NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Minimally invasive percutaneous surgical techniques with internal fixation for correcting hallux valgus

Hallux valgus is a deformity of the big toe joint, often causing pain in the foot. The big toe bends towards the other toes, and a bony lump (called a bunion) appears on the side of the foot at the base of the big toe.

Under local or general anaesthesia, 1 or more small cuts are made through the skin (percutaneous) of the big toe. Bone-cutting surgical tools are put through the cuts and are used to remove the bunion and divide 1 or more of the bones at the front of the foot. The divided bones are secured either with wires, screws or plates (internal fixation). The operation is monitored using X-rays or an endoscope (a thin, flexible tube with a camera on the end). The aim is to straighten the big toe joint to reduce pain and other symptoms and preserve joint movement. Compared with standard (open) surgery, this procedure uses smaller cuts to the foot (minimally invasive).

NICE is looking at minimally invasive percutaneous surgical techniques with internal fixation for correcting hallux valgus. This is a review of NICE's interventional procedures guidance on <u>surgical correction of hallux valgus</u> <u>using minimal access techniques</u>.

NICE's interventional procedures advisory committee met to consider the evidence and the opinions of professional experts with knowledge of the procedure.

This document contains the <u>draft guidance for consultation</u>. Your views are welcome, particularly:

- comments on the draft recommendations
- information about factual inaccuracies
- additional relevant evidence, with references if possible.

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

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This is not NICE's final guidance on this procedure. The draft guidance may change after this consultation.

After consultation ends, the committee will:

- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance
- prepare a second draft, which will go through a <u>resolution process</u> before the final guidance is agreed.

Please note that we reserve the right to summarise and edit comments received during consultation or not to publish them at all if, in the reasonable opinion of NICE, there are a lot of comments or if publishing the comments would be unlawful or otherwise inappropriate.

Closing date for comments: 7 March 2024.

Target date for publication of guidance: June 2024

1 Draft recommendations

- 1.1 Use minimally invasive percutaneous surgical techniques with internal fixation as an option for correcting hallux valgus with standard arrangements in place for clinical governance, consent and audit.
- 1.2 These challenging techniques should only be done by a clinician with specific training and specialist experience in the procedure techniques.
- Clinicians should enter details about everyone having these procedures onto a registry, which could include the <u>BOFAS</u> registry. This should include:
 - details of patient selection
 - the technique used
 - the type of implant used
 - short and longer-term patient-reported outcomes.

Why the committee made these recommendations

Evidence from a mixture of studies on a wide variety of techniques suggests that minimally invasive techniques work as well as standard open surgical techniques. Evidence also suggests that patient-reported outcomes, such as pain and recovery time, are the same as for open surgical techniques. There is no robust evidence that one type of minimally invasive technique works better than another. There are no major safety concerns.

2 The condition, current treatments and procedure

The condition

2.1 Hallux valgus (HV) is more commonly known as a bunion. The big toe is deviated towards the other toes resulting in a bony

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protrusion. This deviation occurs at the first metatarsal phalangeal joint. The small sesamoid bones found beneath the first metatarsal also become displaced as the first metatarsal bone drifts away from its normal position, weakening the big toe. Symptoms include damage to the skin over the bunion, pain and weakness of the forefoot when walking, cosmetic concerns, and difficulty with footwear.

2.2 In a small number of people, bunion development is associated with underlying genetic conditions affecting the structure of the foot (such as ligamentous laxity syndromes and certain neurological conditions). But in most people the aetiology is not clear. Chronic trivial injury to the joint (for example, caused by some types of footwear) may be the cause. The condition is most common in women and in middle and later life.

Current treatments

2.3 Current treatment options include exercises, orthoses (devices to support and align the foot), spacers between the toes to keep them in the correct position, shoe alterations and analgesics to relieve symptoms. Open surgery is considered as standard care when conservative treatments have failed, and severe pain and deformity cause functional impairment. Many different surgical operations are used for treating HV, depending on the nature and extent of the deformity. One commonly used open surgical procedure is distal first metatarsal osteotomy, which divides and repositions the bone of the great toe near to the joint to correct the deformity.

The procedure

2.4 Surgical correction of HV using minimally invasive percutaneous surgical techniques with internal fixation is done as a day case under local or general anaesthesia and in supine position. Lowdose X-ray monitoring or endoscopic images are used. One or

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more small incisions are made close to the hallux metatarsophalangeal joint of the affected toe. The bunion is then removed and the metatarsal is divided surgically (osteotomy). Motorised high torque low speed burrs and surgical jigs aid the complex reduction and fixation steps of the procedure and implant insertion. Temporary wires may be used to toggle the separated parts of the divided bone into the desired position. The bone fragments are then stabilised using plates, specialised screws, or wires. The temporary wires used for toggling pieces of bone are removed. The small incisions are closed and a dressing is applied. After surgery, a dressing or plaster may be used to support the foot in the corrected position until the divided bone heals. People are usually allowed to put weight on the foot immediately.

2.5 The proposed advantages of a percutaneous surgical approach (minimally invasive techniques) are shorter operation time, quicker recovery, less pain, fewer complications, shorter hospital stay, earlier weight bearing and smaller scars.

3 Committee considerations

The evidence

3.1 NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 11 sources, which was discussed by the committee. The evidence included 2 systematic reviews and meta-analyses, 3 randomised controlled trials, 3 retrospective cohort studies (1 with propensity score matching) and 3 case series. It is presented in the <u>summary</u> of key evidence section in the interventional procedures overview. Other relevant literature is listed in table 5 of the overview.

- 3.2 The professional experts and the committee considered the key efficacy outcomes to be: patient reported outcome measures such as reduction in pain, improvement in function, quality of life and patient satisfaction; hallux joint angle correction and maintenance or reduction in deformity; recurrence rate.
- 3.3 The professional experts and the committee considered the key safety outcomes to be: pain, skin irritation, infection, non-union, need for screw removal, reoperation and amputation.
- 3.4 One commentary from a person who has had this procedure was discussed by the committee.

Committee comments

- 3.5 Despite minimally invasive surgery, there is no evidence that osteotomy heals more quickly than standard open surgical procedures.
- 3.6 Although the surgery is minimally invasive, pain in recovery did not appear to be different in the longer term compared with open surgical procedures.
- 3.7 People having the procedure should be informed about the potential for implant removal and recovery time.

Tom Clutton-Brock

Chair, interventional procedures advisory committee [February 2024]

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