Medical and Professional Ethics

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Spotlight on Surgery by Unlicensed Practitioners

The ISHRS posted a consumer alert on January 18, 2017, that stated the following:

Properly trained and licensed physicians (and where allowed by law in the United States, physician assistants and nurse practitioners who practice within the scope of their licenses), should be the only professionals performing certain aspects of hair restoration surgery. This includes:

- Preoperative diagnostic evaluation and consultation
- Surgery planning and surgery execution (including donor hair harvesting, hairline design, and recipient site creation)
- Management of medical issues and possible adverse reactions

There is much debate currently about the practice of unlicensed persons performing the surgical steps of a hair transplant procedure, but why has this issue come about?

Although today it is primarily a problem with Follicular Unit Excision (FUE) both in the donor area with incisions around follicular units and in the recipient area with sharp implanter incisions, it can be argued that the problem originated in handing responsibility to non-licensed persons to dissect Strip Follicular Unit Transplantation (Strip FUT) tissue. Had the original precedence been set to only delegate this duty to doctors, it is unlikely we would be facing this problem today. Even if this task had been delegated to nurses, or other regulated health care professionals, then there would be an avenue for appeal to their governing bodies to control unethical behaviour.

Still, we are where we are, and the challenge now is to curtail an ever-increasing number of non-licensed persons from doing surgery.

The first issue to be considered in the discussion is whether hair transplantation is actually "surgery." The existence of a specific legal definition of hair transplant surgery or in fact of "surgery" varies from country to country, and some countries, like the UK, have no formal medical definition of "surgery." With the strip FUT method, there is little doubt that making the incisions to remove the strip is a surgical procedure. But is the incision step of FUE actually "surgery"? A single dermatological diagnostic punch biopsy would not be considered surgery, but it is the cumulative size of the skin wound created by multiple FUE incisions that differentiates the two.

What then about recipient site incisions? After all, the skin puncture from a hypodermic needle used to take blood is hardly considered "surgery." Why then should multiple incisions with a hypodermic needle or similar sized blade be considered "surgery"? Perhaps because of the cumulative size of all the small incisions? Perhaps because of the risk of bleeding, skin necrosis, and scarring if not performed correctly?

There is little doubt that a higher level of decision making and understanding is necessary to determine where, how many, and how close incisions are made in the recipient area as well as which, and how many, follicular units are removed during FUE. As with many other aspects of medicine, it is the additional training that a doctor and other licensed individuals undertake that informs this higher level of decision making and understanding.

The second issue to consider is the legality, or illegality, of non-licensed persons doing surgery. Again, the explicitness of this varies around the world. In the United States, some states have laws making the matter clear and some do not. In Europe, different countries have varying and sometimes opposing laws, while some countries have no legal clarity. In countries where there is no specific law, some have established medical guidance based on ethics. The ISHRS has recently sent out a poll to all European members to collect data on this subject, which will be summarised in a meeting at the Hollywood World Congress to discuss whether "Hair Transplantation" should be included in a European surgical or non-surgical standard for cosmetic procedures.

There are many experienced and well-respected senior hair transplant surgeons around the world who feel it is perfectly acceptable to let their non-licensed assistants make FUE incisions. No doubt there are many non-licensed persons who are very good at FUE. However, the issue is not "Can it be done?" it is "Should it be done?". The ISHRS's position on this matter is a very clear "NO."

The point is then raised that if the ISHRS does not endorse non-licensed persons to make FUE incisions, under what conditions is it acceptable for a robotic device to be used in hair transplant surgery? The ISHRS's position is that a robotic device should always be under the direct control of a doctor (or other licensed individual practicing within the scope of their license) and this responsibility should also never be delegated to a non-licensed person.

Why do doctors allow their unlicensed assistants to do

Reflective Questions:

Would I let a non-licensed person make FUE incisions in my practice?

What would I do if I had first-hand knowledge of a colleague who allowed non-licensed individuals to make FUE incisions in their practice?

Case Study:

A member of the public raised a concern to the ISHRS regarding a hair transplant surgical assistant making FUE incisions with a suction-assisted device at the practice of an ISHRS member. Evidence was reviewed by the Ethics Committee confirming this and that another ISHRS member at that practice also allowed the assistant to make incisions. A recommendation was made to the Board of Governors and the ISHRS memberships of the doctors were terminated.

ISHRS POSITION STATEMENT ON QUALIFICATIONS FOR SCALP SURGERY

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.* Physicians who perform hair restoration surgery must possess the education, training, and current competency in the field of hair restoration surgery. It is beyond the scope of practice for non-licensed personnel to perform surgery. Surgery performed by non-licensed medical personnel may be considered practicing medicine without a license under applicable law. The Society supports the scope of practice of medicine as defined by a physician's state, country or local legally governing board of medicine.

Adopted by the Board of Governors, 11/15/2014

*Or in countries where it is allowed, a licensed allied health professional practicing within the scope of his or her license.

FUE incisions? It might be that they don't know how to do it themselves, aren't very good at it, or just don't want to do it—perhaps because they find it tedious.

Why do non-licensed persons do FUE incisions? For those who are employed, it might be because they can earn a better income than from doing other things; it may be because their employer endorses them doing it; it may be because they are unaware of the law in their jurisdiction or there is no law prohibiting them doing so; or it may be genuine professional satisfaction from providing a service to patients that they feel skilled to offer. For those who do it independently, or employ doctors to provide an illusion of legitimacy, it is likely because of the significant financial gain that can be achieved.

Certainly, it is deceitful to give the impression to a patient that the doctor will be making the incisions when it will be an unlicensed assistant, but what if the patient is fully aware and consents to a non-licensed person making FUE incisions because the doctor says it is OK and that the individual is very good at it?

It is sad that having moved out of the "doll's hair," "corn row," plug graft era and having made such strides in achieving natural results, the reputation of the hair transplant field should be now threatened by the rising tide of poor results delivered by unlicensed practitioners, especially from overharvesting donor zones and creating unnatural hairlines. It is up to all of us to do our part to educate the public on this bad practice and to encourage patients to ask questions before the surgery, such as "Who will be doing the FUE incisions?" and "Who will be making the recipient site incisions?" Also, during the surgery, patients should ensure the person they were told would do the FUE incisions actually does them. Patients should be encouraged to blow the whistle if this is not the case and, if the doctor involved is an ISHRS member, to report the matter to the ISHRS.

Editor's note: This is another important article that hopefully leads to an active debate. One debate would be about hair transplantation being listed in a European regulation as a cosmetic procedure (surgical or non-surgical). But most cases of hair transplantation are for the reconstruction of androgenetic and cicatricial alopecia. It should not be considered cosmetic or aesthetic because it is actually a therapeutic procedure to treat alopecia. The European colleagues will discuss this topic in Hollywood.

The other debate would be about the role of non-physician personnel in hair transplantation. Regarding the delegation of some parts of hair restoration, the international situation is very diverse. There are many differently trained categories of personnel. In general, there are at least 3 categories: physicians, licensed personnel, and non-licensed assistants who have been trained by the doctor only.

In the United States, there are so-called licensed physician assistants and licensed nurse practitioners, who in some jurisdictions have a license to work independently under a doctor's supervision. For some procedures, the doctor does not even need to be present in the practice.

In many European countries, such as Germany, some tasks may be delegated to licensed nurses and physician assistants as long as the responsible doctor regularly checks the procedure and is immediately available (next door).

For hair transplantation, it is medical consensus and part of the guidelines that microscopic graft dissection and blunt placing may be delegated while the planning, anesthesia, strip excision, and recipient site creation is reserved for the physician only.

The question is if creating recipient site incisions during follicular unit excisions (FUE) is a critical surgical task that should also be performed by the doctor personally, even though other licensed personnel would be allowed to do it, too. Many colleagues argue that this is the case. And they would like to keep full control of donor harvesting as well as recipient site incisions.

Other colleagues allow licensed personnel to do FUE. They warn that many patients would otherwise go to clinics with other standards or abroad that can offer the procedure for a lower price. They also say that for high graft numbers, fatigue of a single surgeon is a problem. Sharing this task with licensed personnel or delegating it completely would solve this problem. But new problems may arise from this approach and some conditions should apply.

While some licensed personnel may be allowed to do surgery and perform FUE in some countries, it would certainly be in the interest of the patient that a physician remain responsible for the surgery as a whole.

A physician should supervise the recipient site incisions and the FUE and be immediately available in case of any problems. This includes regular checks of the patient's well-being, anesthesia, bleeding and graft quality, and clear instructions regarding the donor zone and harvesting density. Preferably, the doctor should initially or repeatedly do FUE personally during each procedure to determine the instruments, technique, and feasibility of FUE in the individual patient. Depth-control instrumentation further reduces the medical risks. To improve the skills of licensed personnel, a curriculum and training program as well as standards for physician supervision could be established by the individual practice or in general guidelines.

The best interest of the patient should always be a priority. This involves quality, swiftness, and affordability of the procedure, but above all, patient safety.

We would be happy to publish your opinion or report of your regional situation in upcoming issues. —AF ■