IAAPS GUIDELINES FOR HAIR TRANSPLANT SURGERY

DECEMBER 5 2022

It is emphasized that the objective of these guidelines is to recommend minimum standards for practice of HT. The principles outlined in these guidelines are of a general nature only, minimal in their level and are not meant to cover all situations. It should be understood that these recommendations are by no means binding and universal, represent minimum standards only and as in all surgical techniques, variations in techniques are possible. It is also further clarified that these are based on current literature, and as science evolves, these guidelines could also change in future. Where published evidence is not available, consensus expert opinion is presented.

The taskforce emphasizes that each patient has to be treated on his/her own merit and that these guidelines do not limit the physician from making an appropriate choice or the necessary innovation for a given patient. The taskforce recognizes that the treating surgeon is best suited to decide what is needed for a given patient in a given situation. Innovations in medicine need flexibility in approach and these guidelines do not limit the surgeon from undertaking innovative research.

ELIGIBLITY TO FERFORM HAIR TRANSPLANT PROCEDURE

HAIR TRANSPLANTATION is an actual surgery, where hair follicles are transferred from one part of the body mostly from scalp and, or other hair bearing areas of the body to the bald area on the scalp or elsewhere. This procedure is similar to the principles of Skin Grafting followed routinely in many PLASTIC & RECONSTRUCTIVE SURGICAL procedures. This surgery is of long duration, but done under local anesthesia. Usually it is a relatively safe procedure, when operated by a qualified trained surgeon at a hospital/clinic / center which is registered by local health authorities and having all standard protocol of surgery. Multiple holes/slits/sites are created over scalp and or other parts of body, which are equivalent to tiny surgical wounds, then the hair follicle or follicles are implanted in these slits/sites/holes.

In hair transplant surgical procedure the hair follicles (also called grafts) and/or a strip of skin having hair follicles are harvested from scalp and or other part of patients body. Any breach of skin (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 Registered Medical Practitioner (RMP) i.e practitioner of Modem Medicine. The surgeon who perform hair restoration surgery must possess the education, training and current competency in the field of hair restoration surgery including:

- adequate knowledge in hair physiology,
- pathogenesis of scarring and non-scarring alopecia,
- anatomy and physiology of scalp including scalp vasculature and nerve supply,
- adequate clinical skill to identify patients who are candidates for hair transplant surgery
- contraindications for hair transplant including active scarring alopecia,
- adequate knowledge and clinical skill pertaining to the medical treatment of alopecia
- pre and post-transplant medical care,
- acquired basic knowledge and skill base in surgeries pertaining to skin and its appendages,
- adequate training and knowledge pertaining to medical issues and possible adverse reactions that can arise during the hair transplant surgery including basic life support and resuscitation measures.

The hair transplant should preferably be undertaken only by those who have surgical grooming like formal surgical training such as MCh/DNB Plastic surgery, MD/DNB Dermatology with adequate grooming in dermatological surgical procedures. It is also noted that the above-named specialties have Hair transplantation as a core topic in their curriculum.

The following aspects of hair restoration surgery should only be performed by a hair transplant surgeon:

- Patients' consultation, examination, planning, diagnostic evaluation, and management of hair loss and or baldness.
- Surgery planning, explanation about surgery to be done
- Surgery execution including Donor hair harvesting, Hairline design, Recipient site creation and Management of other patient medical issues and possible adverse reactions
- Post-operative care

It is unethical for a RMP to train an individual to perform/assist surgery who is not an accredited health professional licensed to do so.

MINIMUM REQUIREMENTS IN A HOSPITAL / CLINIC / CENTER PERFORMING HAIR TRANSPLANT SURGERY

The day care theatre should be equipped with facilities for monitoring and handling emergencies including emergency drugs, Boyles machine, intubation sets and ambu bag. A plan for handling emergencies should be in place and all nursing staff should be familiar with the emergency plan. It is ideal to have a standby anesthetist. the decision of having anesthetist is discretion of surgeon based on medical conditions of patients.

Hair Transplant as with any other surgical procedure, may have complications and

requires skills and training in appropriate patient selection, differential diagnoses and surgical techniques and appropriate post procedure care to optimize outcomes. It is suggested that anyone who wishes to perform these procedures should be adequately knowledgeable and trained and should ensure that they have adequate infrastructure and manpower to manage any issues that may arise due to procedure performed.

Aesthetic Procedures including Hair Transplant are not an Emergency Surgery, and hence there is no case for allowing any untrained person to do it under the pretext of "Exceptional Circumstances".

- It may be noted that watching in workshops or on YouTube or similar platforms is not adequate training to start hair transplant.
- Assistants or OT technicians; should be from a medical background, such as nurses, lab technicians, pharmacists. However, they need to be provided structured, systematic, and proper training (responsibility will lie with the hair transplant surgeon) in all aspects of both surgery and disinfection, sterilization, patient communication etc.
- Surgical assistants/technicians should perform tasks only under the supervision of surgeon.

The surgeon should ensure that the patient undergoing such a surgery should have adequate preoperative clearances from the medical specialists and the anesthetist.
The surgeon should have a well-equipped postoperative recovery room with facilities for monitoring of vitals and adequate record keeping.

The surgeon should have an anesthesia back up with all the requisite resuscitative equipment and drugs in place. If the surgery is done in a day care center and or in a clinic, then the centre/clinic shall have an agreement with a hospital having ICU facilities where in case of emergency the patient can be referred for management of complications or emergency situation.

HAIR TRANSPLANT SURGERY

BEFORE SURGERY

- Consultation, assessment, counselling by Primary Surgeon himself.
- Proper investigations to exclude co-morbidities
- Consent including of likely complications and sub-optimal results
- Making the patient fully aware of fee without offering unethical discounts, schemes, freebies etc.
- Designing and area of implantation and explanation about the surgery.
- Xylocaine sensitivity testing

DURING SURGERY

- Standard protocol of surgery like recording of vital parameters and drug record
- LOCAL ANAESTHESIA
- IV patency line
- After giving local anaesthesia surgeon makes slits. Premade slits are not necessary if surgeon himself is planning to implant the grafts.
- Surgeon does strip harvesting and or follicles harvesting from donor area.
- The grafts are implanted in pre-made slits either by surgeon and or by trained staff.
- During surgery patient general condition is monitored
- During surgery trained technicians assist the surgeon
- The slivering and follicle dissection, counting and sorting and storage of grafts are done by trained technicians under supervision of surgeon.

AFTER SURGERY.

- After the surgery standard dressing can be done as per surgeons protocol
- Details instructions are given for care and medicine

UNETHICAL VIOLATIONS

The below mentioned examples of common Violations, which cover the are unethical.

1. Surgery being conducted independently by any RMP except Dermatologists and Plastic Surgeons who has no training of hair transplant cannot perform the hair transplant independently. So to perform hair transplant knowledge and training in the field of hair restoration is a must. However, any RMP is permitted to assist the Surgery being performed by a competent Specialist like a Plastic Surgeon or competent Dermatologist.

2 Nurses, technicians or any other Para medical person are allowed to assist a competent Specialist performing the Surgery. However, it is not permitted for them to do this Surgery independently.

3 Dentists are not permitted to do Hair Transplant Surgery, as this Surgery is beyond the Scope of Dentistry "Jaws, Teeth and Oral Cavity': as defined in Dentist Act 1948 Section 2.1.1.

4 Any person performing this Surgery in violation of 1,2,3 must be seen as committing a Criminal Assault (Battery), and booked as per the severity of the injury under prevailing Laws.

5 Hair Transplant may not be performed at any location (Clinic/parlour, etc) that is not registered as a Day Care Centre OR Hospital with the Local/ State Authorities.
6. As hair transplant procedure is a surgery, so it shall be done in a designated operating room either in a hospital set up or a day care centre or clinic. The centre/clinic/hospital shall be registered and shall follow all aseptic precautions, equipped to manage emergency situations, hygienic, common facilities, tie up with higher medial centre for quick transfer of patient if required. There are guidelines drawn by the health ministry under head of 'CLINICAL EXTABILISHMENT ACT' for day care centre or hospital. The centre shall follow all the guide line given by health authorities.

ETHICAL ISSUES

The use of trademarks or service marks as commercial names for a hair restoration procedure, without disclosing the scientific basis for the procedure, its complications and side effects is not in the public interest. Nor is it in the public interest to use a commercial name to market a procedure that is described under a commonly accepted name in the medical literature, without revealing the name used in the medical literature. Professional disagreements should be aired in a forum of peers. Denigration that aims at destroying another physician's practice is morally reprehensible. Physicians who market their services have a responsibility for "truth in advertising."

The following advertisements are considered to be misleading the public:

1. Inaccurate Credentials. Incorrectly claiming to be certified by the AHRS-I, ABHRS or claiming to be a member or Fellow of the ISHRS, and otherwise stating or suggesting any expertise in hair restoration surgery that is false.
2. Misrepresenting Board Certification. Physicians should identify their specific medical specialty certifying board when marketing their board certification in the public domain language, such as "board certified hair restoration surgeon" is not acceptable.

3. Misrepresenting Photographs. Publishing photographs of other physicians' patients in any manner that states or suggests that they are patients of the publishing practice.
4. Copyright/Trademark Violations in General. Republishing or otherwise representing the photographs, publications, trade names, logos, or other trademarks of another practitioner without permission in violation of the owner's copyrights and/or trademarks.
5. Misleading Language. Use of the following terms and phrases in marketing by a hair restoration surgeon may mislead the public:

- "Scarless surgery"
- "No incision"
- "No touch"
- "No cutting"
- "Cloning"
- "Hair multiplication"
- "Non-invasive"
- "Eliminates the need for additional procedures"
- "Pain free or no pain"
- "Unlimited grafts"
- "Guaranteed results"

CHARGES FOR THE SURGERY

The surgery cost should be based on the number of follicular units/follicles/package for a particular surface area as per the surgeon's routine pricing practice. However, each term unit/graft/follicle should be explained and the patient should be familiar with the terminology. Costs should be informed beforehand to the patient and documented in the consent form.

TRANSPARENCY

Transparency in the HT surgery should be followed in the following aspects:

- The physician who will be performing the surgery and the role of assistants should be informed to the patient prior to the surgery.
- The role of the surgeon and the role of assistants should be documented – who does what
- Hairline design, once accepted by the patient and the surgeon, should be documented with an image.
- Number of grafts/ follicles/ area to be covered initially planned and actually performed should be disclosed to the patient and documented with images. The discharge slips should document the number of units of each type, 1/2/3/4 hairs total; number of units; and total number of hair separately.

- Provision of counting the grafts can be explained to the patient.
- The need for the medical management/chances of inadequate growth/ thinning of grafted follicles with time post-HT should be discussed with the patient and documented.
- Charging for the surgery should be only for viable follicles that are transplanted.

Documentation and Consent

- A medical record is admissible as documentary evidence in a legal suit. So it is important to maintain a meticulous record of clinical details of the patient, the counselling process, consent taking, detailed preoperative, operative, and postoperative notes and instructions, and follow-up visits.
- Preoperative documentation should include the details about any preexisting health issues, drug allergy, photograph id lignocaine test dose, baseline vital parameters, hairline design planned, planned number of grafts to be harvested, expected results with duration, donor adequacy, continuation of medical management if required, and the possibility of a second surgery after a particular period.
- Intraoperative records should include the vital parameters, drugs administered and their dosage, complications if any and the remedial measures that were carried out, number of grafts planted, the area of scalp covered the details of the surgical team, and the duration of the surgery with the timings of the beginning and the end of each stage of the surgery.
- Immediate postoperative records should have the following details: vital parameters after the surgery, duration of observation post-surgery, complications if any at the end of the surgery, remedial measures taken, postoperative prescription and advice, emergency contact number for communication, and the details of the follow-up visit.
- The patient's failure to adhere to post-procedure consultations, neglect of precautions, and noncompliance of instructions, if any, should also find place in the record.
- Both manual signed records and computerized data help in the standardization, storage, and easy retrieval of records.
- Photographs taken before, during, and after the procedure provide adequate proof of the outcome of the procedure.
- Medical records of HT must be preserved for five years, but those pertaining to malpractice suits must be preserved till the final settlement of the case.
- The aesthetic surgeon or the hospital is vested with the custodial ownership of records. However, on request, these should be provided to the patient within 72 h.
- The Consumer Protection Act can condone a delay in filing a case of negligence beyond the prescribed limitation of two years from the date of occurrence.
- Consent in the medical field can be defined as an instrument of mutual communication between a doctor and a patient with an expression of authorization/ permission/ choice by the latter for the doctor to act/not act in a particular way.
- Lack of informed consent is a frequent cause of allegations of medical negligence.

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Sterilization and Disinfection of Operation Theater and Instruments

- The operation table, chair, light, shelves, and sink should be wet mopped daily free of dust, with water and the use of a broom should be avoided. Chemical disinfectant is recommended for the floor. The wet mop used should be left in a proper place to dry.
- The OT trolley should be mopped with a chemical disinfectant or isopropyl alcohol before surgery and between two surgeries.
- The floor and other areas of blood spillage should be mopped with a chemical disinfectant. The operating room wall and ceiling need to be cleaned periodically.
- The use of a fan in the OT should be avoided, as it causes aerosolization of dust.

- Regular maintenance of the air conditioner is necessary. The tonnage of air conditioner depends on the size of the room to ensure adequate cooling.
- After an HT surgery, the instruments should be rinsed in 0.5% chlorine for 10 min and then should be washed in water and scrubbed with a brush before sending them for sterilization.
- Linen, draped, gowns: Should be washed with a detergent at 71degrees for 25 min, and then sent for sterilization.

FUMIGATION

Formaldehyde fumigation can be done initially during a start-up of the theater or after an overhaul cleaning process. Formaldehyde 6%, glutaraldehyde 6%, and benzalkonium chloride 5% can be used by adequate trained personnel wearing appropriate protective devices. A combination of stabilized hydrogen peroxide 11% w/v and diluted silver nitrate solution 0.01% w/v is an ideal aerial disinfectant and OT fumigant acting as a sterilant at a recommended concentration of 20% at 1 h contact time. Fumigation should be done daily or prior to each surgery.

In between two operative procedures on the same day, spot cleaning of operation tables, theater equipment with disinfectant solution is recommended. In case of spillage of blood/body fluids, decontamination with bleaching powder/chlorine solution should be done. Fumigation should be repeated prior to the second surgery, if performed on the same day.

AUTOCLAVE

- All material should be dried and wrapped in cloth or medical grade paper.
- The instruments should be laid so that all surfaces come in contact with heat.
- Time depends on individual recommendations, but it is usually 121 degrees for 15 min.

Chemical sterilization of instruments:

- Cleaned, disinfected, and dried instruments should be fully soaked in a steel or plastic container having 2% glutaraldehyde for 8–10 h.
- After 10 h, using autoclaved water (100 mL of water autoclaved for 20 min and not boiled water) the instruments should be washed, dried, packed, and stored in a sterile tray. Note that the contact time for high-level disinfection is just 20 min compared with the 10 h required for sterilization.

Sterilization of follicular unit excision machines and implanters:

Heat- and moisture-sensitive electronic goods and other implanters are sterilized using ethylene oxide sterilization.

PREOPERATIVE CONSIDERATIONS

A detailed preoperative evaluation of the patient's medical status is essential. It is recommended to get the patient assessed opined upon by a treating doctor or an independent physician regarding the patient's eligibility to undergo HT.

Anesthesia, resuscitation, and emergency preparedness

An emergency situation in HT surgery, although rare, may arise. This part of the guidelines recommends the minimum standard of care in LA administration, emergency preparedness, and treatment of an emergency situation.

Anesthesia for hair transplantation

It is recommended that the medications and solution be labeled, and the labels should include the following: medication or solution name – strength, diluent name, and volume (if not apparent from the container) that have been verified both verbally and visually by two individuals of the HT team.

As the procedure involves anesthesia being delivered in a stepwise manner and not at one time, the dosage of the medication and the time of administration should be documented and the details can be displayed on a board nearby and visible to the surgeon.

Allergy testing for local anesthesia

In preoperative screening, it is recommended to ask the patient whether there has been any exposure to local anesthetic (dental procedures, etc.), or whether the patient has ever had an adverse reaction or side effect from an anesthetic or any other drug. Sensitivity to local anesthetics may be either due to the anesthetic itself or due to the preservatives.

Skin tests (prick/puncture and intracutaneous) have evolved as a reliable technique for the diagnosis of IgE-mediated drug reactions. The peak reactivity of prick/puncture tests is 15–20 min, at which time both wheal and erythema diameters (or areas) should be recorded in millimeters and compared with positive and negative controls. It should be recognized that prick testing will detect only the immediate type of hypersensitivitiy reactions: It may not detect delayed reactions and, hence, is not foolproof.

Delayed allergic reactions to local anesthetics

Cutaneous symptoms and systemic complaints occurring between 1 h and several days after LA injections may be encountered in some patients. Inflammatory reactions confined to the injection site represent the most common, if not the only, clinical manifestation of late-type LA allergy. Delayed anaphylaxis to LA should be diagnosed by excluding the other causes of systemic symptoms.

Patients with true allergy to amide local anesthetics present a challenge in HT surgery for providing adequate care with appropriate intraoperative pain management. In case of

allergic reactions to amide group anesthetics, ester-type anesthetics can be considered. Cross-reactivity between the amide and ester groups, although rare, had been reported to occur. The taskforce recommends that the patients with proven LA allergy should be referred to specialized allergy clinics for further evaluation with a skin prick test and they should be challenged with an unrelated LA to predict future safety.

Emergency Preparedness in Hair Transplantation

Plastic surgeries are classified into three types by the American Association for Accreditation of Ambulatory Surgery Facilities: Class A, minor plastic surgery procedures performed under local, regional, or topical anesthesia; Class A/B, minor or major plastic surgeries performed under intravenous or parenteral sedation, analgesia, or dissociative drugs; and Class A/B/C, major plastic surgeries performed under general anesthesia requiring external support of vital body functions. Surgeries are classified into three types based on the levels of Surgical Complexity: Level 1

- Minimal risk to the patient independent of anesthesia
- Minimally invasive procedures with little or no blood loss
- Often done in an office setting with the operating room principally for anesthesia and monitoring.

HT surgery is categorized as Level I surgery and the facility it is performed in is Class A.

Monitoring the following equipment is mandatory for an HT OT:

1. Non-mercury/digital blood pressure apparatus
2. Stethoscope
3. Pulse oximeter
4. Glucometer
5. Digital thermometer
6. Weighing scale

Resuscitative Equipment Necessary for Hair Transplant Operation Theater

Resuscitation equipment should be located either in the room or within the premises, to allow basic cardiopulmonary resuscitation.

1. Intravenous access cannulas and IV sets
2. Laryngoscope
3. Endotracheal tubes
4. Suction equipment
5. Xylocaine spray
6. Airways: oropharyngeal and nasopharyngeal
7. Ambu Bag: Adult

8. Oxygen cylinders with flow meter/ tubing/catheter/face mask/nasal prongs
9. Defibrillator with accessories (AED preferable)
10. Equipment for dressing/bandaging/suturing
11. ECG Machine

Emergency Drugs Necessary for Hair Transplant Operation Theater

1. Inj Adrenaline 1 mg
2. Inj Hydrocortisone 100 mg
3. Inj Atropine 1 mL
4. Inj. Pheniramine maleate 10 mL
5. Inj. Promethazine 1 mL
6. Inj. Deryphyline 2 mL
7. Inj. Frusemide 4 mL
8. Inj. Metoclopramide 2 mL
9. Inj. Dexamethasone 2 mL
10. Inj. Diazepam 10 mL
11. Inj. Dicyclomine Hydrochloride 2 mL
12. Inj. Ligocaine without preservative 30 mL
13. Inj. Intralipid 20% 500 mL
14. Inj. 5% dextrose infusion 100 mL
15. Inj. Normal saline 500 mL

Regular inspection of the drugs just mentioned to check their expiry dates should be done periodically.

Life Support Training

Though rare, an HT surgeon may encounter an unresponsive patient or a sudden collapse in a patient. Preventing hypoxic brain damage is the most important task for the surgeon. The surgeon should have been trained in emergency resuscitation skills. If not, an anesthetist should be available for care in such situations. In addition, at least another member of the HT team should be trained in Basic Life Support.

REFERENCE

- NMC GUIDE LINES PASSED ON DATED 30 September 2022 ORDER NO R-13014/18/2022-Ethics
- Hair Transplant Practice Guidelines, Venkatram Mysore, Muthuvel Kumaresan,[1] Anil Garg,[2] Aman Dua,[3] Aniketh Venkatram,[1] Kapil Dua,[3] Mayank Singh,[4] C Madura,[5] Ram Chandran,[6] Rajendra Singh Rajput,[7] Sandeep Sattur,[8] and Sukhbir Singh[9,] J Cutan Aesthet Surg. 2021 Jul-Sep; 14(3): 265–284. doi: 10.4103/JCAS.JCAS_104_20

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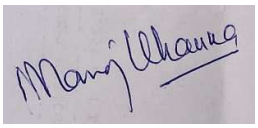
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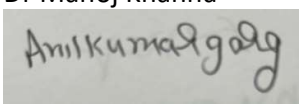
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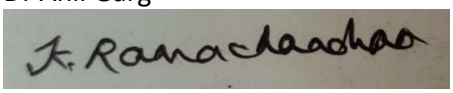
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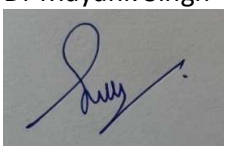
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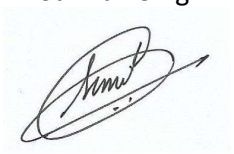
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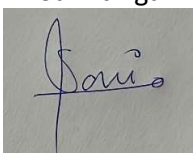
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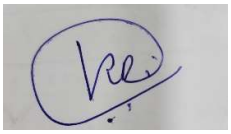
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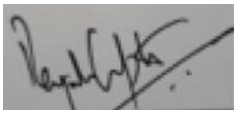
Dr Rajat Gupta


Dr Aniketh Venkataram