

# NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

## INTERVENTIONAL PROCEDURES PROGRAMME

### Interventional procedure overview of surgical correction of hallux valgus using minimal access techniques

Hallux valgus is a deformity of the big toe. The big toe tilts outwards, crowding the smaller toes, and a bony lump (called a bunion) appears on the inside of the foot.

Under local or general anaesthesia, one or more small cuts are made to insert bone-cutting instruments. These are used to remove the bunion and to divide one or more of the bones of the front of the foot. The divided bones may need to be stabilised with wires, screws or plates. The aim is to correct the tilting of the big toe. The operation is monitored by X-rays or an endoscope (a telescope for looking inside the body). Compared with standard (open) surgery, this procedure uses smaller cuts to the foot and X-rays or endoscopy to see inside the foot.

## Introduction

The National Institute for Health and Clinical Excellence (NICE) has prepared this overview to help members of the Interventional Procedures Advisory Committee (IPAC) make recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and specialist opinion. It should not be regarded as a definitive assessment of the procedure.

## Date prepared

This overview was prepared in July 2009.

## Procedure name

- Surgical correction of hallux valgus using minimal access techniques.

## Specialty societies

- British Orthopaedic Association (BOA)
- British Orthopaedic Foot & Ankle Society (BOFAS)
- Society of Chiropodists & Podiatrists (Feet for Life)

## Description

### ***Indications and current treatment***

Hallux valgus is more commonly known as a bunion. In a small minority of patients, bunion development is associated with underlying genetic conditions affecting the structure of the foot (e.g. ligamentous laxity syndromes and certain neurological conditions). However, in most patients the aetiology is not clear. Chronic trivial injury to the joint (e.g. caused by inappropriate footwear) may be implicated. The condition is most common in women and in middle and later life.

In hallux valgus the big toe is deviated towards the other toes and a bony protrusion (a bunion) is formed on the inner foot. The small sesamoid bones found beneath the first metatarsal (which augment the function of the flexor tendon in bending the big toe downwards) also become displaced as the first metatarsal bone drifts away from its normal position, thereby weakening the big toe. Symptoms include irritated skin over the bunion, pain and weakness of the forefoot when walking, and cosmetic problems.

Conservative or non-operative treatment consists of footwear modification, with avoidance of high heels and use of a shoe with a wide toe box. Insoles may be used to support the foot, and spacers placed between the toes to keep them in the correct position. Many different surgical operations are employed for treatment of hallux valgus, depending on the nature and extent of the problem. One commonly used surgical procedure is distal first metatarsal osteotomy using an open surgical approach, which divides and repositions the bone of the great toe near to the joint to correct the deformity. The proposed advantages of a minimal access approach for this procedure are shorter operation time, quicker recovery, less pain, fewer complications, shorter stay in hospital, earlier weight bearing and smaller scars.

### ***What the procedure involves***

The procedure is performed with the patient under local or general anaesthesia and in the supine position. The surgery may be monitored using X-ray or endoscopic images. One or more small incisions are made on the inner side of the foot close to the bunion and the big toe joint. Special burs are introduced and the bunion is removed. The metatarsal bone is then divided. Temporary wires may be used to toggle the separated parts of the divided bone into the desired position in order to correct the deformity. The bone fragments are then fixed into their new positions using plates, screws or wires. The temporary wires used for toggling pieces of bone are removed. The small incisions are closed if necessary and a dressing is applied. A plaster may be used to support the foot in the corrected position until the divided bone heals. Patients are usually allowed to put weight on the foot immediately. If wires have been used to maintain the corrected bone positions, they may be removed at approximately 8 weeks after surgery.

## **List of studies included in the overview**

This overview is based on 755 patients (1018 feet) from 10 case series<sup>1,2,3,4,5,6,7,8,9,10</sup>.

Other studies that were considered to be relevant to the procedure but were not included in the main extraction table (table 2) have been listed in appendix A.

## **Efficacy**

The evidence relates to studies that varied in osteotomy technique (in relation to the location, shape and fixation of the osteotomy, and in the methods of visualisation or guidance). Where bone fixation was undertaken, it was usually, but not always, with use of Kirschner wires.

## **Hallux joint angle correction**

Case series of 204, 83, 15 and 13 patients reported postoperative decreases in preoperative mean hallux angle from 26° to 7.5° ( $p < 0.05$ )<sup>1</sup>; 33° to 14° ( $p < 0.05$ )<sup>3</sup>; 32° to 14.1° ( $p = 0.04$ )<sup>9</sup>; and 25° to 5° and then (second follow-up) 12° ( $p < 0.0001$ )<sup>10</sup>, respectively. Case series of 82 and 31 patients reported mean hallux angle corrections of 17.8° ( $p < 0.05$ )<sup>5</sup> and 11.8° ( $p < 0.001$ )<sup>8</sup>, respectively. There were corresponding improvements in other radiographic measures of hallux valgus and sesamoid bone position.

## **Pain**

A case series of 204 patients (301 feet) reported that 84.3% (70/83) who responded to the patient survey had no pain postoperatively, 8.4% (7/83) had decreased pain and 1.2% (1/83) had increased pain<sup>1</sup>.

Case series of 83, 82 and 31 patients reported a mean postoperative American Orthopaedic Foot & Ankle Society (AOFAS) pain score of 37 (standard deviation [SD] 6.0)<sup>3</sup>, 36.3 (SD 6.2)<sup>5</sup> and 35.7 (SD 5.0)<sup>8</sup> respectively. This score is out of 40, where high scores indicate lower levels of pain.

A case series of 64 patients (98 feet) reported that 95% (61/64) of patients had no pain at follow up (average follow up: 8 years and 9 months)<sup>6</sup>.

## **Patient satisfaction**

A case series of 204 patients (301 feet) reported that 73.5% (61/83) of patients who returned a follow-up survey were very pleased with the outcome of the procedure, 12% (10/83) were somewhat pleased, 3.6% (3/83) were not totally / not satisfied and 3.6% (3/83) regretted having the surgery<sup>1</sup>. Of those who responded, 94% (78/83) would recommend the procedure to others.

A case series of 143 patients (182 feet) reported that 89% (127/143) of patients were very satisfied with the outcome of the procedure, and the remaining 11% (16/143) were partly satisfied. In comparison, 86% (123/143)

of examiners were very satisfied and 14% (20/143) partly satisfied with the outcome of the procedure<sup>2</sup>.

A case series of 83 patients (94 feet) reported that 95.7% (90/94) of patients were satisfied with the outcome of the procedure and 4.3% (4/94) were dissatisfied. The dissatisfied patients included 2 patients with recurrence of hallux valgus, 1 patient with stiffness of the first metatarsophalangeal joint and 1 patient with hallux varus postoperatively<sup>3</sup>.

A case series of 83 patients (90 feet) reported that 81% of patients were very satisfied, 16% were partially satisfied and 3% were dissatisfied with the outcome of the procedure<sup>4</sup>. A case series of 37 patients (54 feet) reported that 92.6% (33/37) of patients were satisfied and 7.4% (4/37) were not satisfied with the outcome of the procedure<sup>7</sup>. A case series of 64 patients (98 feet) reported that 81% (52/64) of patients were satisfied with the cosmetic result of the procedure<sup>6</sup>.

A case series of 31 patients (47 feet) reported that 90.3% (28/31) of patients would be willing to undergo the same operation again<sup>8</sup>.

## **Safety**

### **Recurrence of hallux valgus**

A case series of 83 patients (94 feet) reported recurrence of hallux valgus postoperatively in 2.1% (2/94) of feet<sup>3</sup>. Both required revision surgery. A case series of 83 patients (90 feet) reported postoperative recurrence in 2.1% (1/47) of patients; 43.4% (36/83) of patients in this series were lost to follow-up<sup>4</sup>. A case series of 82 patients (118 feet) reported postoperative recurrence in 0.8% (1/118) of feet, described as progressive and accompanied by pain and severe limitation in walking<sup>5</sup>. A case series of 64 patients (98 feet) reported recurrence of hallux valgus in 1 patient requiring a further procedure<sup>6</sup>. In a case series of 13 patients (13 feet), hallux valgus recurred in 38.5% (5/13) of patients postoperatively, defined as a final angle  $<15^{\circ}$ ; one patient was treated with revision chevron osteotomy<sup>10</sup>.

### **Osteonecrosis**

A case series of 13 patients (13 feet) reported postoperative osteonecrosis in 7.7% (1/13) of patients<sup>10</sup>.

### **Hallux varus**

Case series of 204 (301 feet) and 83 (94 feet) patients reported postoperative hallux varus in 0.33% (1/301)<sup>1</sup> and 1.1% (1/94)<sup>3</sup> of feet respectively. In the latter study, hallux varus developed 1 year after surgery and was treated with extensor hallucis longus transfer.

### **Deep infection**

A case series of 82 patients (118 feet) reported deep infection at the osteotomy site in 1 patient<sup>5</sup>. This was treated with intravenous antibiotics and

resolved in 2 weeks. A case series of 31 patients (47 feet) reported that 2.1% (1/47) had a deep infection which healed when the Kirschner wire was removed 3 weeks postoperatively; however, hallux valgus recurred in these patients<sup>8</sup>. A case series of 64 patients (98 feet) reported 4.1% (4/98) of feet with deep infection postoperatively<sup>6</sup>.

### **Superficial infection**

Case series of 204, 143, 83 and 15 patients (301, 143, 83 and 21 feet) reported postoperative superficial infection in 3.65% (11/301) (responded to standard treatment)<sup>1</sup>, 4.4% (8/182)<sup>2</sup>, 8.5% (4/47)<sup>4</sup> and 4.8% (1/21) (managed with oral antibiotics and bed rest for 5 days)<sup>9</sup> of patients respectively. A case series of 13 patients reported 7.7% (1/13) with superficial cellulitis that resolved with oral antibiotics<sup>10</sup>.

### **Non-union / delayed union / malunion**

A case series of 204 patients (301 feet) reported 1.32% (4/301) cases with delayed union<sup>1</sup>. A case series of 13 patients reported that 7.7% (1/13) patients developed a nonunion with no radiographic evidence of healing at 27 weeks. The same study reported 69.2% (9/13) with dorsal malunion postoperatively<sup>10</sup>.

### **Joint stiffness**

Case series of 83, 83 and 31 patients (94, 90 and 47 feet) reported postoperative joint stiffness in 1.1% (1/94) (symptomatic stiffness of the first metatarsophalangeal joint)<sup>3</sup>, 2.1% (1/47) (persistent stiffness)<sup>4</sup> and 4.3% (2/47)<sup>8</sup> of patients respectively.

### **Stress fracture of second metatarsal**

A case series of 204 patients (301 feet) reported that 2.32% (7/301) of patients developed a stress fracture of the second metatarsal. The author speculates that some of these fractures occurred after intraoperative scoring of the second metatarsal cortex with a bur, causing it to weaken<sup>1</sup>.

### **Thromboembolic**

In a case series of 37 patients (54 feet), 1 patient (2.7%) developed a deep vein thrombosis (DVT)<sup>7</sup>.

## Literature review

### *Rapid review of literature*

The medical literature was searched to identify studies and reviews relevant to surgical correction of hallux valgus using minimally invasive techniques. Searches were conducted of the following databases, covering the period from their commencement to 28/07/2009: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and other databases. Trial registries and the Internet were also searched. No language restriction was applied to the searches (see appendix C for details of search strategy). Relevant published studies identified during consultation or resolution process that are published after this date may also be considered for inclusion.

The following selection criteria (table 1) were applied to the abstracts identified by the literature search. Where selection criteria could not be determined from the abstracts the full paper was retrieved.

**Table 1 Inclusion criteria for identification of relevant studies**

Characteristic	Criteria
Publication type	Clinical studies were included. Emphasis was placed on identifying good quality studies. Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, or a laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising study methodology, unless they reported specific adverse events that were not available in the published literature.
Patient	Patients with hallux valgus.
Intervention/test	Surgical correction using minimally invasive techniques
Outcome	Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy.
Language	Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.

### *Existing assessments of this procedure*

There were no published assessments from other organisations identified at the time of the literature search.

### *Related NICE guidance*

Below is a list of NICE guidance related to this procedure. Appendix B gives details of the recommendations made in each piece of guidance listed.

## **Interventional procedures**

- Metatarsophalangeal joint replacement of the hallux. NICE interventional procedures guidance 140 (2005). Available from [www.nice.org.uk/IPG140](http://www.nice.org.uk/IPG140)

**Table 2 Summary of key efficacy and safety findings on surgical correction of hallux valgus using minimally invasive techniques**

Abbreviations used: AOFAS = American Orthopaedic Foot and Ankle Society; DASA = distal articular set angle; FSE = fibular sesamoid excursion; HA = hallux abductus; IM = intermetatarsal; IMA = intermetatarsal angle; MJP = metatarsophalangeal joint; MTP = metatarsophalangeal; PASA = proximal articular set angle; ROM = range of motion; TSP = tibial sesamoid position.					
Study details	Key efficacy findings			Key safety findings	Comments
<p>Weinberger et al (1991)<sup>1</sup></p> <p>Study type: <b>retrospective case series</b></p> <p>Country: USA</p> <p>Study period: Dec 1984 – December 1988</p> <p>Study population: patients with hallux abducto valgus n = <b>204 (301 bunionectomies)</b></p> <p>Age: 48.6 years (mean) range: 14–76 years</p> <p>Sex: 88.4% (180/204) female</p> <p>Inclusion criteria: only patients where a distal metaphyseal osteotomy was not performed were excluded. Patients whose latest postoperative radiograph was taken while they were still wearing postoperative strapping were also excluded.</p> <p>Technique: percutaneous metatarsal osteotomy using fluoroscopy for visualisation and no internal fixation (all performed by the first author).</p> <p>Follow-up: <b>8.3 months (mean) range: 2–39 months</b></p> <p>Conflict of interest: None reported</p>	N = 301	Mean (SD)	range	<p><i>Complications</i></p> <p>Infections: 11/301 (3.65%) (all minor and superficial which responded to standard treatment)</p> <p>Stress fracture of 2nd metatarsal: 7/301 (2.32%) (author speculates that some of these fractures occurred after Intraoperative scoring of the 2nd metatarsal cortex with a bur causing it to weaken)</p> <p>Dehiscence: 3/301 (0.99%)</p> <p>Tape laceration: 1/301 (0.33%)</p> <p>Excessive bone callus formation: 6/301 (1.99%)</p> <p>Decreased ROM of first MJP: 2/301 (0.66%)</p> <p>Hallux varus: 1/301 (0.33%)</p> <p>Delayed union: 4/301 (1.32%)</p> <p>Intraoperative 2nd metatarsal fracture: 1/301 (0.33%)</p> <p>Pain 2nd metatarsal: 4/301 (1.32%)</p> <p>Intraoperative bur breakage: 1/301 (0.33%)</p> <p>Osteomyelitis: 0/301 (0%)</p> <p>Avascular necrosis: 0/301 (0%)</p>	<p>Unclear when postoperative patient satisfaction questionnaires were sent out.</p>
	Intermetatarsal (IM) distance (pre)	29.9 (3.6)	22-45		
	Intermetatarsal (IM) distance (post)	23.9 (3.1)	14-36		
	Hallux Abductos angle (HA) (pre)	26 (8.3)	4-59		
	Hallux Abductos angle (HA) (post)*	7.5 (6.3)	-19-32		
	Tibial sesamoid position (TSP) (pre)	4.5 (1.3)	2-7		
	Tibial sesamoid position (TSP) (post)	2.7 (1.1)	1-7		
	Fibular sesamoid excursion (FSE) (pre)	15.6 (2.5)	10-25		
	Fibular sesamoid excursion (FSE) (post)	12.7 (2.4)	1-22		
	Proximal articular set angle (PASA) (pre)	12.6 (6.4)	0-39		
	Proximal articular set angle (PASA) (post)	6.6 (5.6)	-7-40		
	Distal articular set angle (DASA) (pre)	4.5 (3)	0-20		
Distal articular set angle (DASA) (post)	4.5 (4.4)	-14-22			
<p>IM is measured in mm; all other outcomes are degrees.</p> <p>*difference between pre- and postoperative measures is significant (p &lt; 0.05)</p> <p><i>Postoperative change in first metatarsal declination</i></p> <p>&gt;= (+3): 47/301 (15.6%) dorsiflexion</p> <p>(-3) to (+3): 147/301 (48.8%) relatively unchanged</p> <p>&gt;= (-3): 107/301 (35.5%) plantarflexion</p> <p><i>Patient satisfaction</i></p> <p>83/200 = 41.5% surveys returned):</p> <p>Very pleased: 61/83 (73.5%); somewhat pleased: 10/83 (12.0%); not totally / not satisfied: 3/83 (3.6%); regret having surgery: 3/83 (3.6%); no response: 6/83 (7.2%).</p> <p>Would you recommend this surgery to others? Yes: 78/83 (94.0%); no: 4/83 (4.8%); no response = 1/83 (1.2%).</p> <p>For people in pain before surgery, how would you describe level of pain now (post surgery)? No pain: 70/83 (84.3%); decreased pain: 7/83 (8.4%); same level of pain: 0/83 (0%); increased pain: 1/83 (1.2%); no response: 5/83 (6%)</p>					

Abbreviations used: AOFAS = American Orthopaedic Foot and Ankle Society; DASA = distal articular set angle; FSE = fibular sesamoid excursion; HA = hallux abductus; IM = intermetatarsal; IMA = intermetatarsal angle; MJP = metatarsophalangeal joint; MTP = metatarsophalangeal; PASA = proximal articular set angle; ROM = range of motion; TSP = tibial sesamoid position.

Study details	Key efficacy findings				Key safety findings	Comments
Portaluri (2000) <sup>2</sup>  Study type: <b>case series</b> Country: Italy Study period: Dec 1996 – Feb 1999  Study population: patients with painful hallux valgus deformity of the first metatarsal joint  n = <b>143</b> (182 feet) Age: 42.8 years (mean), SD 14.7 Sex: 128/143 = 89.5% female  Inclusion criteria: none stated  Technique: percutaneous distal osteotomy (Bösch technique) using fluoroscopy for visualisation and Kirschner wire for fixation.  Follow-up: <b>16.4 months (mean), SD 2.4</b>  Conflict of interest: none reported		Preoperative mean (SD)	Postoperative mean (SD)	Correction mean (SD)	<b>Complications</b> Early accidental removal of Kirschner wire: 2/182 (1.1%) Superficial infection: 8/182 (4.4%) Deep infection: 0/182 (0%) Kirschner wire decubitus: 2/182 (1.1%) Intolerance to strapping: 2/182 (1.1%) Circulation disease (ischaemia of the big toe): 0/182 (0%) Necrosis of first metatarsal head: 0/182 (0%)	In 64 feet (35.2%) additional procedures were required to correct other conditions.  Preoperative pain at MTP bursa caused by: – shoe wearing friction: 155/182 (85%) – moderately painful metatarsalgia of the central rays: 58/182 (32%) – painful 5th ray: 12/182 (7%) – pronation syndrome: 4/182 (2%).
	IMA (degrees)	14 (5)	7 (3)	7 (5)		
	MTP angle (degrees)	27 (9) (range: 11–53)	10 (7) (range: 0–31)	16 (8) (range: 0–45)		
	PASA (degrees)	14 (6) (range: 2–27)	7 (5) (range: 0–18)			
	Sesamoids (degrees)	3 (0.6)	1 (1.5)			
	All measurements were significantly different postoperatively					
	At follow-up, all patients were asymptomatic on the first ray. A mild residual metatarsalgia of the remaining rays was observed in 6/182 feet (3%).					
	134/143 (94%) successful managed weight-bearing ambulation the day after surgery. The remaining patients managed this within 4 days of the operation.					
	All 182 feet demonstrated radiographic osteotomy healing within 6 months of surgery. Clinical stability and unrestricted ambulation was achieved within 45 days in all cases.					
	Plantarisation (i.e. angulation of the osteotomy) of 1st metatarsal head at follow-up:					
	Plantarised: 106/182 (58%)					
	Neutral: 74/182 (41%)					
	Dorsiflexed: 2/182 (1%)					
	Lateral displacement rate: 54% +/- 22 (postoperative), 33% +/- 20 (follow-up)					
	Satisfaction:					
		Patient	Examiner			
	Very satisfied	127/143 (89%)	123/143 (86%)			
	Partly satisfied	16/143 (11%)	20/143 (14%)			
	Unsatisfied	0 (0%)	0 (0%)			

Abbreviations used: MJP = metatarsophalangeal joint; ROM = range of motion; HA = hallux abductus; IM = intermetatarsal; FSE = fibular sesamoid excursion; TSP = tibial sesamoid position; PASA = proximal articular set angle; DASA = distal articular set angle; IMA = intermetatarsal angle; MTP = metatarsophalangeal; AOFAS = American Orthopaedic Foot and Ankle Society						
Study details	Key efficacy findings				Key safety findings	Comments
<p>Lui et al (2008)<sup>3</sup></p> <p>Study type: <b>retrospective case series</b></p> <p>Country: China</p> <p>Study period: July 2001 – Sept 2005</p> <p>Study population: patients with hallux valgus deformity needing surgical correction</p> <p>n = <b>83</b> (94 feet)</p> <p>Age: 45.6 years (mean) range: 14-89 years</p> <p>Sex: 75/83 = 90.4% female</p> <p>Inclusion criteria: only patients with manual correction of the 1,2-IMA and percutaneous screw fixation were included. Patients with first metatarsal osteotomy were excluded. Patients with adjuvant procedures e.g. arthroscopic Lapidus arthrodesis) were also excluded.</p> <p>Technique: soft tissue distal procedure using arthroscope for visualisation and screw for fixation.</p> <p>Follow-up: <b>30.45 months (mean) range : 24–74 months</b></p> <p>Conflict of interest: none ('authors report no conflict of interest')</p>		Preoperative mean (SD)	Postoperative mean (SD)	P value	<p><i>Complications</i></p> <p>Recurrence of hallux valgus: 2/94 (2.1%) (one foot had first tarsometatarsal hypermobility and was treated with endoscopic soft tissue procedure and arthroscopic Lapidus arthrodesis; the other one was revised with Scarf osteotomy).</p> <p>Hallux varus: 1/94 (1.1%) developed 1 year after surgery and was treated with extensor hallucis longus transfer.</p> <p>Skin impingement pain by the knot of the medial capsular placcation suture: 1/94 (1.1%) treated by removal of knot and fixation screw 8 weeks after surgery.</p> <p>Symptomatic stiffness of 1st MJP with motion of 15°: 1/94 (1.1%) treated with arthroscopic release.</p> <p>Breakage of screw before removal: 1/94 (1.1%)</p>	<p>Preoperatively, all patients complained of bunion pain and difficulty wearing shoes; 25/83 (30.1%) complained of first MJP pain with joint line tenderness.</p>
	Hallux valgus angle (degrees)	33 (7) (range: 20–58)	14 (5) (range: 4–30)	<0.05		
	IMA (degrees)	14 (3) (range: 10–26)	9 (2) (range: 5–18)	<0.05		
	Distal metatarsal angle (degrees)	9 (6) (range: 0–28)	6 (5) (range: 0–23)	NS		
	Sesamoid position	5 (1) (range: 2–7)	3 (1) (range: 1–5)	<0.05		
	ROM of 1st MJP (degrees)	71 (range: 40–130)	69 (range: 15–130)			
	<p>Postoperative scores:</p> <p>AOFAS pain score (out of 40): 37 mean (SD 6)</p> <p>Functional capacity score (out of 45): 43 mean (SD 3)</p> <p>Hallux valgus alignment score (out of 15): 13 mean (SD 3)</p> <p>Overall score (out of 100): 93 mean (SD 8)</p>					
	<p>Patients satisfied with procedure: 90/94 (95.7%)</p> <p>Patients dissatisfied with procedure: 4/94 (4.3%) including 2 patients with recurrence, patient with stiffness of 1st MJP and patient with hallux varus.</p>					

Abbreviations used: AOFAS = American Orthopaedic Foot and Ankle Society; DASA = distal articular set angle; FSE = fibular sesamoid excursion; HA = hallux abductus; IM = intermetatarsal; IMA = intermetatarsal angle; MJP = metatarsophalangeal joint; MTP = metatarsophalangeal; PASA = proximal articular set angle; ROM = range of motion; TSP = tibial sesamoid position.

Study details	Key efficacy findings	Key safety findings	Comments																
<p>Sanna and Ruiu (2005)<sup>4</sup></p> <p>Study type: <b>case series</b></p> <p>Country: Italy</p> <p>Study period: Jan 2001 – Dec 2002</p> <p>Study population: patients with hallux valgus</p> <p>n = <b>83</b> (90 feet)</p> <p>Age: 58.9 years (mean)</p> <p>Sex: not reported</p> <p>Inclusion criteria: not reported</p> <p>Technique: percutaneous linear distal osteotomy Using fluoroscopy for visualisation and Kirschner wire for fixation.</p> <p>Follow-up: <b>30.5 months (mean) range : 25–46 months</b></p> <p>Conflict of interest: none reported</p>	<table border="1" data-bbox="695 354 1339 683"> <thead> <tr> <th></th> <th>Preoperative mean</th> <th>Postoperative mean</th> <th>Mean correction achieved</th> </tr> </thead> <tbody> <tr> <td>IMA (degrees)</td> <td>15 (range: 10–23)</td> <td>9.1</td> <td>5.9</td> </tr> <tr> <td>1st MJP angle (degrees)</td> <td>32 (range: 14–55)</td> <td>12.5</td> <td>19.5</td> </tr> <tr> <td>PASA</td> <td>15.6 (range: 0–39)</td> <td>3</td> <td>12.5</td> </tr> </tbody> </table> <p>Groulier score (takes into account degree of valgus, pain on the exostosis, movement of the hallux, metatarsal pain , degree of varus and function):</p> <p>Excellent (58–70 points): 82%</p> <p>Good (49–57 points): 10%</p> <p>Fair (24–48 points): 8%</p> <p>Poor (0–23 points): 0%</p> <p>Patient satisfaction:</p> <p>Very satisfied: 81%</p> <p>Partially satisfied: 16%</p> <p>Discontent: 3%</p>		Preoperative mean	Postoperative mean	Mean correction achieved	IMA (degrees)	15 (range: 10–23)	9.1	5.9	1st MJP angle (degrees)	32 (range: 14–55)	12.5	19.5	PASA	15.6 (range: 0–39)	3	12.5	<p>No non-union or necrosis of head of 1st MTP reported.</p> <p>Persistent stiffness: 1/47 (2.1%)</p> <p>Recurrence of hallux valgus: 1/47 (2.1%)</p> <p>Superficial infection: 4/47 (8.5%)</p> <p>Pressure sore of the Kirschner wires: 3/47 (6.4%)</p> <p>Wire loosening: 3/47 (6.4%)</p> <p>Loss of wire 1 week after surgery: 1/47 (2.1%)</p> <p>Persistent skin paresthesia: 1/47 (2.1%)</p>	<p>Follow-up: 36/83 (43.4%) of patients lost to follow-up</p> <p>Other surgical procedures were conducted for 10/83 (12%) including 8 for hammer deformity of 2<sup>nd</sup> toe, 1 claw toe deformity and 1 Civinini-Morton syndrome.</p>
	Preoperative mean	Postoperative mean	Mean correction achieved																
IMA (degrees)	15 (range: 10–23)	9.1	5.9																
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<p>Magnan et al (2005)<sup>5</sup></p> <p>Study type: <b>case series</b></p> <p>Country: Italy</p> <p>Study period: 1996 – 2001</p> <p>Study population: patients with painful mild–moderate hallux valgus</p> <p>n = <b>82</b> (118 feet)</p> <p>Age: 56.3 years (mean), SD 13.1 years, range 17–79 years</p> <p>Sex: 77/82 = 94% female</p> <p>Inclusion criteria: patients must have been followed for more than 2 years.</p> <p>Technique: percutaneous distal osteotomy using fluoroscopy for visualisation and Kirshner wire for fixation.</p> <p>Follow-up: <b>35.9 months (mean), SD 10.9, range 24–78 months</b></p> <p>Conflict of interest: none ('the authors did not receive grants or outside funding in support of their research or preparation of the manuscript')</p>	<p>Total postoperative AOFAS pain score (N = 82) out of 40: 36.3 (mean), SD 6.2</p> <table border="1" data-bbox="695 354 1373 565"> <thead> <tr> <th>AOFAS Postoperative Pain score</th> <th>Number of feet (%)</th> <th>Number of patients</th> </tr> </thead> <tbody> <tr> <td>No pain</td> <td>83 (70%)</td> <td>56</td> </tr> <tr> <td>Mild, occasional</td> <td>26 (22%)</td> <td>17</td> </tr> <tr> <td>Moderate</td> <td>9 (7.6%)</td> <td>7</td> </tr> <tr> <td>Severe, constant</td> <td>0</td> <td>0</td> </tr> </tbody> </table> <p>Functional capacity (N=82) out of 45: 38.1 (SD 5.1)</p> <p>Hallux alignment: Excellent (15 points): 88 feet (75%) in 60 patients; mild asymptomatic alignment (8 points): 27 feet (23%) in 19 patients; recurrence of hallux valgus (0 points): 3 feet (2.5%) in 3 patients; overall alignment score: 13.8 (mean), SD 3.9.</p> <p>Total AOFAS score (out of 100): 88.2 (mean), SD 12.9, range 40–100</p> <p>Patient satisfaction: 107/118 (91%) satisfied and 11/118 (9%) dissatisfied.</p> <table border="1" data-bbox="695 789 1465 1125"> <thead> <tr> <th></th> <th>Preoperative mean (SD)</th> <th>Postoperative mean (SD)</th> <th>Correction mean (SD)</th> </tr> </thead> <tbody> <tr> <td>IMA (degrees)</td> <td>12.3 (3) (range 10–20)</td> <td>7.3 (2.7) (range 4–16)</td> <td>5.1 (3)</td> </tr> <tr> <td>HA angle (degrees)</td> <td>31.5 (10.2) (range 18–42)</td> <td>13.7 (6.7) (range 7–25)</td> <td>17.8 (9.7)</td> </tr> <tr> <td>Distal metatarsal articular angle (degrees)</td> <td>14.2 (6.4) (range 3-22)</td> <td>6.7 (4.6) (range 0–15)</td> <td></td> </tr> <tr> <td>Sesamoid position</td> <td>2 (0.8)</td> <td>0.4 (0.6)</td> <td></td> </tr> </tbody> </table> <p>All outcomes are significantly different postoperatively (p &lt; 0.05)</p> <p>Plantar displacement of 1st metatarsal: plantar angulation: 58/118 (49%); dorsiflexion of the head: 14/118 (12%); and neutral: 46/118 (39%).</p>	AOFAS Postoperative Pain score	Number of feet (%)	Number of patients	No pain	83 (70%)	56	Mild, occasional	26 (22%)	17	Moderate	9 (7.6%)	7	Severe, constant	0	0		Preoperative mean (SD)	Postoperative mean (SD)	Correction mean (SD)	IMA (degrees)	12.3 (3) (range 10–20)	7.3 (2.7) (range 4–16)	5.1 (3)	HA angle (degrees)	31.5 (10.2) (range 18–42)	13.7 (6.7) (range 7–25)	17.8 (9.7)	Distal metatarsal articular angle (degrees)	14.2 (6.4) (range 3-22)	6.7 (4.6) (range 0–15)		Sesamoid position	2 (0.8)	0.4 (0.6)		<p><i>Complications</i></p> <p>Deep infection at osteotomy site: 1/118 (0.8%) (treated with intravenous antibiotics and resolved in 2 weeks)</p> <p>Superficial skin irritation from Kirschner wire: 2/118 (1.7%)</p> <p>Permanent numbness of the hallux: 3/118 (2.5%)</p> <p>Nonunions: 0</p> <p>Progressive recurrence of hallux valgus with pain and severe limitation in walking: 1/118 (0.8%)</p> <p>Limited motion of 1st MJP (&lt;30°): 8/118 (6.8%)</p> <p>Hallux varus: 0</p>	<p>Conservative treatment (wearing comfortable or modified shoes, use of insoles and skin care) for at least 1 year had failed for all patients prior to surgery.</p> <p>All patients complained of pain in the area of the first metatarsal head, mainly due to pressure from footwear. One patient had an ulcerated bunion and 64/188 (54%) had pain under the lesser metatarsals prior to surgery.</p>
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<p>Bosch (2000)<sup>o</sup></p> <p>Study type: <b>case series</b></p> <p>Country: Austria</p> <p>Study period: Dec 1984–Feb 1987 (follow-up: 1994–1995)</p> <p>Study population: patients with painful hallux valgus with metatarsus primus varus.</p> <p>n = <b>64</b> (98 feet)</p> <p>Age: 49 years (mean), (range: 17–78)</p> <p>Sex: 60/64 = 94% female</p> <p>Inclusion criteria: no age limits.</p> <p>Technique: percutaneous distal osteotomy (Bösch technique) using fluoroscopy for visualisation and Kirschner wire for fixation.</p> <p>Follow-up: <b>8 years 9 months (mean)</b>,</p> <p>Conflict of interest: none reported</p>	<table border="1"> <thead> <tr> <th></th> <th>Preoperative mean</th> <th>Postoperative mean</th> </tr> </thead> <tbody> <tr> <td>Hallux valgus angle</td> <td>36° (range: 14–54°)</td> <td>19° (range: 7–40°)</td> </tr> <tr> <td>Intermetatarsal angle</td> <td>13° (range: 6–18°)</td> <td>10° (range: 3–18°)</td> </tr> </tbody> </table> <p>67% (66/98) had a preoperative hallux valgus angle &gt;30°</p> <p>81% (52/64) were satisfied with the cosmetic result and 95% (61/64) had no pain at follow up.</p>			Preoperative mean	Postoperative mean	Hallux valgus angle	36° (range: 14–54°)	19° (range: 7–40°)	Intermetatarsal angle	13° (range: 6–18°)	10° (range: 3–18°)	<p><i>Complications</i></p> <p>Deep infection: 4/98 (4.1%)</p> <p>Bone healing delayed more than 6 weeks: 4/98 (4.1%). Resection of the dorsomedial edge of the metatarsal was necessary to ease pressure discomfort in 2 cases.</p> <p>Recurrence of hallux valgus requiring a further procedure: 1/98 (1%)</p> <p>Lengthening of the extensor tendon required: 1/98 (1%)</p> <p>No cases of hallux varus, pseudarthrosis or necrosis.</p>	<p>114 feet originally operated on between 1984–1987. Loss to follow-up = 14% (16/114).</p>
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<p>Giannini et al (2003)<sup>7</sup></p> <p>Study type: <b>case series</b></p> <p>Country: Italy</p> <p>Study period: NR</p> <p>Study population: patients with mild to moderate reducible deformity with a hallux angle up to 40 degrees and intermetatarsal angle up to 20 degrees.</p> <p>n =<b>37</b> (54 feet)</p> <p>Age: 48 years (mean) , range: 10-70 years</p> <p>Sex: 34/37 = 92% female</p> <p>Exclusion criteria: patients older than 75 years, severe deformity of the IMA of more than 20°, severe degenerative arthritis or stiffness of the metatarsal or metatarsophalangeal joint, and severe instability of the cuneometatarsal or metatarsophalangeal joint.</p> <p>Technique: minimally invasive linear distal metatarsal osteotomy (SERI technique – simple, effective, rapid, inexpensive). Fluoroscopy is not used and Kirschner wire for fixation..</p> <p>Follow-up: <b>36 months (mean), range 22–52 months</b></p> <p>Conflict of interest: none reported</p>	<p>AOFAS score (out of 100):</p> <p>Mean: 81 points</p> <p>Excellent: 64.8% (35/54)</p> <p>Good: 18.5% (10/54)</p> <p>Fair: 9.2% (5/54)</p> <p>Poor: 7.4% (4/54)</p> <p>(Author states that all fair and poor results are the result of incorrect indication such as severe arthritis or incorrect surgical technique with an incomplete correction)</p> <p>All osteotomies healed well with callus evidence after an average of 3 months (on radiographic evaluation). In 9.2% (5/54) of patients, radiographic healing of the osteotomy occurred more than 4 months after surgery.</p> <p><i>Patient satisfaction:</i></p> <p>7.4% (4/37) not satisfied with the procedure, 92.6% (33/37) satisfied.</p>	<p>No serious complications (e.g. avascular necrosis of the metatarsal head or nonunion of the osteotomy)</p> <p>Skin inflammation around Kirschner wire outlet at the tip of the great toe: 5.5% (3/54)</p> <p>Deep vein thrombosis: 2.7% (1/37)</p> <p>Transfer metatarsalgia with plantar callosities under the 2nd and 3rd metatarsal heads: 7.4% (3/54)</p>	

Abbreviations used: AOFAS = American Orthopaedic Foot and Ankle Society; DASA = distal articular set angle; FSE = fibular sesamoid excursion; HA = hallux abductus; IM = intermetatarsal; IMA = intermetatarsal angle; MJP = metatarsophalangeal joint; MTP = metatarsophalangeal; PASA = proximal articular set angle; ROM = range of motion; TSP = tibial sesamoid position.																														
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<p>Lin et al (2009)<sup>8</sup></p> <p>Study type: <b>case series</b></p> <p>Country :Taiwan</p> <p>Study period: Sept 2005 – Dec 2006</p> <p>Study population: patients with hallux valgus deformities</p> <p>n =<b>31</b> (47 feet)</p> <p>Age: 40.8 years (mean), range 13–63 years</p> <p>Sex: 27/31 = 87.1% female</p> <p>Inclusion criteria: painful primary mild–moderate hallux valgus deformity with a 1st metatarsal angle &lt;= 15 degrees. Exclusion criteria: hallux rigidus or a history of previous surgery on the affected hallux. All patients receive conservative treatment for at least 2 months before surgery.</p> <p>Technique: minimally invasive distal metatarsal osteotomy (modified from Magnan et al (2006)<sup>11</sup>). Fluoroscopy is not used and Kirschner wire is used for fixation.</p> <p>Follow-up: <b>23.7 weeks (mean), range 16–68 weeks</b></p> <p>Conflict of interest: none reported</p>	<table border="1"> <thead> <tr> <th></th> <th>Preoperative mean (SD)</th> <th>Follow-up mean (SD)</th> <th>Correction mean (SD)</th> <th>p</th> </tr> </thead> <tbody> <tr> <td>Hallux valgus angle</td> <td>26 (4.9) (range 18–36.9)</td> <td>14.2 (6.7) (range 0–26.3)</td> <td>11.8 (5.8) (range 3.5–24.5)</td> <td>&lt;0.001</td> </tr> <tr> <td>First IMA</td> <td>11.6 (1.6) (range 8–14.7)</td> <td>5.3 (2.3) (range 0.1–10.3)</td> <td>6.3 (2.1) (range 2.2–11.4)</td> <td>&lt;0.001</td> </tr> </tbody> </table>		Preoperative mean (SD)	Follow-up mean (SD)	Correction mean (SD)	p	Hallux valgus angle	26 (4.9) (range 18–36.9)	14.2 (6.7) (range 0–26.3)	11.8 (5.8) (range 3.5–24.5)	<0.001	First IMA	11.6 (1.6) (range 8–14.7)	5.3 (2.3) (range 0.1–10.3)	6.3 (2.1) (range 2.2–11.4)	<0.001	<table border="1"> <thead> <tr> <th>AOFAS scores</th> <th>Mean (SD), range</th> </tr> </thead> <tbody> <tr> <td>Pain (out of 40)</td> <td>35.7 (5), 30–40</td> </tr> <tr> <td>Function (out of 45)</td> <td>43.6 (2.3), 40–45</td> </tr> <tr> <td>Alignment (out of 15)</td> <td>13.4 (3), 8–15</td> </tr> <tr> <td>Total (out of 100)</td> <td>92.7 (6.2), 78–100</td> </tr> </tbody> </table>	AOFAS scores	Mean (SD), range	Pain (out of 40)	35.7 (5), 30–40	Function (out of 45)	43.6 (2.3), 40–45	Alignment (out of 15)	13.4 (3), 8–15	Total (out of 100)	92.7 (6.2), 78–100	<p>Patient opinion: 28/31 (90.3%) patient were willing to undergo the same operation again.</p>	<p><i>Complications</i></p> <p>Stiffness: 2/47 (4.3%)</p> <p>Pin tract infection: 6/47 (12.8%)</p> <p>Deep infection: 1/47 (2.1%) healed when Kirschner wire was removed 3 weeks postoperatively; however, the deformity recurred.</p> <p>No episodes of nonunion, malunion, overcorrection, transfer metatarsalgia or osteonecrosis.</p>	
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Study details	Key efficacy findings				Key safety findings	Comments																	
<p>Maffulli et al (2005)<sup>9</sup></p> <p>Study type: <b>case series</b></p> <p>Country: UK</p> <p>Study period: not reported</p> <p>Study population: patients with hallux valgus</p> <p>n =<b>15</b> (21 feet)</p> <p>Age: 46.5 years (mean), SD 12, range 28–64 years</p> <p>Sex: 100% female</p> <p>Inclusion criteria: hallux valgus angle up to 40° and the IMA is up to 20°. Exclusion criteria: severe deformity of the IMA &gt;20°, severe degenerative disease or stiffness of the MJP and severe instability of the metatarsocuneiform or MJP.</p> <p>Technique: minimally invasive distal metatarsal subcapital osteotomy . Fluoroscopy is not used and Kirschner wire used for fixation.</p> <p>Follow-up: <b>25 months (mean), SD 3.2 months</b></p> <p>Conflict of interest: none reported</p>	<table border="1"> <thead> <tr> <th data-bbox="680 354 909 418"></th> <th data-bbox="909 354 1119 418">Preoperative mean (SD)</th> <th data-bbox="1119 354 1329 418">Postoperative mean (SD)</th> <th data-bbox="1329 354 1539 418">p-value</th> </tr> </thead> <tbody> <tr> <td data-bbox="680 418 909 492">Hallux valgus angle (degrees)</td> <td data-bbox="909 418 1119 492">32 (12) (range 28–42)</td> <td data-bbox="1119 418 1329 492">14.1 (4.7) (range 7.5–22)</td> <td data-bbox="1329 418 1539 492">0.04</td> </tr> <tr> <td data-bbox="680 492 909 565">DMAA (degrees)</td> <td data-bbox="909 492 1119 565">13.1 (6.2) (range 5.5–21.5)</td> <td data-bbox="1119 492 1329 565">7 (4.2) (range 5–12)</td> <td data-bbox="1329 492 1539 565">0.03</td> </tr> <tr> <td data-bbox="680 565 909 638">1st IMA (degrees)</td> <td data-bbox="909 565 1119 638">11.5 (4) (range 10–17)</td> <td data-bbox="1119 565 1329 638">7.5 (3) (range 3–11)</td> <td data-bbox="1329 565 1539 638">0.04</td> </tr> <tr> <td data-bbox="680 638 909 711">Sesamoid position</td> <td data-bbox="909 638 1119 711">2 (0.8)</td> <td data-bbox="1119 638 1329 711">0.5 (0.6) (range 0–1)</td> <td data-bbox="1329 638 1539 711">0.03</td> </tr> </tbody> </table>		Preoperative mean (SD)	Postoperative mean (SD)	p-value	Hallux valgus angle (degrees)	32 (12) (range 28–42)	14.1 (4.7) (range 7.5–22)	0.04	DMAA (degrees)	13.1 (6.2) (range 5.5–21.5)	7 (4.2) (range 5–12)	0.03	1st IMA (degrees)	11.5 (4) (range 10–17)	7.5 (3) (range 3–11)	0.04	Sesamoid position	2 (0.8)	0.5 (0.6) (range 0–1)	0.03	<p><i>Complications</i></p> <p>Superficial infection: 1/21 (4.8%) managed with oral antibiotics and bed rest for 5 days.</p>	
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Abbreviations used: MJP = metatarsophalangeal joint; ROM = range of motion; HA = hallux abductos; IM = intermetatarsal; FSE = fibular sesamoid excursion; TSP = tibial sesamoid position; PASA = proximal articular set angle; DASA = distal articular set angle; IMA = intermetatarsal angle; MTP = metatarsophalangeal; AOFAS = American Orthopaedic Foot and Ankle Society					
Study details	Key efficacy findings			Key safety findings	Comments
<p>Kadakia et al (2007)<sup>10</sup></p> <p>Study type: <b>prospective case series</b></p> <p>Country: USA</p> <p>Study period: June 2005 – Oct 205</p> <p>Study population: patients with mild–moderate hallux valgus deformities</p> <p>n = <b>13</b>(assumed 13 feet)</p> <p>Age: 52 years (mean), range 13–63 years)</p> <p>Sex: 12/13 = 92.3% female</p> <p>Inclusion criteria: hallux valgus angle &lt;40°. Patients with rheumatoid arthritis, diabetes, prior hallux surgery or hypermobility were eligible.</p> <p>Technique: percutaneous distal metatarsal osteotomy. Fluoroscopy is not used and Kirschner wire used for fixation (based on the technique described by Giannini et al (2003)<sup>7</sup>).</p> <p>Follow-up: <b>130 days (mean), range 50–207 days</b></p> <p>Conflict of interest: none reported</p>		Preoperative mean	First postoperative mean (2 week follow-up)	Final follow up mean (6 week follow-up)	<p><i>Complications</i></p> <p>Osteonecrosis: 1/13 (7.7%)</p> <p>Nonunion with no evidence of radiographic healing at 27 weeks: 1/13 (7.7%)</p> <p>Superficial cellulitis that resolved with oral antibiotics: 1/13 (7.7%)</p> <p>Deep infection: 0</p> <p>Recurrent hallux valgus (final angle &gt;15°: 5/13 (38.5%). (One was treated with revision chevron osteotomy)</p> <p>Dorsal malunion: 9/13 (69.2%)</p> <p>Hallux varus: 0</p> <p>Authors report that “we cannot recommend his procedure for correction of hallux valgus given more reliable available procedures, particularly the distal metatarsal chevron osteotomy and are no longer performing this procedure at our institution”.</p> <p>Conservative management including shoe modifications, orthotic intervention or both failed in all patients.</p> <p>Concomitant procedures included 1 hallux metatarsophalangeal lateral soft-tissue release, 5 lesser metatarsal osteotomies, 2 arthrodeses of the 2<sup>nd</sup> toe proximal interphalangeal joint and 1 lateral closing wedge calcaneal osteotomy with gastrocnemius recession.</p>
Hallux valgus angle (degrees)	25 (range: 16-33)	5 (range: -1-12)	12 (range: 1-24)		
IMA (degrees)	10.3 (range: 7-14)	4.8 (range: 1-10)	6.4 (range: 2-10)		
Dorsal angulation (degrees)	0	10.8 (range: 6-15)	15.9 (range: 10-22)		
<p>Both the hallux valgus angle and the IMA are significantly different postoperatively compared with preoperatively, and at final follow-up compared with postoperatively (hallux valgus angle: <math>p &lt; 0.0001</math>; IMA: <math>p &lt; 0.001</math>). The dorsal angulation was significantly different at final follow-up compared with postoperatively (<math>p &lt; 0.0197</math>).</p> <p>Radiographic union (bridging callus noted at osteotomy site on all three radiographic views): 12 patients (92.3%) had radiographic union at 13 weeks (mean), range 5–23 weeks</p>					

### ***Validity and generalisability of the studies***

- All the studies presented in this overview are case series.
- Different techniques were employed across the studies, in particular there is variability in visualisation (techniques with both 'direct' and endoscopic vision have been described, with or without fluoroscopic control) therefore, it is unclear how the results could be generalised.

### **Specialist Advisers' opinions**

Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College. The advice received is their individual opinion and does not represent the view of the society.

Mr Stephen Bendall and Mr Andrew Robinson (British Orthopaedic Foot & Ankle Society)

- One of the Specialist Advisers performs this operation regularly and uses minimally invasive chevron procedures for moderate hallux valgus deformity. He reports that it is not an easy procedure. The other Specialist Adviser had never performed this procedure but does undertake open hallux valgus surgery.
- Both Specialist Advisers consider this to be a novel procedure of uncertain safety and efficacy, and state that fewer than 10% of specialists are engaged in this area of work.
- The comparator is the equivalent open procedure (120 different techniques) and one of the Specialist Advisers is currently undertaking a clinical trial to look at minimally invasive strategies versus open chevron osteotomies.
- Efficacy outcomes: improvement in pain and deformity leading to better function. One of the Specialist Advisers reports using scoring systems such as the AOFAS score and radiological measurements to measure efficacy. Also suggests the Short Form-36 and Oxford foot score as other measures of

benefit. The other Specialist Adviser indicated that patient satisfaction, radiographic measurement of correction of deformity and pedobarography (foot pressure measurement) are also useful efficacy outcomes.

- Adverse events: nerve injury including complex regional pain syndrome 2%, superficial infection 1%, toe stiffness 8%, skin necrosis (use of burr) 2%, osteomyelitis 1%, non-union of osteotomy 1%, DVT 2%, tendon injury 5%, removal of screw fixation 1%, recurrent deformity 3% and fracture 2%. One of the Specialist Advisers reports personally seeing tendon injury to the extensor hallucis longus tendon, tender scars and sensitivity of the skin, stiffness of the first metatarsophalangeal joint, superficial wound infection and nonunion. This Adviser also states that recurrence is an important adverse event and quotes adverse event data from Magnan et al 2005 (see table 2). This Adviser recommends using a low speed burr with a high torque to minimise wound problems from burning of the skin or bone. The other Specialist Adviser added that burning of the soft tissues, damage to the nerves and blood vessels of the foot, inflammatory reaction to bone debris, necrosis of the first metatarsal and malpositioning or shortening of the first metatarsal (leading to excess weight bearing on the lesser toes leading to severe foot pain 5–10 years postoperatively) are also theoretical adverse effects of the procedure. This Adviser is aware of cases of recurrence, nerve and blood vessel injury and debris in the first metatarsal joint leading to synovitis. This Adviser is also concerned that the surgery may take longer leading to increased morbidity and costs.
- Training and facilities: one Adviser stated that no specialist equipment is required although X-ray is needed for visualisation. The other Adviser reported that surgeons who develop a subspecialty will be taught in fellowship positions and by visitations to other units already performing the procedure.
- One Specialist Adviser indicated there would be a moderate potential impact on the NHS. He states there is considerable interest in this procedure,

especially from patients, and this demand will need management as not all cases are suitable and not every surgeon will be trained. Surgical time is less than the open operation and this may have a positive effect for the NHS. The Adviser reports that it is unlikely to increase in uptake until there is stronger clinical data. The other Adviser stated that there could be a major impact on the NHS, and that if the procedure is safe and efficacious it could be carried out in most or all district general hospitals. He reported that the last big development in hallux valgus surgery (the scarf osteotomy) 'went from nothing, to the most widely used osteotomy for hallux valgus over a period of 5 years or so. I would anticipate that minimally invasive surgery would spread faster than this, as there is now an increased interest in foot surgery'.

- One of the specialist advisers reported that the British Orthopaedic Foot and Ankle Surgery Society (BOFAS) has set up an advisory committee to advise on the implementation, and dissemination of this procedure.

## **Patient Commentators' opinions**

NICE's Patient and Public Involvement Programme were unable to obtain patient commentary for this procedure.

## **Issues for consideration by IPAC**

- Should the MIS technique be specified in the guidance?

## References

1. Weinberger BH, Fulp JM, Falstrom P et al. (1991) Retrospective evaluation of percutaneous bunionectomies and distal osteotomies without internal fixation. *Clinics in Podiatric Medicine & Surgery* 8:111-136.
2. Portaluri M. (1-1-2000) Hallux valgus correction by the method of Bosch: a clinical evaluation. [Review] [27 refs]. *Foot & Ankle Clinics* 5:499-511.
3. Lui TH, Chan KB, Chow HT et al. (2008) Arthroscopy-assisted correction of hallux valgus deformity. *Arthroscopy* 24:875-880.
4. Sanna P and Ruiu GA. (2005) Percutaneous distal osteotomy of the first metatarsal (PDO) for the surgical treatment of hallux valgus. *Chirurgia Degli Organi di Movimento* 90:365-369.
5. Magnan B, Pezze L, Rossi N et al. (2005) Percutaneous distal metatarsal osteotomy for correction of hallux valgus. *Journal of Bone & Joint Surgery - American Volume* 87:1191-1199.
6. Bosch P, Wanke S, and Legenstein R. (2000) Hallux valgus correction by the method of Bosch: a new technique with a seven-to-ten-year follow-up. *Foot Ankle Clin* 5:485-4vi.
7. Giannini S, Ceccarelli F, Bevoni R et al. (1-1-2003) Hallux valgus surgery: the minimally invasive bunion correction (SERI). *Techniques in Foot and Ankle Surgery* 2:11-20.
8. Lin YC, Cheng YM, Chang JK et al. (2009) Minimally Invasive Distal Metatarsal Osteotomy for Mild-to-moderate Hallux Valgus Deformity. *Kaohsiung Journal of Medical Sciences* 25:431-437.
9. Maffulli N, Oliva F, Coppola C et al. (2005) Minimally invasive hallux valgus correction: a technical note and a feasibility study. *Journal of Surgical Orthopaedic Advances* 14:193-198.
10. Kadakia AR, Smerek JP, and Myerson MS. (2007) Radiographic results after percutaneous distal metatarsal osteotomy for correction of hallux valgus deformity. *Foot & Ankle International* 28:355-360.
11. Magnan B, Bortolazzi R, Samaila E et al. (2006) Percutaneous distal metatarsal osteotomy for correction of hallux valgus. Surgical technique. [Review] [16 refs]. *Journal of Bone & Joint Surgery - American Volume* 88:Suppl-48.

## Appendix A: Additional papers on surgical correction of hallux valgus using minimal access techniques

The following table outlines the studies that are considered potentially relevant to the overview but were not included in the main data extraction table (table 2). It is by no means an exhaustive list of potentially relevant studies.

Article	Number of patients/follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Qu J, Cao L, Liu Z et al. (2006) The effect of micro-trauma technic with small incision on treating hallux valgus. [Chinese]. Chung-Kuo Hsiu Fu Chung Chien Wai Ko Tsa Chih/Chinese Journal of Reparative & Reconstructive Surgery 20:50-52.	Case series  n = 136 (263 feet)  Follow-up: 19 months (mean)	84/136 (61.8%) excellent 48/136 (35.3%) good 3/136 (2.2%) fair 1/136 (0.7%) poor	Insufficient detail in English abstract  Larger studies included in table 2
De PM, Ripoll PL, Vaquero J et al. (2003) Percutaneous hallux valgus repair by multiple osteotomies. [Spanish]. Revista de Ortopedia y Traumatologia 47:406-416.	Case series  n = 64  Follow-up: NR	Mean correction of 5° in the intermetatarsal angle and 8° degrees in the PASA. Transfer metatarsalgia occurred in 25% of cases.	Insufficient detail in English abstract  Larger studies included in table 2
Zirattu G, Fadda M, Manunta A et al. (2005) Distal osteotomy of the first metatarsus in the treatment of valgus toe. [Italian]. Minerva Ortopedica e Traumatologica 56:127-133.	Case series  n = 40  Follow-up: NR	Positive results (very good, good and moderate were obtained in 90% of cases and 93% of patients were satisfied.	Insufficient detail in English abstract  Larger studies included in table 2
Zorzi R, Pessina R, Confalonieri N et al. (2004) Mini-invasive technique (percutaneous distal osteotomy) in abduct-valgus hallux treatment: Outcome in 42 treated patients. [Italian]. Minerva Ortopedica e Traumatologica 55:73-78.	Case series  n = 40  Follow-up: NR	87.5% patients said they would undergo percutaneous distal osteotomy again.	Insufficient detail in English abstract  Larger studies included in table 2
Ruffer M, Martini F, Pfeil J. (2006) The operative treatment of the juvenile Hallux valgus by minimally invasive modified Kramer osteotomy. [German]. Fuss und Sprunggelenk 4:240-246.	Case series  n = 15  Follow-up: NR	Preoperative MPA = 32° (mean) Postoperative MPA = 13° (mean) Preoperative IMA = 12° (mean) Postoperative IMA = 5° (mean) Conclude that a modified Kramer procedure is effective in correcting hallux valgus	Insufficient detail in English abstract  Larger studies included in table 2

Article	Number of patients/follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
<p>Lucaccini C, Zambianchi N, Zanotti G. (2008) Distal osteotomy of the first metatarsal bone in association with sub-talar arthroerisis, for hallux valgus correction in abnormal pronation syndrome. <i>Chirurgia Degli Organi di Movimento</i> 92:145-148.</p>	<p>Case series</p> <p>n = 14 (16 feet)</p> <p>Follow-up: 4 years and 4 months (mean), range 4–6 years</p>	<p>Pain at metatarsal bunion relived in all patients, 7 cases of metatarsalgia before surgery and 1 after surgery.</p> <p>Radiographic results:</p> <ul style="list-style-type: none"> <li>• Metatarsal phalangeal angle reduced from 28° to 13.3° (mean).</li> <li>• Intermetatarsal angle reduced from 13.5° to 7.4°(mean).</li> <li>• PASA reduced from 13.8° to 4.1°.</li> <li>• Sesamoid bone position reduced from 3–4 to 2 (mean)</li> <li>• Costa Bertani angle reduced from 130° to 124° (mean)</li> </ul> <p>All patients satisfied with the treatment.</p>	<p>Larger studies included in table 2</p>
<p>Van Enoo RE, Cane EM. (1986) Minimal incision surgery. A plastic technique or a cover-up? <i>Clinics in Podiatric Medicine &amp; Surgery</i> 3:321-335.</p>	<p>Case report</p> <p>n = 6</p> <p>Follow-up: NR</p>	<p>All successful procedures. No complications reported.</p>	<p>Larger studies included in table 2</p>
<p>Toepp FC, Salcedo M. (1991) First metatarsal closing base wedge osteotomy using real-time fluoroscopy. <i>Clinics in Podiatric Medicine &amp; Surgery</i> 8:137-151.</p>	<p>Case report</p> <p>n = 1</p> <p>Follow-up: 15 years</p>	<p>Preoperative IMA: 16° Postoperative IMA: 4° Preoperative HA angle: 23° No complications reported. 15-year examination revealed excellent hallux range of motion and no recurrence of hallux valgus deformity.</p>	<p>Larger studies included in table 2</p>

## Appendix B: Related NICE guidance for surgical correction of hallux valgus using minimal access techniques

Guidance	Recommendations
Interventional procedures	<p data-bbox="440 506 1247 569"><b>Metatarsophalangeal joint replacement of the hallux. NICE interventional procedures guidance 140 (2005)</b></p> <p data-bbox="440 604 597 636"><b>1 Guidance</b></p> <p data-bbox="440 642 1401 772">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.</p> <p data-bbox="440 810 1401 968">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 <i>Information for the public</i> is recommended.</p> <p data-bbox="440 1005 1369 1104">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.</p> <p data-bbox="440 1142 1390 1205">1.4 Further research will be useful in establishing the long-term outcomes of different types of prosthesis.</p>

## Appendix C: Literature search for surgical correction of hallux valgus using minimal access techniques

Database	Date searched	Version/files
Cochrane Database of Systematic Reviews – CDSR (Cochrane Library)	28/07/09	Issue 3, 2009
Database of Abstracts of Reviews of Effects – DARE (CRD website)	28/07/09	N/A
HTA database (CRD website)	28/07/09	N/A
Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane Library)	28/07/09	Issue 3, 2009
MEDLINE (Ovid)	28/07/09	1950 to July Week 3 2009
MEDLINE In-Process (Ovid)	28/07/09	July 27, 2009
EMBASE (Ovid)	28/07/09	1980 to 2009 Week 30
CINAHL (NHS Evidence)	28/07/09	1981 to Present
BLIC (Dialog DataStar)	28/07/09	1995 to date

Trial sources searched on 22/07/09

- National Institute for Health Research Clinical Research Network Coordinating Centre (NIHR CRN CC) Portfolio Database
- Current Controlled Trials *meta*Register of Controlled Trials – *m*RCT
- Clinicaltrials.gov

Websites searched on 22/07/09

- National Institute for Health and Clinical Excellence (NICE)
- Food and Drug Administration (FDA) - MAUDE database
- Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP – S)
- Australia and New Zealand Horizon Scanning Network (ANZHSN)
- General internet search

The following search strategy was used to identify papers in MEDLINE. A similar strategy was used to identify papers in other databases.

### MEDLINE search strategy

The MEDLINE search strategy was adapted for use in the other sources.

1	Osteotomy/
2	Osteotom*.tw.
3	1 or 2
4	Percutaneous*.tw.
5	3 and 4

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6	Surgical Procedures, Minimally Invasive/
7	(Mini* adj3 invasive* adj3 (surg* or tech* or procedur* or incision* or correct* or treat* or therap* or method*)).tw.
8	((Keyhole* or key-hole* or key* hole*) adj3 (surg* or tech* or procedur* or incision* or correct* or treat* or therap* or method*)).tw.
9	MIS.tw.
10	(Percutane* adj3 distal* adj3 metatarsal* adj3 osteotom*).tw.
11	PDO.tw.
12	Fluoroscopy/
13	Fluoroscop*.tw.
14	Fluorescen*.tw.
15	Fluorophotograph*.tw.
16	Photofluoroscop*.tw.
17	Radiofluoroscop*.tw.
18	Micromotor.tw.
19	or/5-18
20	Hallux Valgus/
21	(Hallux* adj3 (valgus* or abduct*)).tw.
22	(Metatars* adj3 primus* adj3 varus*).tw.
23	Bunion*.tw.
24	(Toe* adj3 (deformit* or malformat*)).tw.
25	or/20-24
26	19 and 25
27	Animals/ not Humans/
28	26 not 27