

Prosthetic Hair Fibre Implantation Standards

Box 1: Working Group Members, Professions and Affiliations		
Mr Greg Williams (Chair)	Plastic Surgeon and Hair Transplant Surgeon	Cosmetic Practice Standards Authority (CPSA)
Dr Nilofer Farjo	Hair Restoration Surgeon	Private Hair Transplant Practice
Mr Reza Nassab	Plastic Surgeon	Private Hair Transplant Practice
Mr Amir Sadri	Plastic Surgery Trainee	NHS
Mr Alex Armstrong	Plastic Surgery Trainee	NHS

INTRODUCTION

Hair Loss (alopecia) is common, has a multitude of aetiologies, affects all genders and age groups, and is not dependent on the aging process. Hair Restoration can be medical, surgical, or non-surgical.

The Royal College of Surgeons *Professional Standards for Cosmetic Surgery* defines cosmetic surgery as "the choice to undergo an operation, or invasive medical procedure, to alter one's physical appearance for aesthetic rather than medical reasons". Prosthetic Hair Fibre Implantation satisfies this criterion.

As it is low-medium risk: usually only requires local anaesthetic and performed as an outpatient, Prosthetic Hair Fibre Implantation is classed as Level 1b invasive surgery.

For the purpose of the CPSA, Hair Restoration Surgery (HRS) includes Hair Transplant Surgery and Prosthetic Hair Fibre Implantation but does not include surgical flaps.

Prosthetic Hair Fibre Implants are foreign bodies that are inserted through the skin. As long as they remain in situ, they require a high level of hygiene to prevent infection. They cause dermal fibrosis and can result in permanent visible scarring.

Prosthetic Hair Fibre Implants may be used in isolation or in combination with Hair Transplant Surgery. Only doctors who perform hair transplant surgery will be able to adequately determine which patients are suitable for Prosthetic Hair Fibre Implantation, Hair Transplant Surgery, or a combination.

Only doctors who perform Hair Transplant Surgery should perform Prosthetic Hair Fibre Implantation.

Doctors who perform Prosthetic Hair Fibre Implantation should therefore have the same depth of knowledge as those who perform Hair Transplant Surgery as detailed in the CPSA Hair Transplant Surgery Standard.

Box 2. Identified risk level, consent and cooling off

Risks to patient

Prosthetic Hair Fibre Implantation risks to patient:

- From sedation if used
- allergic reaction
- excessive sedation
- hypoventilation and hypoxemia
- unconsciousness
- death
- From local anaesthetic
- allergic reactions
- cardiovascular/neurological toxicity
- coma
- death
- Fainting/feeling unwell
- From recipient site
- recipient site bleeding
- swelling/oedema
- bruising
- infection (folliculitis or cellulitis)
- foreign body reaction
- granuloma
- scarring
- shock loss (effluvium) of existing hair
- discomfort/pain
- dysaesthesia
- breaking of fibres
- curling of fibres
- splitting of fibres
- prosthetic hair fibre retraction under skin
- prosthetic hair fibre loss
- aesthetic morbidity
- Psychological

	 failure to meet expectations morbidity from poor aesthetic outcomes
Risks to practitioner	 Prosthetic Hair Fibre Implantation risks to practitioner Blood borne virus transmission risk - Hepatitis B and other vaccinations are recommended for Hair Transplant Surgeons in keeping with the Overarching Principles regarding Occupational Health Needle stick injuries should be managed according to national guidelines Personal protective equipment is advised Adequate practitioner indemnity is required in keeping with the Overarching Principles regarding Professionalism
Consent	 Guidance from the Royal College of Surgeons <i>Professional Standards for Cosmetic Surgery</i> should be followed which says: You must be familiar with the guidance in <i>Consent: Patients and Doctors Making Decisions Together.</i> If you are the doctor who will be carrying out the intervention, it is your responsibility to discuss it with the patient and seek their consent – you must not delegate this responsibility. It is essential to a shared understanding of expectations and limitations that consent to a cosmetic intervention is sought by the doctor who will perform it, or supervise its performance by another practitioner.
Cooling off	 Guidance from the RCS Professional Standards for Cosmetic Surgery should be followed which says You must give the patient the time and information they need to reach a voluntary and informed decision about whether to go ahead with an intervention. The amount of time patients need for reflection and the amount and type of information they will need depends on several factors. These include the invasiveness, complexity, permanence and risks of the intervention, how many intervention options the patient is considering and how much information they have already considered about a proposed intervention. You must tell the patient they can change their mind at any point.

	Box 3. Premises requirements
Premises requirements	General guidance in Overarching Principles regarding Environment should be followed
Clinical and practice environment	Practice environment Prosthetic Hair Fibre Implantation must be undertaken in a CQC registered facility Prosthetic Hair Fibre Implantation may be performed in a Treatment Room or Operating Room and these must comply with national standards Room layout general features as per Overarching Principles including Patient privacy and dignity must be respected at all times The lighting available should be sufficient Hand held mirrors must be available for the patient to see themselves Stainless steel trolleys must be available for instruments to be placed on with appropriate clean covers A wall clock or timer should be visible There should be sufficient ventilation. The clinic couch, trolley and surfaces must be able to be appropriately cleaned and disinfected between patients The floor must be impervious and easy to clean Dedicated handwashing facilities must be present in each room Sharps and clinical waste disposal must be provided Room layout specific to Prosthetic Hair Fibre Implantation There should be a clinical couch available with a reclining, multi-positioning back rest and access on three sides. As patients having Prosthetic Hair Fibre Implantation may faint, the couch must have the ability to go into the Trendelenburg position A height adjustable stool or seat should be available if necessary for the Hair Transplant Surgeon
Equipment	 Prosthetic Hair Fibre Implantation procedure Prosthetic Hair Fibres can be implanted with manual or automated devices Where possible, all instruments should be single use and disposable Instruments referred to as single use by the manufacturer must not be re-used If instruments, devices, tools and equipment are re-used the manufacturer's instructions on cleaning,

	decontamination and sterilisation must be followed and guidance in Dept of Health HTM 01-01 Decontamination of Surgical Instruments must be followed General guidance in Overarching Principles regarding Emergency Care to be followed including • Resuscitation equipment should be within the premises and checked daily • Resuscitation trolley should contain Epipen x 2, oxygen • Practitioners should be aware of the nearest AED
Clinical waste and sharps requirements	 A sharps bin should be available for glass bottles, needles and sharp disposable instruments Blood and body fluid contaminated non-sharp supplies should be disposed of in orange bags in an individual sealed bag per patient Sharps and waste should be collected by licensed practitioners Needle stick injuries should be managed as per national guidance

	Box 4. Education and Training requirements
Education and training requirements	General guidance in Overarching Principles regarding Education and Trainings should be followed
HEE level	Hair Transplant Surgeon is at Level 6 because a medical degree is required
Degree and qualification requirements	Medical degree required GMC full registration and licence
Entry on to the voluntary register Two-tier	Provisional Hair Restoration Surgery Registration Completion of Level 7 Hair Restoration Surgery Theory course AND Certification of Royal College of Surgeons Basic Surgical Skills Course or equivalent

	 Full Hair Restoration Surgery Registration Certification by International Board of Hair Restoration Surgery (IBHRS) / American Board of Hair Restoration Surgery (ABHRS) OR Equivalent AND Certification of Royal College of Surgeons Basic Surgical Skills Course or equivalent
Resuscitation	General guidance in Overarching Principles regarding Emergency Care should be followed • Hair Transplant Surgeons should have valid BLS training and keep this up to date
Continual professional development (CPD)	 General guidance in Overarching Principles regarding CPD and Appraisal should be followed Hair Transplant Surgeons should complete 50 CPD points related to Hair Restoration Surgery At least 25 of these CPD points should be external Internal, e.g reading journals, e-Learning, internal training, internal management or leadership External: courses, conferences, external teaching, management or leadership

Box 5. Supervision	
Assessment of patient	General guidance in Overarching Principles regarding Supervision and Accountability should be followed Specific to Prosthetic Hair Fibre Implantation • Patients having Prosthetic Hair Fibre Implantation must be seen by a Hair Transplant Surgeon • The number of prosthetic hair fibres to be implanted, and the intended recipient area should be agreed in principle prior to the day of surgery • The Hair Transplant Surgeon is responsible for all information given to the patient by a Hair Transplant Clinic Advisor. The above are independent of whether the doctor works for himself/herself or is employed by a clinic
Role of Hair	Hair Transplant Surgeons may be supported by one or more Hair

Transplant Clinic Patient Advisor working with Hair Transplant Surgeon	 Must introduce themselves and their role to the patient Must not pretend to be doctors or mislead patients into thinking they are Must maintain patient confidentiality Must not make medical diagnoses Must not make surgical recommendations including hair transplant surgery design, graft/follicle number estimation, donor harvesting method May record patient demographic and health related information May give the patient general information including about hair loss surgical and medical treatment options, the Prosthetic Hair Fibre Implantation procedure, and administrative processes Must have adequate indemnity in keeping with the Overarching Principles regarding Professionalism
Performing procedure Independent practitioner	 Only GMC licensed doctors can perform Prosthetic Hair Fibre Implantation Prosthetic Hair Fibre Implants may be used in isolation or in combination with Hair Transplant Surgery Only doctors who perform hair transplant surgery will be able to determine which patients are suitable for Prosthetic Hair Fibre Implantation, Hair Transplant Surgery, or a combination Only doctors who perform Hair Transplant Surgery should perform Prosthetic Hair Fibre Implantation All surgical steps of the procedure must be done by the Hair Transplant Surgeon

Box 6. Procedure	
Procedure	General guidance in Overarching Principles regarding Patient Journey should be followed
Supervision requirements	 All surgical steps of the procedure must be done by the Hair Transplant Surgeon Non-surgical steps performed by an assistant are the responsibility of the Hair Transplant Surgeon

Patient positioning Patient Comfort	 Patients should be positioned comfortably prone, supine, tilted or sitting according to the Hair Transplant Surgeon's preference As Prosthetic Hair Fibre Implantation procedures may be several hours long, attention should be given to pressure area protection As Prosthetic Hair Fibre Implantation may be several hours long, patients should be kept hydrated and snacks/meals provided Audio-visual entertainment will assist in alleviating boredom Toilet breaks should be offered and appropriate discreet facilities available
Local anaesthesia	 The majority of Prosthetic Hair Fibre Implantation are done under local anaesthesia with or without local nerve blocks Safe doses of local anaesthetic should be adhered to Concentrations/volume of all local anaesthetic given must be recorded
Safe sedation	Specific to Prosthetic Hair Fibre Implantation Oral sedation may be given for anxiolysis/light sedation IV sedation may occasionally be given General guidance in Overarching Principles regarding Sedation should be followed
Role of Hair Transplant Surgeon	All the Principles in the Royal College of Surgeons <i>Professional Standards for Cosmetic Surgery</i> should be followed by Hair Transplant Surgeons • The Hair Transplant Surgeon is responsible for the patient's care, clinical journey, and hair transplant surgery outcome • The Hair Transplant Surgeon is responsible for the nonsurgical steps of the procedure performed by any assistants working with him/her • The Hair Transplant Surgeon is responsible for all advertising and website content relating to his practice/services The above are independent of whether the doctor works for himself/herself or is employed by a clinic
Role assistants	Hair Transplant Surgeons may be helped by assistants who

working with Hair Transplant Surgeon	 Must hold valid Disclosure and Barring Service (DBS) check Must have appropriate and up to date immunisations Must introduce themselves and their role to the patient Must not pretend to be doctors or mislead patients into thinking they are Must maintain patient confidentiality Must not perform surgical steps of the procedure May perform non-surgical steps of the procedure including assisting the Hair Transplant Surgeon with surgical steps, prepping the surgical site, cleaning the surgical site
Skin preparation	 Patients should be encouraged to wash their hair the night before the Prosthetic Hair Fibre Implantation The hair and scalp should be washed with an antiseptic solution of the hair transplant surgeon's choice prior to surgery
Sterility of procedure	 It is not possible to sterilise hair Because Prosthetic Hair Fibres are being implanted into the scalp and are at a high risk of becoming infected it is important to try to reduce bacterial contamination as much as possible
Test patch	 All patient should have a test patch of Prosthetic Hair Fibre Implantation 4-6 weeks prior to large numbers of implants to ensure no skin reaction. If a skin reaction occurs appropriate management might include removal of Prosthetic Hair Fibre Implants, topical treatment, systemic oral treatment

	Box 7. Record of procedure
Record of Procedure	General guidance in Overarching Principles regarding Medical Records and Information Governance should be followed
Date and time of procedure (each page)	The date and time of the procedure should be recorded along with the patient name
Medications	General guidance in Overarching Principles regarding Medicines

given	 Should be followed Doses and times of all medications administered should be recorded The name of the prescriber should be recorded Medications dispensed should be clearly labelled with
Medication dispensed	name of patient, name of medication, dosing regime, quantity dispensed, and any other relevant information • Medications dispensed should be recorded in the notes
Prosthetic Hair Fibre Implants	 The number of Prosthetic Hair Fibre Implants inserted should be recorded The number of fibres per Prosthetic Hair Fibre Implants inserted should be recorded The colour/s of Prosthetic Hair Fibre Implants inserted should be recorded The shape of the Prosthetic Hair Fibre Implants inserted should be recorded
Anatomical drawings and post-operative photographs	 The area of Prosthetic Hair Fibre Implantation should be identified on the operation notes The area implanted should be photographed immediately post-operatively
Name/role and signature of practitioner easily identified	The name/role and signature of the Hair Transplant Surgeon should be easily identified
Names of assistants should be recorded	The names of all assistants involved in the procedure should be easily identified
Notes	 The notes should be contemporaneous, in order and in logical follow The notes should be safely stored The notes should be kept in line with information governance, for a minimum of 7 years, conforming to information governance standards
Conforms to Information	Hair Transplant Surgeons must comply with CQC Information Governance Requirements

governance standards	
Photographs	 All patients having Prosthetic Hair Fibre Implantation should have appropriate pre and post-operative photographs Standardised background and lighting should be aimed for Standard views might include Anterior frontal facial including hairline Anterior downward tilt to including forelock and midscalp Right lateral/oblique head Left lateral/oblique head Anterior hairline close-up Right oblique temporal hairline close-up Left oblique temporal hairline close-up Posterior occipital head Upward tilt posterior head including crown Crown close-up

Box 8. Patient follow-up	
Patient follow- up	General guidance in Overarching Principles regarding Discharge, Follow-up and Patient Satisfaction should be followed
Appropriate follow up	 15-20% of inserted Prosthetic Hair Fibre Implants can be expected to be lost annually Prosthetic Hair Fibre Implants may become infected Patients should be followed up frequently in the first few months after insertion and at regular intervals thereafter to monitor the Prosthetic Hair Fibre Implants
Patient given contact telephone number	All patients must be given an emergency contact number for out of hours concerns both in the early post-op period and in the longer term
Supply written information	 All patients should be given detailed written post-operative instructions regarding aftercare, washing, and hygiene requirements for Prosthetic Hair Fibre Implants Written instructions on what products can and cannot be used on Prosthetic Hair Fibre Implants should be given Instructions on combing/brushing, styling, cutting, colouring the Prosthetic Hair Fibre Implants should be

	given
Informed of complications to look for	 All patients should be warned about complications to look for including Discomfort/pain Swelling Bleeding Infection (folliculitis and cellulitis)
What to do in an emergency	 Call using the emergency contact number If contact not possible, attend A/E if urgent
Patient given opportunity to feedback – complain or compliment	All patients should be given the opportunity to offer positive and negative experiences in a written feedback form
Adverse event reporting	As a medical device, all adverse events and patient complaints regarding Prosthetic Hair Fibre Implants should be reported to MHRA via the yellow card system https://www.gov.uk/guidance/the-yellow-card-scheme-guidance-for-healthcare-professionals

	Box 9. Logbook and Case Numbers
Logbook	 Hair Transplant Surgeons should keep a logbook of patients operated on including date, name, gender, and Prosthetic Hair Fibre Implant numbers Contemporaneous Digital or paper
Number of cases required to achieve Prosthetic Hair Fibre Implantation competence	 Prior to achieving competence in Prosthetic Hair Fibre Implantation, Hair Transplant Surgeons must have achieved competence in hair transplant surgery (see number of cases to achieve Hair Transplant Surgery competence in CPSA Hair Transplant Surgery standard) Insertion of 50 Prosthetic Hair Fibre Implants manually Insertion of 50 Prosthetic Hair Fibre Implants with automated device
Number of	12 Prosthetic Hair Fibre Implantation cases per year

annual cases to maintain practice	should be carried out per year to maintain practice
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CPD and Appraisal	 Box 10. CPD and appraisal General guidance in Overarching Principles regarding CPD and Appraisal should be followed
Appraisal	Hair Transplant Surgeons must declare their Prosthetic Hair Fibre Implantation practice as part of their GMC appraisal/revalidation process
Related annual conference, teaching or leadership role	 Hair Transplant Surgeons must belong to a professional hair transplant society or association Attendance at hair transplant surgery meetings should satisfy the society/association's membership criteria
Logbook demonstrating adequate case numbers	Hair Transplant Surgeons should keep a logbook demonstrating at least 12 Prosthetic Hair Fibre Implantation cases per year to maintain Prosthetic Hair Fibre Implant practice
Audit	 Annual audit by clinic or individual must be produced of activity and complications Audits should be discussed at morbidity and mortality meetings at least once per year Hair Transplant Surgeons working as lone practitioners should organise joint morbidity and mortality meetings
Patient reported outcome measures (PROMs)	Every patient should be offered the opportunity to feedback their outcomes at the end of every patient episode (rather than encounter) and formal quantitative and qualitative patient reported outcome measures (PROMs) are recommended
Review of complaints and compliments	Logs must be maintained for complaints and compliments according to CQC requirements

Work based assessments	Hair Transplant Surgeons must satisfy GMC appraisal and revalidation requirements
Annual appraisal including this scope of work	Hair Transplant Surgeons must satisfy GMC appraisal and revalidation requirements
For regulated professionals: Five yearly revalidation including this scope of work	Hair Transplant Surgeons must satisfy GMC appraisal and revalidation requirements

Box 11. Infection control and decontamination	
Infection control and decontaminatio n	General guidance in Overarching Principles regarding Infection Control should be followed
Handwashing policy	Handwashing must be performed as per 6 stages of accepted handwashing policy
Handwashing assessments	As per CQC (mandatory 3 monthly hand washing audit)
Sharps handling	 Sharps must be handled carefully Needle-stick injuries should be treated in line with national guidance: Ensure patient safety, remove sharp, irrigate the wound, go to A&E or follow local policy; ask patient for BBV status and to go for blood test at hospital, if they agree to do so
Sharps disposal	Sharps should be disposed of in a designated sharps bin
Blood borne virus awareness	Hair Transplant Surgeons must be aware of the risk of blood borne viruses and use universal precautions at all

	times
Decontami- nation process	 Single use instruments should be used wherever possible Re-usable instruments should be cleaned and sterilised according to the guidance in Dept of Health HTM 01-01 Decontamination of Surgical Instruments
Human waste/liquid management policy	As recommended by CQC
Waste disposal/ management policy	 Authorised third party waste management Hazardous non-sharps waste should be individually disposed of per patient in the orange, sealed bin bag
Sterility of Procedure	 Specific to Prosthetic Hair Fibre Implantation It is not possible to sterilise hair Because Prosthetic Hair Fibres are being implanted into the scalp and are at a high risk of becoming infected it is important to try to reduce bacterial contamination as much as possible Sterile gloves can be used by the by the Hair Transplant Surgeon and assistants when inserting Prosthetic Hair Fibre Implants Sterile gowns should be used Sterile drapes should be used Aseptic technique should be utilised

	Box 12. Advertising
Fees and Advertising	 General guidance in Overarching Principles regarding Fees and Advertising should be followed including Must be truthful and factual Must comply with Advertising Standards Authority's Guidance on the Marketing of Surgical and Non-surgical Cosmetic Procedures Must avoid financial inducements such as discounts and time limited offers

Box 13. Medical Tourism	
Medical Tourism	General guidance in Overarching Principles regarding Medical Tourism to be followed.
	 Specific to Prosthetic Hair Fibre Implantation Patients may travel long distances within the UK and even form overseas to have Prosthetic Hair Fibre Implantation done by a preferred Hair Transplant Surgeon Arrangements for emergency care, support and long term follow up must be made clear to the patient