you will be involved and look forward to receiving your abstracts and ideas for an excellent ISHRS World Congress.

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2020 Meetings Calendar

Please follow this link to a listing of upcoming HRS meetings: <https://ishrs.org/upcoming-events/>

2020 ISHRS directly sponsored/supported meetings:

March 19-22, 2020

Cowgirl Hair Loss Workshop
An ISHRS Regional Workshop
International Society of Hair Restoration Surgery
Houston, Texas, USA

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June 12-14, 2020

EURO 2020 Athens:
European World Live Surgery Masters Workshop
International Society of Hair Restoration Surgery
Athens, Greece

For more information: www.ishrs.org

July 24-25, 2020

Hair Transplant 360 Cadaver Workshop & FUE Hands-on Workshop
In collaboration with the International Society of Hair Restoration Surgery
St. Louis, Missouri, USA

<http://pa.slu.edu>

For more information: pa@slu.edu

October 21-24, 2020

28th World Congress of the ISHRS
Westin Playa Bonita
Panama City, Panama

For more information: www.28thannual.org



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Calendar of Hair Restoration Surgery Events

<http://www.ishrs.org/content/upcoming-events>

DATES	EVENT/VENUE	SPONSORING ORGANIZATION(S)	CONTACT INFORMATION
FEB 26-29, 2020	6th Annual Latin American FUE Workshop <i>Cancun, Mexico</i>	Organizing Chairman: Sara L. Salas, MD	www.informes@workshop-latc.com
FEB 29-MAR 1, 2020	BAHRS 2020 Annual Spring Conference <i>London, UK</i>	British Association of Hair Restoration Surgery www.bahrs.co.uk	office@bahrs.co.uk
MAR 6-8, 2020	HAIRCON 2020 11th Annual Congress of AHRS, India <i>Mumbai, India</i>	Association of Hair Restoration Surgeons – India Organizing Chairman: Sandeep S. Sattur, MCh www.ahrsindia.org	www.haircon2020.com drsattur@yahoo.com
* MAR 19-22, 2020	ISHRS Regional Workshop: Cowgirl Hair Loss Workshop—Art & Perfection, Female Hair Loss <i>Houston, Texas, USA</i>	International Society of Hair Restoration Surgery Hosted by Carlos J. Puig, DO, FISHRS	cpuig@hairdoctexas.com
APR 24-26, 2020	7th AAHR Scientific Meeting: FUE – Asia <i>Bangkok, Thailand</i>	Asia Association of Hair Restoration Surgeons	www.aahrsasia.org
MAY 22-24, 2020	Italian Society for Hair Science and Restoration International Conference <i>Florence, Chianti</i>	Società Italiana di Tricologia (Sitri)	info@sitri.it
MAY 23-24, 2020	6th International Congress of the KSHRS 2020 <i>Seoul, Korea</i>	Korean Society of Hair Restoration Surgery	www.koreanhair.or.kr/
* JUN 12-14, 2020	ISHRS Euro 2020: European World Live Surgery Workshop <i>Athens, Greece</i>	International Society of Hair Restoration Surgery	http://euro2020ishrs.org/
JUN 18-20, 2020	19th EHRS Meeting <i>Sheffield, UK</i>	European Hair Research Society	www.ehrs2020.org
* JUL 24-25, 2020	12th Annual Hair Transplant 360 Cadaver Workshop & FUE Hands-On Workshop <i>St. Louis, Missouri, USA</i>	Saint Louis University School of Medicine, Practical Anatomy & Surgical Education In collaboration with the International Society of Hair Restoration Surgery http://pa.slu.edu	pa@slu.edu
JUL 29-AUG 1, 2020	8th Brazilian Congress of Hair Restoration <i>Rio de Janeiro, Brazil</i>	Brazilian Association of Hair Restoration Surgery	eventos@abcrc.com.br
OCT 19-20, 2020	3rd SILATC Meeting & Live Surgery Workshop <i>Panama City, Panama</i>	Iberolatinoamerican Society of Hair Transplant Surgery	Drs. David Perez-Meza/ Marie Schambach Silatcpanama2020@gmail.com
* OCT 21-24, 2020	28th World Congress of the ISHRS Westin Playa Bonita <i>Panama City, Panama</i>	International Society of Hair Restoration Surgery www.28thannual.org	www.28thannual.org

* 2020 meetings that qualify for the ISHRS member educational maintenance requirement

REMINDER

ISHRS full **Members** and **Fellow Members** are required to attend 1 ISHRS-approved meeting every 3 years to maintain their member category.

ISHRS WORLD CONGRESS SCHEDULE

28TH WORLD CONGRESS

October 21-25, 2020
Panama City | Panama

29TH WORLD CONGRESS

October 20-23, 2021
Lisbon | Portugal

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Mission: To achieve excellence in medical and surgical outcomes by promoting member education, international collegiality, research, ethics, and public awareness.

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 Asian Association of Hair Restoration Surgeons
 Association of Hair Restoration Surgeons-India
 Australasian Society of Hair Restoration Surgery
 Brazilian Society of Hair Restoration Surgery
 British Association of Hair Restoration Surgery
 China Association of Hair Restoration Surgery
 French Society of Hair Restoration Surgery
 German Society of Hair Restoration
 Hair Restoration Society of Pakistan
 Hellenic Academy of Hair Restoration Surgery
 Ibero Latin American Society of Hair Transplantation
 International Society of Hair Restoration Surgery
 Italian Society for Hair Science and Restoration
 Japanese Society of Clinical Hair Restoration
 Korean Society of Hair Restoration Surgery
 Paraguayan Society of Hair Restoration Surgery
 Polish Society of Hair Restoration Surgery
 Swiss Society of Hair Restoration Surgery
 Thai Society of Hair Restoration Surgeons



Editorial Guidelines for Submission and Acceptance of Articles for the *Forum* Publication

- Articles should be written with the intent of sharing scientific information with the purpose of progressing the art and science of hair restoration and benefiting patient outcomes.
- If results are presented, the medical regimen or surgical techniques that were used to obtain the results should be disclosed in detail.
- Articles submitted with the sole purpose of promotion or marketing will not be accepted.
- Authors should acknowledge all funding sources that supported their work as well as any relevant corporate affiliation.
- Trademarked names should not be used to refer to devices or techniques, when possible.
- Although we encourage submission of articles that may only contain the author's opinion for the purpose of stimulating thought, the editors may present such articles to colleagues who are experts in the particular area in question, for the purpose of obtaining rebuttal opinions to be published alongside the original article. Occasionally, a manuscript might be sent to an external reviewer, who will judge the manuscript in a blinded fashion to make recommendations about its acceptance, further revision, or rejection.
- Once the manuscript is accepted, it will be published as soon as possible, depending on space availability.
- All manuscripts should be submitted to forumeditors@ishrs.org.
- A completed Author Authorization and Release form—sent as a Word document (not a fax)—must accompany your submission. The form can be obtained in the Members Only section of the Society website at www.ishrs.org.
- All photos and figures referred to in your article should be sent as **separate** attachments in JPEG or TIFF format. Be sure to attach your files to the email. Do NOT embed your files in the email or in the document itself (other than to show placement within the article).
- Images should be sized no larger than 6 inches in width and should be named using the author's last name and figure number (e.g., TrueFigure1).
- Please include a contact email address to be published with your article.

Submission deadlines:

April 5 for May/June 2020 issue

June 5 for July/August 2020 issue

August 5 for September/October 2020 issue

October 5 for November/December 2020 issue

Please note submission address:

forumeditors@ishrs.org

Classified Advertising Guidelines for Submission

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