



# Surgical correction of hallux valgus using minimal access techniques

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# 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 <u>assess and reduce the environmental impact of implementing NICE recommendations</u> wherever possible.

#### 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 the <u>information for the public</u> is
    recommended.
  - 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

- 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.

# 2.3 Efficacy

This section describes efficacy 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.

2.3.1 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 of 94) and 1% (1 of 118) of treated feet in case series of 83 and 82 patients respectively (timing of events not stated).
- In a case series of 204 patients (301 feet), 83 reported preoperative pain. Of these, 84% (70 of 83) reported no pain after the operation, 8% (7 of 83) had decreased pain and 1% (1 of 83) had increased pain (mean follow-up 8.3 months). A series of 64 patients reported that 95% (61 of 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 of 83) of survey respondents were very pleased with the procedure, 12% (10 of 83) were somewhat pleased, 4% (3 of 83) were not satisfied and 4% (3 of 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

This section describes 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.

- 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 of 98) of feet in the series of 64 patients (98 feet).
- 2.4.2 Osteonecrosis was reported in 8% (1 of 13) of patients in a case series of 13

patients (13 feet), but the timing of event was not stated.

- 2.4.3 Delayed union was reported in 1% (4 of 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 nonunion 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 of 301), not otherwise described, and 1% (1 of 94), 1 year after surgery and 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 of 301) of feet in the case series of 204 patients, but timing of events was 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).

### Information for patients

NICE has produced <u>information on this procedure for patients and carers</u>. 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 <u>Healthcare Improvement Scotland</u>.

#### Accreditation

