NHS England

Hand and upper limb reconstruction using vascularised composite allotransplantation (HAUL-VCA)

Reference: NHS England D00/P/a

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Publications Gateway Reference:	**03715**
Document Purpose	Policy
Document Name	D00/P/a Hand Transplantation for Forearm Loss
Author	Specialised Commissioning Team, NHS England
Publication Date	July 2015
Target Audience	Local Team Assistant Directors of Specialised Commissioning; Regional Team IFR Leads; Finance Leads; Local Team Pharmacists; Chairs of Clinical Reference Groups; Members of Clinical Reference Groups and registered stakeholders; Acute Trust Chief Executives; Acute Trust Medical Directors; Acute Trust Chief Pharmacists
Additional Circulation List	Regional Medical Directors; Regional Directors of Specialised Commissioning; Regional Clinical Directors of Specialised Commissioning; Regional Directors of Nursing
Description	NHS England will routinely commission this specialised treatment in accordance with the criteria described in this policy.
Cross Reference	
Superseded Docs (if applicable)	
Action Required	
Timing / Deadlines (if applicable)	
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Document Status

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Contents

1 Executive summary

Policy statement

NHS England will routinely commission hand transplantation in accordance with the criteria outlined in this document.

In creating this policy NHS England has reviewed this clinical condition and the options for its treatment. It has considered the place of this treatment in current clinical practice, whether scientific research has shown the treatment to be of benefit to patients, (including how any benefit is balanced against possible risks) and whether its use represents the best use of NHS resources.

This policy document outlines the arrangements for funding of this treatment for the population in England.

Equality statement

NHS England has a duty to have regard to the need to reduce health inequalities in access to health services and health outcomes achieved as enshrined in the Health and Social Care Act 2012. NHS England is committed to fulfilling this duty as to equality of access and to avoiding unlawful discrimination on the grounds of age, gender, disability (including learning disability), gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, gender or sexual orientation. In carrying out its functions, NHS England will have due regard to the different needs of protected equality groups, in line with the Equality Act 2010. This document is compliant with the NHS Constitution and the Human Rights Act 1998. This applies to all activities for which NHS England is responsible, including policy development, review and implementation.

Plain language summary

Hand transplantation is used to replace a defective or amputated hand or arm using parts from a deceased donor. The transplanted arm is able to sense its surroundings,

move naturally with strength and dexterity, looks, feels and heals like a natural hand. Immunosuppressive drug therapy is taken to stop the body rejecting the transplant.

Hand transplant is an established procedure worldwide but is not currently routinely commissioned by the NHS in England. For a small minority of suitable patients, transplant offers an alternative to a prosthesis (artificial hand).

The estimated need is for transplants for between two and four patients per annum.

2 Introduction

Hand transplant is more technically known as hand and upper limb reconstruction using vascularised composite allotransplantation (HAUL-VCA).

Worldwide, approximately 80 hand transplants have been performed.
Success rates are high provided patients are selected carefully and fully prepared psychologically.

3 Definitions

Hand and upper limb allotransplant offers amputees the only method of reconstruction that looks and functions like a normal hand. The hand will move with strength and dexterity, will sense its surroundings, will feel warm to the touch and heal itself when injured.

4 Aims and Objectives

This policy aims to:

- Outline the policy for provision of hand transplant to patients of the NHS in England

The objectives are to:

- Outline the scientific evidence
- Outline the costs of hand transplant
- Set out a commissioning policy

5 Epidemiology and needs assessment

Hand and upper limb reconstruction using vascularised composite allotransplantation (HAUL-VCA) is appropriate to reconstruct an absent upper limb or hand, lost as result of trauma or infection or a defective upper hand or limb. HAUL-VCA should, ordinarily, only be offered to those for whom current reconstructive techniques or prostheses are unsuitable or unsatisfactory.

Up to 20% of the adult population with upper limb amputations choose not to use prosthesis. Of those that do accept a prosthesis, as many as 26% of adults and 45% of children and adolescents are dissatisfied with their device and choose not to use them. Reasons cited include poorly developed fine motor control, absence of sensory function, weight and a lack of warmth and humanness (Biddiss EA. Prosthet Orthot Int 2007 31: 236).

HAUL-VCA is an alternative to a prosthesis in very small subset of upper limb amputees who are both physically and psychologically suited and in whom the benefits outweigh the risks of immunosuppression.

Hand and upper limb allotransplant offers amputees the only method of reconstruction that looks and functions like a normal hand. The hand will move with strength and dexterity, will sense its surroundings, will feel warm to the touch and heal itself when injured.

Reconstruction of the absent hand using allotransplantation has additional, less readily quantifiable benefits such as improved self-image, and improved psychological and social function (Petruzzo P, Transplantation 2010;90:1590).

Hand transplant recipients have enhanced activities of daily living and the majority return to employment.

Data from 1996 estimates there are 1,285,000 upper and lower limb amputees in the US, representing 0.4% of the population (CDC. National Health Interview Survey.

Atlanta: Centers for Disease Control, 1996), with an incidence of 50,000 new cases per year (Esquenazi, A. Disability & Rehabilitation, 2004; 26:831). The total number of upper limb amputees in England is not known, but the prevalence is likely to be similar to that of the United States, representing 250,000 individuals and 10,000 amputations per year. Data suggests that one in four amputations performed occur in the upper limb.

No data currently exist to quantify the fraction of upper limb amputees that may be suitable for HAUL-VCA. It is, however, anticipated that this subgroup will be small. Of 20 patients previously screened as part of a pilot HAUL-VCA programme in England, only two patients have been both suitable and, after discussion of the inherent risks of the procedure, willing to proceed. The number of patients that will seek the procedure and meet the stringent inclusion criteria including approval for surgery following psychological counselling is estimated to be between two and four patients per year.

In one US programme, with similar inclusion and exclusion criteria to the England programme, of 600 patients screened, only six have been considered suitable and received a transplant (Kaufman CL. World experience after more than a decade of clinical hand transplantation: update from the Louisville hand transplant program. Hand Clin. 2011;27:417–21).

Patients suitable for HAUL-VCA must be highly motivated; generally fit and well; must have failed a trial of, or be unsuitable for, a prosthesis; be able to balance complex issues of risk and benefit; and be psychologically suitable (show understanding, appropriate expectations, have adequate coping mechanisms, be able to accept a donor limb etc). HAUL-VCA is not currently considered suitable for congenital limb absence or for those who have required amputation secondary to the presence of tumour.

Although an increase in referrals may be anticipated to follow successful transplantation, the likely growth of the procedure will remain small due to the stringent inclusion criteria.

It is likely that there are a significant number of upper limb amputees in the UK who may wish to explore the possibility of HAUL-VCA. Many of these will be excluded on receipt of their referral because of inherent characteristics (congenital, too young, previous history of malignancy, co-morbidities). Complex assessment, performed within a specialist setting by a multidisciplinary team is required to carefully select the small proportion of amputees that may benefit from transplantation.

6 Evidence base

HAUL-VCA is an alternative to prosthetics and is indicated especially in those cases of distal loss where prostheses fail, or offer an inferior solution.

Due to the level of amputation, prosthetics are not suitable for all. In such situations, no alternative therapies exist.

Due to the low number of procedures performed and the unique nature of each case, no randomised controlled trials comparing the outcomes of HAUL-VCA to alternative treatments (prostheses no reconstruction) exist.

It is expected from international results that hand transplantation will be superior in all patient reported outcome measures to prostheses.

International data is collected and collated by the International Registry for Hand and Composite Tissue Transplantation (IRHCTT, www.handregistry.com), who publish updated case series biennially.

The IRHCTT data reveal that HAUL-VCA recipients express satisfaction with cosmetic, sensory, functional, and social outcomes after transplantation.

A composite functional score developed by IRHCTT shows 40% of all HAUL-VCA recipients achieve an ‘excellent’ outcome, whereas 53% achieve ‘good’ and 7% achieve ‘fair’ outcomes. No transplants have resulted in a ‘poor’ outcome.

Protective sensation has been achieved in all patients within 12 months and, as time progressed, 90% showed tactile and 72% of them discriminative sensibility.

The majority (70%) return to work and 75% report an increased quality of life (Petruzzo P, Transplantation 2010;90:1590).

Data extrapolated from analogous surgical techniques suggest that hand transplant is likely to have excellent clinical outcomes. Replantation of a traumatically detached limb (auto transplantation) is technically similar to HAUL-VCA. In one study, limb replantation resulted in a good or excellent function in 50% of cases, whereas prosthetics failed to produce a good or excellent outcome in any case (Graham B, J Hand Surg 1998;23A:783). Indeed, one may expect better outcomes from HAUL-VCA when compared to replantation, through the beneficial secondary effects of the immunomodulatory drug Tacrolimus which, whilst required for immunosuppression, also enhances speed and quality of nerve regeneration (Gold BG. J Neurosci 1995;15:7509).

A study evaluating functional outcomes following HAUL-VCA showed marked improvement in a standardised test of upper limb function, the DASH (disabilities of arm, shoulder and hand) score. In their series, DASH score improved by a mean of 27.6 ± 19.04 points (Landin L. Transpl Int. 2012;25:424). To put this in context, a carpal tunnel release improves the DASH score by a mean of 12 points.

Hand and upper limb allotransplant offers amputees the only method of reconstruction that looks and functions like a normal hand. The hand will move with strength and dexterity, will sense its surroundings, will feel warm to the touch and heal itself when injured. Reconstruction of the absent hand using allotransplantation has additional, less readily quantifiable benefits such as improved self-image, and improved psychological and social function. Hand transplant recipients have enhanced activities of daily living and the majority return to employment.

7 Rationale behind the policy statement

For a small minority of suitable patients, transplant offers an alternative to a prosthesis.

8 Criteria for commissioning

Hand and upper limb reconstruction using vascularised composite allotransplantation (HAUL-VCA) is appropriate to reconstruct a defective upper limb or hand or an absent upper limb or hand, lost as result of trauma or infection. HAUL-VCA should, ordinarily, only be offered to those for whom current reconstructive techniques or prostheses are unsuitable or unsatisfactory.

Protocol-based evaluation leads to the majority of potential candidates not being accepted for treatment on current standards. Those that are accepted following psychological, surgical, immunological and medical screening and after detailed occupational therapy assessment should proceed to an offer of waiting list for hand transplantation.

This policy has been agreed on the basis of NHS England's understanding of the likely price of care associated with enacting the policy for all patients for whom NHS England has funding responsibility, as at the time of the policy's adoption. Should these prices materially change, and in particular should they increase, NHS England may need to review whether the policy remains affordable and may need to make revisions to the published policy.

9 Patient pathway

Patients will need to be adults (18+) in order to have sufficient psychological maturity. There is no upper age limit for referral to the service.

The national caseload of new patients requiring evaluation each year is anticipated to be approximately ten or 12.

In year two, it is envisaged that up to 30 new patients will be seen and discharged as not suitable, (comprises 10 patients who will be discharged at their first outpatient appointment or first follow-up and 20 patients who will have a first outpatient

appointment and up to six outpatient assessments before being discharged from the pathway due to being unsuitable for surgery). Two patients are expected to successfully complete assessment and go to receive a transplantation, (one unilateral, one bilateral). By year five, the number of patients to receive transplantations is likely to increase to a maximum of four.

Patients should be referred to the service from secondary care practitioners working in areas such as hand, plastic and orthopaedic surgery and from rehabilitation centres.

Patients who, on the basis of their referral letter, may be suitable for hand transplantation, should be invited to a multidisciplinary outpatient appointment at which clinical and laboratory assessment is performed and verbal and written information provided to the patient. All core components of the team (surgeons including orthopaedic and plastic surgeons, transplant physicians, immunologists, prosthetists and psychologists) should be in attendance.

The protocol-led evaluation pathway should lead to the majority of potential candidates not being accepted for treatment on current standards. Those that are accepted following psychological, surgical, immunological and medical screening and after detailed occupational therapy assessment should proceed to an offer of waiting list for hand transplantation.

During the waiting period, patients should continue to be monitored for immunologic status and sensitisation which contributes to a virtual cross match at the time of donation. Specialist Nurses in Organ Donation (SNODs) employed by NHS Blood & Transplant (NHSBT) maintain vigilance for a suitable donor using visual and biometric data. NHS Blood and Transplant will remain responsible for all aspects of organ procurement.

On identification of a potential donor, the patient should be admitted, a time of offer cross match and Human Leukocyte Antigen (HLA) screen performed and donation offered if appropriate.

If donation is accepted, the patient should follow a standard surgical protocol, through the analogous procedure of microsurgical replantation of amputated limbs.

Following transplantation, a protocol exists for monitoring for acute rejection, which, unlike solid organ transplants, manifests itself visibly and standard immunological protocols are followed in its management.

Physiotherapy and occupational therapy protocols should be in place for the early and intermediate management and for early mobilisation as an outpatient.

The hand transplant service requires the following components:

Diagnosis and Assessment:

- Assessment for suitability and provision of prosthetic limbs.
- Laboratory based biochemical, immunological, haematological and virological and bacteriological assessment.
- Transplant physician assessment.
- Surgical assessment.
- Psychological assessment.
- Radiological assessment (Plain radiographs and occasionally MRI assessment).

Operative Components:

- A single operating theatre and specialised microsurgical operating department staff are required.
- An operating microscope and microsurgical instruments are required.

Post-Operative Components:

- Routine postoperative care provided, initially in the high dependency unit followed, two to three days later by standard ward care.
- Postoperative physiotherapy and occupational therapy provided three times per week for the first three months.
- Therapeutic drug monitoring at regular intervals.

- Psychological support to facilitate adjustment and acceptance of transplanted hand to ensure best patient outcomes.
- Outpatient follow up - weekly for four weeks then monthly for six months in year one
- Outpatient follow up in year two, up to one appointment per month

10 Governance arrangements

Hand transplantation is a highly specialised procedure. It is expected that up to two Specialist Acute Centres in England will provide transplants to between two and four patients per annum.

Auditing and monitoring. Functional and psychological outcomes will be closely monitored. Normal arrangements will apply for reporting to NHS Blood and Transplant in line with legal and other requirements for solid organ transplantation.

11 Mechanism for funding

Contractual arrangements are managed via the responsible NHS England commissioning hub.

12 Audit requirements

As HAUL-VCA remains a developing procedure, continued, careful data collection is required. Audits will also include quality, outcome and patient satisfaction audits

Reporting will be required to the NHS England Highly Specialised Services Commissioning Team which to be included in reports to the Rare Disease Advisory Group, (RDAG) to report on progress and as compared to international comparisons to include:

- Monthly activity monitoring
- Annual patient outcomes

- In addition NHS Blood and Transplant will monitor patient and graft survival and undertake the evaluation of pre-existing and de-novo donor HLA specific sensitisation on outcome.

13 Documents which have informed this policy

Commissioning for Patients: Guidelines for National Commissioning of Specialized Services for Patients of All ages with limb loss. (Department of Health 2011.

National Service Specification for Amputee Rehabilitation.

National Service Framework for long-term conditions (2005).

British Society of Rehabilitation Medicine (2003), Amputee and Prosthetic Rehabilitation –standards and guidelines (2nd edition) section 4.19, British Society of Rehabilitation Medicine, London.

National Prosthetic Centre Managers Group (2010), National Service Specification for Prosthetic and Amputee Rehabilitation Services, National Prosthetic Centre Managers Group, Preston.

Royal College of Physicians & British Society of Rehabilitation Medicine (2010), Medical rehabilitation in 2011 and beyond. A report of a working party (6.21), London.

British Association of Prosthetists and Orthotists (2005), Guidelines for best practice No 1: The Role of the Prosthetist/Orthotist (Issued 2000 and then re-issued in February 2005, British Association of Prosthetists and Orthotists, Paisley.

Upper limb Prosthetic Rehabilitation – Guidance document. College of Occupational Therapists (2006) College of Occupational Therapists Ltd. 106-114 Borough High St, London SE1 1LB.

14 Links to other policies

National Service Specification: Complex Disability Equipment-Prosthetic Specialised Services for People of All Ages with Limb Loss.

National Service Framework for long-term conditions (2005).

This policy follows the principles set out in the ethical framework that govern the commissioning of NHS healthcare and those policies dealing with the approach to experimental treatments and processes for the management of individual funding requests (IFR).

15 Date of review

This policy will be reviewed in April 2018 unless information is received which indicates that the proposed review date should be brought forward or delayed.

References

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