NICE guidance

Automated percutaneous mechanical lumbar discectomy

Interventional procedures guidance
Published: 23 November 2005

www.nice.org.uk/guidance/ipg141

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 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 NICE'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 Metatarsophalangeal (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 out of 11), 79% (46 out of 58) and 100% (7 out of 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 out of 90) of implants and 94% (30 out of 32) of patients (mean follow-ups of 3 years and 8 years, respectively).

2.3.2 Four studies reported that between 74% (29 out of 39) and 88% (7 out of 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 overview.

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 out of 49) and 71% (41 out of 58) of implants. Fractures were seen radiologically in 0% (0 out of 106) to 29% (21 out of 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 out of 11) and 8% (3 out of 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 overview.

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 protheses 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.

Sources of evidence

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

Information for the public

NICE has produced information for the public on this procedure. It explains the nature of the procedure and the decision made, and has been written with patient consent in mind.

ISBN: 978-1-4731-6453-6

Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.