





Review Article 441

Patient Counselling and Medicolegal Aspects of Hair Transplant Surgery

Sandeep Suresh Sattur¹ Indu Sandeep Sattur¹

¹Department of Plastic Surgery, HAIRREVIVE- Centre for Hair Restoration and Skin Rejuvenation, Mumbai, Maharashtra, India

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Address for correspondence Sandeep Suresh Sattur, MCh, HAIRREVIVE- Centre for Hair Restoration and Skin Rejuvenation, 103, Options Commercial Centre, Dr Vasant Awsare Marg, Milan Subway Road, Santacruz West, Mumbai, Maharashtra, India 400054 (e-mail: drsattur@yahoo.com).

Abstract **Keywords**

- ► medical negligence
- medical malpractice
- hair transplantation
- ► informed consent
- medicolegal implications in hair transplantation

Hair transplantation being an elective aesthetic surgery, the importance of informed consent cannot be overstated. Explaining the condition of hair loss, the causes, progress, prognosis, and all available treatment options is a part of this process. Providing conflict-free information, ensuring that the patient comprehends this information, and allowing him/her to make the decision to authorize the surgeon to perform the procedure is the moral obligation of the hair transplant surgeon. The benefits of this approach are noticeable and one of the most effective ways to have a satisfied patient and reduce the possibility of claims.

Introduction

Evaluation of the risk-benefit ratio is critical to the conduct of hair transplant surgery, as it is both elective and nonessential from a medical perspective. In the scenario of increasing malpractice suits being filed, the two key factors are growing patient awareness and lack of understanding of legal principles by the concerned doctors, as conventional medical education does not cover this.²⁻⁴ It is thus imperative for all doctors practicing hair transplant surgery to be well-versed with the medicolegal issues pertaining to the practice of hair restoration. Being unaware of legal requirements is not a valid excuse in the court of law. Moreover, being included in the ambit of Consumer Protection Act and the Service tax has changed the projection of doctors as providers of medical services to mere service providers hence; they are more accountable.5

Acknowledgment of informed consent from the patient and commitment from the hair transplant surgeon to deliver should be the crucial part of the consultation.

As hair restoration surgery does not deal with any specific clinical/medical needs, there is a very low tolerance for any complications arising from the procedure. The majority of malpractice claims in aesthetic surgery are due to inadequate communication between surgeon and patient and poor patient selection and not due to surgical error.^{4,6}

Prevailing Legal System

Doctors can be charged against under various laws/system in India, and legal liability in relation to such procedures may arise out of tort law, consumer protection laws, contract law and the Indian Penal Code, 1860.^{2,5,7}

Tort law is a branch of law that is primarily developed as "judge-made law" and relies on principles set out in previous judgments. The seminal case under Indian law, Jacob Mathew v. State of Punjab, lays down the requirements for medical negligence-"it must be shown that the accused doctor did something or failed to do something which in the given facts and circumstances no medical professional in

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his ordinary senses and prudence would have done or failed to do." 5

To prove a case of negligence prima facie, a patient has to prove the four elements (four Ds) of medical malpractice—duty, dereliction (negligence or deviation from the standard of care), damages, and direct cause.⁸

The doctor is bound in a fiduciary relationship with the patient, and this is the basis of his duties toward the patient. ⁴ The standard of care provided by the doctor should be on par with that of other doctors of good standing in the community, which ensures that no harm befalls the patient. It is obligatory of the doctor to have the requisite competence and knowledge to deliver his/her services but at all times have the patient's best interest in mind.

Breach or dereliction of this duty arises when the doctor delivers services below the accepted standard of care. A simple example of this is the failure to provide proper informed consent to a patient by not, for instance, disclosing the important risks of a hair transplant.

A patient suffers injuries or damages because of dereliction of duty. The doctor's conduct assumes the character of nonlegitimacy when, in the event of an invalid or absent informed consent, postoperative complications occur, resulting in a breach of the individual's rights to health and self-determination.¹

Finally, the damages or injuries have to be shown to have a causal link to the breach of duty. The surgery has to be linked to complications. Even if there were no complications, the nonlegitimacy of the doctor's conduct would remain as such, in that the unjustified breaching of the right to self-determination would persist, but the patient would likely not have a viable negligence action against the doctor.^{1,4}

Lawsuits in Hair Transplantation

It is important to understand the basis of negligence and medical malpractice in hair transplantation. These two terms have been used interchangeably but actually have different connotations. The difference between medical negligence and medical malpractice is the intent and the inference is made by the attorneys.

Medical negligence does not involve intent and happens when a doctor causes harm to a patient unknowingly (a mistake), either through simple ignorance or failing to take action where it is needed. While the act or omission is definitely negligence, it does not rise to the point of medical malpractice, because the medical provider did not commit the action either with the intent to cause harm or the knowledge that the patient might suffer harm.^{9,10}

Medical negligence in hair transplantation may arise due to increased scarring in the donor area (over harvesting), inadequate density, bald patches (coalescence of donor sites), unaesthetic hair line, misdirected implantation of grafts, etc.

On the other hand, medical malpractice occurs in many of the same settings. But unlike negligence, in the case of malpractice, the medical professional is aware of the potential consequences of his/her actions (or nonactions) and proceeds anyway. It was not intentional in that he wanted to harm the patient, but it was intentional, because he knew that by doing so, the risk of harm was present. Some steps in hair transplant surgery, although a team-based surgical procedure, are not delegated to the technicians, for example, harvesting grafts or creating recipient sites, delivering local anesthesia, etc. A case in example is the delegation of surgery to technicians. The hair transplant surgeon delegates the harvesting of grafts to the technicians. The patient files the lawsuit stating that the hair transplant procedure was "performed in a manner below the acceptable standard or standards of medical practice." His alleged injuries include, among other things, deformity of the hairline, scarring, growth failure, psychological trauma, and monetary damages, as the surgery was not performed by the doctor but by technicians. ¹¹

Further, liability may also arise where the person conducting the procedure can be charged under Section 304-A the Indian Penal Code, 1860 for causing damages amounting to rash and negligent act.¹² To prosecute a medical professional for negligence under criminal law, it must be shown that the hazard taken by the accused doctor should be of such a nature that the injury which has resulted was most likely imminent.⁵ Furthermore, in India, the Supreme Court has held that "for fixing criminal liability on a doctor or surgeon the standard of negligence required to be proved should be so high as can be described as gross negligence or recklessness. Mere inadvertence or some degree of want of adequate care and caution might create civil liability but would not suffice to hold him criminally liable."¹³

In case the procedure is performed by the doctor under the terms of a contract or agreement, liability may arise in the form of contractual damages, as may be stipulated under the contract or an amount, as may be decided by the courts, depending on the damage caused to the patient.¹⁴

Patient Consultation

Consultation is a critical step in the path to having a satisfied patient. A successful and good doctor always listens to their patients. The first part is to try and understand the concerns of the patient. Sometimes, a patient's concerns might be different from what seems obvious on inspection. Having heard the patient out, the doctor can proceed to examination. After examining the patient, the doctor can convey his assessment to the patient, and keeping in mind the patient's concerns and expectations, outline the feasible treatments. Specifically, in relation to hair loss management, putting across the facts that hair loss is going to progress with age, patients may need multiple hair transplants through his lifetime, depending on the progress of his hair loss, and they also may need to use medications for a long period of time, is crucial. The information should convey that the process of hair transplant does not create new hair but redistributes existing hair; hence, the density of coverage will not be the same as that was before the patient went bald. Outline the limitations of the treatment, especially the fact that it may not be possible to cover all the bald areas satisfactorily in cases of advanced baldness. Along with

this, it is important to mention all the avenues that could help deal with the hair loss problem, like maintaining a shaved look, medical treatment and camouflage (scalp micropigmentation [SMP]), including the ones that are not provided by the hair transplant surgeon like a hair system/wig, etc. In any surgical endeavor, there would always be some risk. This risk is extremely minimal with hair transplantation. It is best to mention even the rarest of potential adverse issues, which may not seem relevant to the concerned patient. Complete transparency and conflict-free advice maintained throughout the consultation helps gain the patient's trust. Herein, various options are presented to the patients, from among which they must make an informed choice. In any case, the patient has to be a partner in the decision-making. The Bolam test which was devised to ascertain whether a doctor or other medical professional has breached their duty of care to a patient actually supported medical paternalism over a patients' autonomy. 7,15 However, this test is no longer used in many countries, and especially with respect to cosmetic surgeries, patient autonomy is the final word. 16,17

Many transplant clinics hair employ consultants/marketing executives to rope in patients, who are given incentives to "seal the deal." These marketing executives in their bid to make a sale end up promising a lot more than what can be accomplished by the procedure. Patients may also be easily misled with advertisements in the media and on the Internet and often come for the consultation with preconceived ideas, expectations and information that may not resonate with the surgeon. 19 Accordingly, they set their expectations, not knowing that the results seen in advertisements may not be factual and that hair transplant outcomes are very individualized, depending on a host of variables like grade of hair loss, donor quality and availability, etc. Setting expectations with respect to the outcome is an important part of the hair transplant consultation. In this case, it is advisable to underpromise and overdeliver. 16

It is important to identify potential red flags during the consultation, which may form the basis of future complications; most commonly, it is the following:

- Unrealistic expectations in terms of density to be achieved or the extent of coverage.
- Presence of significant miniaturization in the donor area.
- Unusual hair loss pattern or presence of alopecic patches elsewhere on the body.
- · Many broken hairs in the affected area.
- · Excessive shedding.
- Presence of scalp inflammation, scalp pain, pruritus.
- · Mental illness.
- Body dysmorphic disorder (BDD).

These conditions could be considered as contraindications or relative contraindications for hair transplantation, and this should be conveyed to the patient without the fear of losing a potential surgical patient.²⁰

Many a time, a patient may have two coexisting conditions on the scalp such as patterned hair loss and a small

patch of alopecia areata. The patient should have an explanation about the implications if one proceeded with hair transplantation, including failure of the surgery and/or exacerbation of the areata. It is always a good policy to seek opinion of a dermatologist when the diagnosis is unclear.

Another commonly encountered scenario is BDD, where patients, who have very limited hair loss or no signs of hair loss, insist on undergoing hair transplantation to further improve the existing hairline. The surgeon needs to counsel these patients carefully and dissuade them from undergoing surgery. The same parameters apply to very young patients.

During the consultation, the surgeon may become aware of coexisting medical comorbidities like diabetes, hypertension, cardiac disease, etc. In such a scenario, it is important to understand that these conditions fall out of the jurisdiction of a hair transplant surgeon, and patient should be referred to the concerned specialist for further management and workup and clarification regarding the eligibility to undergo hair transplantation.

Keeping in mind all of the above-mentioned factors, consultation of a patient can be extremely difficult, and a hair transplant surgeon has to balance the legal requirements, patients' expectations, and common sense required to not lose a patient during a consultation.²¹

Informed Consent

Informed consent is a fundamental legal obligation for all medical procedures including surgical interventions. In fact, not taking informed consent constitutes negligence per se. ¹⁶ Informed consent includes making sure that patients completely understands their condition and the possible remedies to treat it. Regarding hair transplantation, the following aspects should be covered:

- a. The exact nature and prognosis of the hair loss condition.
- b. The nature of the proposed treatment or procedure and necessary adjuvant treatments needed.
- c. The alternative treatments or procedures that are available for his/her condition.
- d. The risks of the proposed and alternative treatments or procedures.
- e. The probable outcome and chances of the success or failure of the treatment 16
- f. The timeline of events starting with the duration of the surgery, postoperative period, and the final result. It is important to mention all the sequelae to hair transplant like swelling, scabs, pain, folliculitis, etc.
- g. The estimated cost of the procedure including pre- and postoperative services

Essentially, providing consent to a patient means entering a contractual obligation with a duty of care to the patient. The contract terms are such that the surgeon provides the service, and the patient pays the fee. ^{18,22} Once the contract has been entered into, it is binding on the surgeon to deliver his best efforts to achieve the patient objectives and the patient to make good on his side of the contractual commitment by paying the doctor.

With regard to the informed consent for hair transplantation, the authors have followed a protocol.

- a. The patient's hair loss issue is treated like a problemsolving exercise. The problem may have many solutions, depending on the patient's expectations, profession, surgical candidacy, and financial status. The options put forward to the patient always include the option of not doing anything. All the pros and cons of the options are discussed. When dealing with pattern hair loss, the following two components of the problem are explained to the patient: the static component, which is the change in facial aesthetics due to receded hair line or frank baldness, and the dynamic component, which is the potential to future hair loss, leading to further change in facial landmarks. Addressing only one component will not achieve the same outcome in the long-term. For successful longterm management of the hair loss problem, a holistic approach of addressing both the components in a holistic manner would be an ideal way to manage this. This would mean staged surgeries and long-term medications.
- b. At the end of the consultation, the patient is given the consent form along with preoperative and postoperative details, which include the sequelae and the adverse outcomes. The patient is made to sign the receipt of the consent form with the date. The patients are asked to come back to the clinic when they have gone through the details, and an opportunity is given to them to clear their doubts regarding the procedure.
- c. On the day of the procedure, the entire procedure along with the markings of the hairline are discussed with the patient in the presence of his relative or an accompanying
- d. Ensure that the consent form is signed by the patients themselves and that all blanks in a preprinted consent form have been duly filled. In addition to the signatures of the patient and the doctor, it should also be signed by a witness (preferably a third party).
- e. The total cost involved in the whole process
- f. Patients should be able to sign a consent form written in a language they understand. Translation of the forms in the commonly used regional languages must be available with the physician.
- g. The last part of the consent involves patients writing in their hand the following lines: "I acknowledge that I have read this form and have understood the contents. I have been given the opportunity to ask questions, and my questions have been answered to my satisfaction. The risks and benefits of this treatment have been explained to me as has been the other options for treatment. I choose to go ahead with hair transplantation." 16

An important point to remember is that signing such a comprehensive consent form by the patient may not protect the doctor from malpractice claims if things go wrong. Even if a documented complication occurs, the onus is still on the surgeon to prove that this occurred despite having followed the standard of care and that there was no deviation from the conduct of a reasonable, competent doctor.¹⁶

Documenting Consent with Video Recording

If the patient is not able to read or write, consent on video may be taken. This could be a more detailed consent, and it helps to address all the points in detail like the ones not covered in the written consent and is more reliable and transparent. In a country like India, this started with the audiovisual recording of informed consent for conducting clinical trials.²³ The patients may not want to talk on camera about their hair loss issues, and the issues of privacy and confidentiality will make it necessary for the doctor to manage the personally identifiable information.

Professional Indemnity Insurance

The financial liability in the event of a medical malpractice lawsuit is huge, and the best way to provision for it is to have professional indemnity insurance. Professional indemnity insurance covering all forms of cosmetic surgery including hair transplantation is a must-have for all hair transplant surgeons.²⁴ Additional insurance covering the staff is also necessary. Professional liability insurance protects the doctor against financial consequences of an error or omission while providing hair loss treatments.

Summary

Informed consent and conflict-free consultation are the moral requirement for any surgery and more so for hair transplant surgery, which is completely elective and is performed not to treat a medical problem but basically improve the patient's quality of life. The receipt of informed consent is not only an ethical necessity but, more importantly, a legal requirement. Crystal clear communication with the patient is key in this process. Ensuring that the patient clearly comprehends the information is as important as communicating it. Finally, patient autonomy is the key to the whole process to avoid medicolegal problems. Patient counselling and informed consent are important tenets in forging a therapeutic alliance with the patient.

Conflict of Interest None declared.

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