Issue date: February 2010

NHS
National Institute for
Health and Clinical Excellence

Surgical correction of hallux valgus using minimal access techniques

1 Guidance

1.1 Current evidence on the efficacy of surgical correction of hallux valgus using minimal access techniques is limited and inconsistent. In addition, the evidence relates to a range of different surgical techniques. The evidence on safety is inadequate. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.

1.2 Clinicians wishing to undertake surgical correction of hallux valgus using minimal access techniques 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 and provide them with clear written information. In addition, the use of NICE's information for patients ('Understanding NICE guidance') is recommended (available from www.nice.org.uk/guidance/IPG332/PublicInfo).
- Audit and review clinical outcomes of all patients having surgical correction of hallux valgus using minimal access techniques (see section 3.1).

1.3 Further research should evaluate clearly described minimal access procedures using well-defined modern forms of osteotomy. Both objective and functional outcome measures should be reported, together with measurements of pain relief and patient satisfaction, including cosmesis. All adverse events should be described.

1.4 NICE may review this procedure on publication of further evidence.

2 The procedure

2.1 Indications and current treatments

2.1.1 In hallux valgus the big toe is deviated towards the other toes and a bony protrusion (a bunion) is formed by medial deviation of the first metatarsal phalangeal joint. There may be damage to the skin over the bunion, pain when walking, cosmetic concerns and difficulty with footwear.

2.1.2 Conservative treatment may include footwear modification, and use of insoles or toe spacers. Common surgical treatment options involve different types of first metatarsal osteotomy.

2.2 Outline of the procedure

2.2.1 Surgical correction of hallux valgus using minimal access techniques is carried out with the patient under local or general anaesthesia and with X-ray or endoscopic monitoring. One or more small incisions are made close to the hallux metatarsophalangeal joint. The bunion is removed and the metatarsal is divided surgically. The bone fragments may be stabilised using plates, screws or wires. A dressing or plaster may be used to support the foot in the corrected position until the divided bone heals.

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, available at www.nice.org.uk/IP782overview

Interventional procedure guidance 332

Interventional procedures guidance makes recommendations on the safety and efficacy of a procedure. The guidance does not cover whether or not the NHS should fund a procedure. Decisions about funding are taken by local NHS bodies (primary care trusts and hospital trusts) after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS.

Interventional procedures guidance is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland. This guidance is endorsed by NHS QIS for implementation by NHSScotland.

NHS Quality Improvement Scotland

2.3 Efficacy

2.3.1 The evidence relates to studies that varied in osteotomy technique (regarding the location, shape and fixation of the osteotomy, and in the methods of visualisation or guidance). Where bone fixation was undertaken, it was usually with Kirschner wires, but use of plates and screws were also reported.

2.3.2 Recurrence of hallux valgus was reported in 2% (2/94) and 1% (1/118) of treated feet in case series of 83 and 82 patients respectively (timing of events not stated).

2.3.3 In a case series of 204 patients (301 feet), 83 reported preoperative pain. Of these, 84% (70/83) reported no pain after the operation, 8% (7/83) had decreased pain and 1% (1/83) had increased pain (mean follow-up 8.3 months). A series of 64 patients reported that 95% (61/64) of patients were pain free at a mean follow-up of 9 years.

2.3.4 Case series of 204 and 168 patients reported postoperative decreases in mean hallux angle from 26° to 7.5° ($p < 0.05$) and 28° to 14° (significance not stated) at mean follow-up of 6 weeks and 31.5 months respectively.

2.3.5 The case series of 204 patients (301 feet) reported that 74% (61/83) of survey respondents were very pleased with the procedure, 12% (10/83) were somewhat pleased, 4% (3/83) were not satisfied and 4% (3/83) regretted having had surgery (mean follow-up 8.3 months).

2.3.6 The Specialist Advisers listed key efficacy outcomes as improvement in pain and deformity, patient satisfaction, radiographic correction of deformity and pedobarography (foot pressure measurement).

2.4 Safety

2.4.1 Deep infection at the osteotomy site was reported in 1 patient (treated by intravenous antibiotics and resolved within 2 weeks) in the case series of 82 patients; 1 patient (Kirschner wire removed after 3 weeks and infection resolved) in a series of 31 patients; and in 4% (4/98) of feet in the series of 64 patients (98 feet).

2.4.2 Osteonecrosis was reported in 8% (1/13) of patients in a case series of 13 patients (13 feet) (timing of event not stated).

2.4.3 Delayed union was reported in 1% (4/301) of feet in the case series of 204 patients (301 feet) (at mean 8.3 month follow-up). A case series of 49 patients (59 feet) reported malunion and non-union in 2 patients each (assessed radiographically at mean follow-up 31.5 months).

2.4.4 Postoperative hallux varus was reported in 0.3% (1/301) (not otherwise described) and 1% (1/94) (1 year after surgery, treated by extensor hallucis longus transfer) of feet in case series of 204 (301 feet) and 83 (94 feet) patients respectively.

2.4.5 Stress fracture of the second metatarsal was reported in 2% (7/301) of feet in the case series of 204 patients (timing of events not stated).

2.4.6 Specialist Advisers expressed concerns about the safety of this procedure. They listed possible adverse events as nerve injury including complex regional pain syndrome, toe stiffness, skin necrosis, osteomyelitis, deep vein thrombosis, tendon injury, removal of fixation screw, recurrent deformity, fracture, tender scars and skin sensitivity. They considered theoretical adverse events to include burning soft tissue, damage to foot blood vessels, inflammatory reaction to bone debris, and first metatarsal malpositioning, shortening or necrosis.

3 Further information

3.1 This guidance requires that clinicians undertaking the procedure make special arrangements for audit. NICE has identified relevant audit criteria and developed audit support (which is for use at local discretion), available from www.nice.org.uk/guidance/IPG332

3.2 For related NICE guidance see www.nice.org.uk

Information for patients

NICE has produced information on this procedure for patients and carers ('Understanding NICE guidance'). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind. See www.nice.org.uk/guidance/IPG332/PublicInfo

Ordering printed copies
Contact NICE publications (phone 0845 003 7783 or email publications@nice.org.uk) and quote reference number N2098 for this guidance or N2099 for the 'Understanding NICE guidance'.

National Institute for Health and Clinical Excellence
MidCity Place, 71 High Holborn, London WC1V 6NA; www.nice.org.uk

ISBN 978-1-84936-176-7
N2098 1P 5.7k Feb 10