

Hand allotransplantation

Interventional procedures guidance

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www.nice.org.uk/guidance/ipg383

Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the [Yellow Card Scheme](#).

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

1 Guidance

- 1.1 Current evidence on the efficacy and safety of hand allotransplantation is inadequate in quantity. In addition, there are risks from the prolonged immunosuppression required after the procedure. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and research.
- 1.2 Clinicians wishing to undertake hand allotransplantation should take the following actions.
 - Inform the clinical governance leads in their Trusts.
 - Ensure that patients and their carers understand the uncertainty about the procedure's safety and efficacy, in particular the need for and risks of long-term immunosuppression, and the fact that functioning of the transplant may be both delayed and limited. Patients should also be provided with clear written information. In addition, the use of NICE's information for patients is recommended.
- 1.3 Hand allotransplantation should be carried out only in units with surgical teams experienced in limb reimplantation and with experts in transplantation medicine. Patients' suitability for hand allotransplantation should be carefully assessed in line with practice recommended by NHS Blood and Transplant. Alternative methods of management should be discussed, as well as appropriate rehabilitation. Units carrying out the procedure should work within the provisions of the Human Tissue Act 2004.
- 1.4 Clinicians should submit data to the International Registry on Hand and Composite Tissue Transplantation and Transplant UK.
- 1.5 Further research into hand allotransplantation should include data on long-term functional outcomes, and any occurrence of malignancy associated with long-

term immunosuppression should be published. NICE may review this procedure on publication of further evidence.

2 The procedure

2.1 Indications and current treatments

2.1.1 Amputation of an extremity may result from trauma, surgery carried out to control pain or a disease process in the affected limb. The usual way to restore some hand function after amputation of the arm is to fit a prosthesis. It may be possible to reimplant the hand after traumatic amputation.

2.2 Outline of the procedure

- 2.2.1 Hand allotransplantation aims to provide a hand that looks more natural than a mechanical prosthesis, and which restores some sensation and movement.
- 2.2.2 Before the procedure, psychological assessment is required of a patient's motivation and likely compliance with postoperative rehabilitation and immunosuppressive medication.
- 2.2.3 A cadaveric limb removed surgically from a donor, below the elbow, is used for the transplant. Its suitability for the recipient is assessed by basic matching for sex, size, appearance, and sometimes genetic matching.
- 2.2.4 Hand allotransplantation is carried out with the patient under general anaesthesia, which may be supplemented by a regional nerve block. A tourniquet may be used for haemostasis. The radius and ulna from the donor limb are fixed to those of the recipient using intramedullary pins or plates. Arteries and veins are anastomosed using standard techniques. The major nerves are repaired and others are joined if possible. Tendons are repaired either individually or in groups.
- 2.2.5 Following the procedure the limb may be immobilised in a plaster splint for a

number of weeks. The patient should undergo intensive rehabilitation, including physiotherapy, occupational therapy and possibly electrostimulation for best restoration of function. Long-term immunosuppression is needed to reduce the possibility of rejection.

Sections 2.3 and 2.4 describe efficacy and safety outcomes from the published literature that the committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the [overview](#).

2.3 Efficacy

- 2.3.1 A case series of 30 patients (38 hands) reported that more than 70% of patients had improved quality of life following hand allotransplantation and that 'most' patients returned to work (absolute figures and follow-up not stated).
- 2.3.2 The case series of 30 patients reported 100% (37 of 37) graft survival at 1- and 2-year follow-up; however, graft failure occurred later in 10 hands because of non-compliance with the immunosuppression regimen (timing not stated). Acute rejection episodes occurred in 85% of patients within the first year; all episodes were reversed when promptly reported and treated.
- 2.3.3 A case report of 1 patient (1 hand) described re-amputation of the transplanted hand after 12 hours because of thrombosis of the radial artery distal to the entry site of a cannula in the donor arm. A case report of 5 patients (5 hands) reported re-amputation of 1 hand at 9-month follow-up because of intractable ischaemia.
- 2.3.4 The case series of 30 patients reported that 90% of patients achieved tactile sensibility and 72% developed discriminative sensibility at follow-ups ranging from 6 months to 9 years (absolute figures not stated).
- 2.3.5 The case report of 5 patients reported an 'excellent' functional outcome in 1 patient, intrinsic muscle recovery in another patient, good function but no intrinsic muscle recovery in 2 patients, and good early progress in the remaining patient (2-month to 10-year follow-up).

- 2.3.6 The specialist advisers listed key efficacy outcomes as hand function, rejection-free survival of the transplant and patient satisfaction.

2.4 Safety

- 2.4.1 Arterial thrombosis and venous thrombosis each occurred in 1 of 37 procedures in the case series of 30 patients; both patients required additional surgery (timing of events not stated).
- 2.4.2 Multiple arteriovenous fistulae requiring additional surgery were reported in 1 of 37 procedures in the case series of 30 patients (timing of events not stated).
- 2.4.3 Indolent (marginal zone) lymphoma was reported in 1 patient in the case report of 5 patients (follow-up ranged from 2 months to 10 years).
- 2.4.4 The case series of 30 patients reported opportunistic infections in 65% of the 29 patients receiving immunosuppression at follow-ups ranging from 6 months to 9 years. These included cytomegalovirus reactivation, cutaneous mycosis, herpes virus and *Clostridium difficile*. Most infections resolved with treatment.
- 2.4.5 The case series of 30 patients reported that metabolic complications related to immunosuppression therapy occurred in 52% (15 of 29) of patients at follow-ups ranging from 6 months to 9 years.
- 2.4.6 The specialist advisers listed adverse events reported in the literature as acute and chronic rejection (when immunosuppression was stopped), poor neurological function of the hand and immunosuppression-induced diabetes. They considered theoretical adverse events to include malignant changes or tumour development and graft-versus-host disease.

3 Further information

Information for patients

NICE has produced [information on this procedure for patients and carers](#). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

4 Update information

Minor changes since publication

January 2012: Minor maintenance.

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Endorsing organisation

This guidance has been endorsed by [Healthcare Improvement Scotland](#).

Accreditation

