

Metatarsophalangeal joint replacement of the hallux

Interventional procedures guidance

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www.nice.org.uk/guidance/ipg140

1 Guidance

- 1.1 Current evidence on the safety and efficacy of metatarsophalangeal joint replacement of the hallux appears adequate to support the use of this procedure provided that the normal arrangements are in place for consent, audit and clinical governance.
- 1.2 Clinicians should ensure that patients fully understand the uncertainties about the place of this procedure in relation to alternative treatment options. Patients should be provided with clear written information and, in addition, use of the Institute's [information for the public](#) is recommended.
- 1.3 Patient selection is important, and should take into consideration the likely intensity and duration of use of the joint based on the patient's activities and aspirations.
- 1.4 Further research will be useful in establishing the long-term outcomes of

different types of prosthesis.

2 The procedure

2.1 Indications

- 2.1.1 Osteoarthritis and rheumatoid arthritis commonly affect the metatarsophalangeal (MTP) joint at the base of the big toe. The joint may become predominantly stiff (hallux rigidus) or deformed (hallux valgus).
- 2.1.2 Conservative treatments include exercise, physiotherapy, analgesics, non-steroidal anti-inflammatory tablets or cream, and steroid injections into the joint. Surgery may be required in patients with severe symptoms that do not respond to conservative measures. The main surgical options are fusion of the joint (arthrodesis), simple excision of the joint (Keller's procedure) and joint replacement with an artificial implant.

2.2 Outline of the procedure

- 2.2.1 MTP joint replacement is carried out under general or regional anaesthesia using tourniquet control. An incision is made over the joint and the capsule is exposed by dividing tissue and retracting tendon. The joint surfaces are excised and the medullary canals of the first metatarsal and proximal phalanx are reamed to accommodate the prosthetic joint implant. A preliminary reduction with a trial implant is done to ensure a snug fit and the implant components are then placed in each canal. The joint capsule is closed and a flexible splint is used postoperatively to maintain the correct position.

2.3 Efficacy

- 2.3.1 The main outcome measures reported were pain relief and patient satisfaction. Three studies reported that 73% (8/11), 79% (46/58) and 100% (7/7) of joints with implants were pain free after mean follow-ups of 17 months, 12 years and 35 months, respectively. Another study including 86 implants reported a statistically significant improvement in

pain scores after the procedure. Two further studies reported pain relief in 66% (59/90) of implants and 94% (30/32) of patients (mean follow-ups of 3 years and 8 years, respectively).

2.3.2 Four studies reported that between 74% (29/39) and 88% (7/8) of patients were completely satisfied with the procedure (mean follow-ups of 12 months and 17 months, respectively). For more details, refer to the Sources of evidence.

2.3.3 Most of the Specialist Advisors stated that this was an established technique. However, there is limited evidence on the durability of the newer implants.

2.4 Safety

2.4.1 The main complication reported was the formation of osteophytes around the implant. This affected between 4% (2/49) and 71% (41/58) of implants. Fractures were seen radiologically in 0% (0/106) to 29% (21/73) of implants, and frequency of fracture was related to the length of time that the implant had been in place. At the follow-up assessment, between 0% (0/11) and 8% (3/37) of implants had needed to be removed (mean follow-ups of 17 and 70 months, respectively). Other complications included malpositioning of the implant, infection, inflammation, dislocation and persistent pain. For more details, refer to the Sources of evidence.

2.4.2 The Specialist Advisors stated that potential adverse events included persistent pain, infection, implant loosening, implant fracture, osteolysis, bone over-production, cyst formation, silastic granulomas and transfer metatarsalgia. Some of these complications may necessitate removal of the joint.

2.5 Other comments

2.5.1 Radiological follow-up may demonstrate fracture of prostheses or immobility of joints in the long term. However, the influence of these changes on symptom relief remains unclear.

3 Further information

- 3.1 The Medicines and Healthcare products Regulatory Agency (MHRA) has issued the following device alert notices: DA2002(03), Screw-Fit Ceramic Toe Joint (Metatarsophalangeal) Replacement Prosthesis; and MDA/2004/009, Moje Press-Fit Ceramic Toe Joint Prosthesis.

Andrew Dillon
Chief Executive
November 2005

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the following document.

['Interventional procedures overview of metatarsophalangeal joint replacement of the hallux'](#), February 2005.

Information for the public

NICE has produced [information describing its guidance on this procedure for patients, carers and those with a wider interest in healthcare](#). It explains the nature of the procedure and the decision made, and has been written with patient consent in mind.

4 About this guidance

NICE interventional procedure guidance makes recommendations on the safety and efficacy of the procedure. It does not cover whether or not the NHS should fund a procedure. Funding decisions are taken by local NHS bodies after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS. It is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland, and is endorsed by Healthcare Improvement Scotland for implementation by NHSScotland.

This guidance was developed using the NICE [interventional procedure guidance](#) process.

We have produced a [summary of this guidance for patients and carers](#). Information about the evidence it is based on is also [available](#).

Changes since publication

23 January 2012: minor maintenance.

Your responsibility

This guidance represents the views of NICE and was arrived at after careful consideration of the available evidence. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of healthcare professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

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Endorsing organisation

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