## 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 October 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 by medial deviation of the first metatarsal phalangeal joint. 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 concerns.

Conservative treatment may include 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 close to the hallux metatarsophalangeal 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 1044 patients (1338 feet) from 1 non-randomised comparative study  $^1$  and 12 case series  $^{2,3,4,5,6,7,8,9,10,11,12,13}$ .

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

A non-randomised comparative study of 72 patients (36 minimal access Bosch technique vs. 36 open Scarf technique) reported postoperative decrease in preoperative mean hallux angle from 27° to 17° (p = 0.03) in the Bosch group and from 28° to 20° (p = 0.04) in the Scarf group<sup>1</sup>

Case series of 204, 168, 83, 49, 15 and 13 patients reported postoperative decreases in preoperative mean hallux angle from 26° to 7.5° (p < 0.05)<sup>2</sup>; 28° to 14° (no p value reported)<sup>3</sup>, 33° to 14° (p < 0.05)<sup>5</sup>; 28.1° to 11° (p < 0.005)<sup>9</sup>, 32° to 14.1° (p = 0.04)<sup>12</sup>; and 25° to 5° and then (second follow-up) 12° (p < 0.0001)<sup>13</sup>, respectively. Case series of 82 and 31 patients reported mean hallux angle corrections of 17.8° (p < 0.05)<sup>7</sup> and 11.8° (p < 0.001)<sup>11</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>2</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>5</sup>, 36.3 (SD 6.2)<sup>7</sup> and 35.7 (SD 5.0)<sup>11</sup> respectively. This score is out of 40, where high scores indicate lower levels of pain.

A case series of 49 patients reported an improvement in mean postoperative AOFAS pain score from 13.5 to 37.4 (p < 0.001)<sup>9</sup>.

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>8</sup>. IP overview: Surgical correction of hallux valgus using minimal access techniques

#### **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 satisfied/not satisfied and 3.6% (3/83) regretted having the surgery<sup>2</sup>. Of those who responded, 94% (78/83) would recommend the procedure to others.

A case series of 168 patients (189 feet) reported that 87% (156/179) of procedures were rated as having a satisfactory outcome at final follow-up (median 13 months)<sup>3</sup>.

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>4</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>5</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>6</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>10</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>8</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>11</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>5</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>6</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>7</sup>. A case series of 64 patients (98 feet) reported recurrence of hallux valgus in 1 patient requiring a further procedure<sup>8</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°; one patient was treated with revision chevron osteotomy<sup>13</sup>.

#### **Osteonecrosis**

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

#### Hallux varus

Case series of 204 (301 feet) and 83 (94 feet) patients reported postoperative hallux varus in 0.33% (1/301)<sup>2</sup> and 1.1% (1/94)<sup>5</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 non-randomised comparative study of 72 patients (36 minimal access Bosch technique vs. 36 open Scarf technique) reported one case of soft tissue infection after the patient had left the end of the Kirschner wire exposed and her cat had licked her toes. The patient required admission to hospital and treatment with elevation, amoxicillin and clavulanic acid for 7 days<sup>1</sup>.

A case series of 82 patients (118 feet) reported deep infection at the osteotomy site in 1 patient<sup>7</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>11</sup>. A case series of 64 patients (98 feet) reported 4.1% (4/98) of feet with deep infection postoperatively<sup>8</sup>.

#### Superficial infection

Case series of 204, 143, 83, 49 and 15 patients (301, 143, 83, 59 and 21 feet) reported postoperative superficial infection in 3.65% (11/301) (responded to standard treatment)<sup>2</sup>, 4.4% (8/182)<sup>4</sup>, 8.5% (4/47)<sup>6</sup>, 2% (1/49)<sup>9</sup> (resolved with oral antibiotics) and 4.8% (1/21) (managed with oral antibiotics and bed rest for 5 days)<sup>12</sup> of patients respectively. A case series of 13 patients reported 7.7% (1/13) with superficial cellulitis that resolved with oral antibiotics<sup>13</sup>.

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

A case series of 204 patients (301 feet) reported 1.32% (4/301) cases with delayed union<sup>2</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>13</sup>. A case series of 49 patients (59 feet) reported 2 cases of malunion and 2 cases of nonunion (assessed radiographically at mean follow-up of 31.5 months)<sup>9</sup>

#### Joint stiffness

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Case series of 168, 83, 83 and 31 patients (189, 94, 90 and 47 feet) reported postoperative joint stiffness in 1.2% (2/168) (severe stiffness in first metatarsophalangeal joint requiring arthrolysis)<sup>3</sup>, 1.1% (1/94) (symptomatic stiffness of the first metatarsophalangeal joint)<sup>5</sup>, 2.1% (1/47) (persistent stiffness)<sup>6</sup> and 4.3% (2/47)<sup>11</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>2</sup>.

#### **Thromboemmolic**

Case series of 168 patients (189 feet) and 37 patients (54 feet), reported that 3 patients (1.8%)<sup>3</sup> and 1 patient (2.7%)<sup>10</sup> respectively developed a deep vein thrombosis (DVT).

#### 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 and updated to 28/10/2009: 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 <a href="https://www.nice.org.uk/IPG140">www.nice.org.uk/IPG140</a>

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

Study details	Key efficacy find	lings			Key safety findings	Comments
Maffulli N (2009) <sup>1</sup>	Bosch group:	Pre- operative	Post- operative	p value	Bosch group Skin reaction at point of exit of	Patients who had minimal incision Bosch osteotomy and met the inclusion criteria were matched with patients (by age and intermetatarsal angle) from a pool of 288 who had undergone open Scarf osteotomies. Matching and evaluation of patients done by senior orthopaedic trainee not involved in initial treatment of patients.
Study type: non-randomised case-matched comparative tudy	AOFAS FAOS	54 ± 10 264 ± 19	85 ± 11 356 ± 28	0.033	Kirschner wire: 8.3% (3/36). Treated with oral antibiotics and elevation.	
Country: Italy / UK	Hallux valgus angle	27 ± 6	17 ± 4	0.03	2 patients kept the tip of the	
Study period: July 2003 – Dec 2006 Study population: patients with hallux valgus	Intermetatarsal angle	15 ± 6	8 ± 3	0.041		
72 (36 minimal incision Bosch vs. 35 open Scarf )	Distal metatarsal articular angle	11 ± 5	7 ± 4	0.03	of the correction obtained by the procedure was lost but the patient was happy with the cosmetic	
Age: Bosch group: 52.6 years (mean); Scarf group: 51.5 years (mean)	Scarf group:	Pre-	Post-	р	result. The other patient sustained a soft tissue infection after 2 weeks (reported that her cat had	
Sex: Bosch group: 100% (36/36) female; Scarf group: 100% (36/36)	AOFAS	operative 51± 13	operative 86 ± 8	value 0.036	licked her toes). This patient recovered after admission to hospital and was treated with elevation, amoxicillin and clavulanic acid for 7 days.  2 patients reported discomfort and had the proximal portion of the	
Patient selection criteria: Inclusion: hallux valgus angle 20–40 degrees, a 1–2 intermetatarsal angle ≤ 20 degrees, a distal metatarsal articular angle ≤ 25 degrees, no radiographic	FAOS Hallux valgus angle	258 ± 22 28 ± 6	358 ± 29 20 ± 6	0.038		
evidence of MTP arthritis, and persistent symptoms. Exclusion: bilateral hallux valgus, previous operation on the affected foot,	Intermetatarsal angle	14 ± 3	8 ± 4	0.04		Retrospective study
severe deformity with intermetatarsal angle > 20 degrees, severe degenerative disease or stiffness of the MTP joint, history of diabetes, peripheral vascular disease, peripheral	Distal metatarsal articular angle	12 ± 6	7 ± 5	0.03	first metatarsal timed under local anaesthetic at 6 months.	
neuropathy, rheumatoid arthritis or other inflammatory diseases Technique: Minimal incision distal osteotomy (Bösch technique) using Kirschner wire for fixation (method of visualisation unclear) vs. open scarf osteotomy using screws for fixation. Both					Scarf group: Intraoperative fracture of the first metatarsal: 8.3% (3/36). These	
procedures performed with patients under general anaesthesia. Follow-up: <b>2.5 years (mean)</b>					patients required a fixation plate.  Removal of fixation screw required because of irritation to	
Conflict of interest: None reported					the skin when wearing shoes: 13.9% (5/36)	

Study details	Key efficacy findings		ey efficacy findings					
Weinberger et al (1991) <sup>2</sup>	N = 301	Mean (SD)	range		Complications	Unclear when		
	Intermetatarsal (IM) distance (pre) Intermetatarsal (IM) distance (post)	29.9 (3.6) 23.9 (3.1)	22-45 14-36		Infections: 11/301 (3.65%) (all	postoperative patient satisfaction		
Study type: retrospective case	Hallux Abductos angle (HA) (pre)	26 (8.3)	4-59		minor and superficial which responded to standard	questionnaires were		
series	Hallux Abductos angle (HA) (post)*	7.5 (6.3)	-19-32		treatment)	sent out.		
Country: USA	Tibial sesamoid position (TSP) (pre)	4.5 (1.3)	2-7		Stress fracture of 2nd			
Study period: Dec 1984 –	Tibial sesamoid position (TSP) (post)	2.7 (1.1)	1-7		metatarsal: 7/301 (2.32%)			
December 1988	Fibular sesamoid excursion (FSE) (pre)	15.6 (2.5)	10-25		(author speculates that some			
Study population: patients with	Fibular sesamoid excursion (FSE) (post)	12.7 (2.4)	1-22		of these fractures occurred			
hallux abducto valgus	Proximal articular set angle (PASA) (pre)	12.6 (6.4)	0-39		after Intraoperative scoring of			
n = 204 (301 bunionectomies)	Proximal articular set angle (PASA) (post)  Distal articular set angle (DASA) (pre)	6.6 (5.6) 4.5 (3)	-7-40 0-20	_	the 2nd metatarsal cortex with			
Age: 48.6 years (mean) range:	Distal articular set angle (DASA) (pre)  Distal articular set angle (DASA) (post)	4.5 (4.4)	-14-22		a bur causing it to weaken)			
14–76 years	IM is measured in mm; all other outcomes are			_	Dehiscence: 3/301 (0.99%)			
Sex: 88.4%( 180/204) female	*difference between pre- and postoperative m		nificant (p < 0	0.05)	Tape laceration: 1/301 (0.33%)			
Inclusion criteria: only patients	Postoperative change in first metatarsal declin	action			Excessive bone callus			
where a distal metaphyseal	>= (+3): 47/301 (15.6%) dorsiflexion	iauori			formation: 6/301 (1.99%)			
osteotomy was not performed were excluded. Patients whose	(-3) to (+3): 147/301 (48.8%) relatively unchar	nged			Decreased ROM of first MJP:			
latest postoperative radiograph	>= (-3): 107/301 (35.5%) plantarlexion	· ·			2/301 (0.66%)			
was taken while they were still wearing postoperative strapping	Patient satisfaction				Hallux varus: 1/301 (0.33%)			
were also excluded.	83/200 = 41.5% surveys returned):				Delayed union: 4/301 (1.32%)			
livere dies exercises	Very pleased: 61/83 (73.5%); somewhat pleas				Intraoperative 2nd metatarsal			
Technique: percutaneous	satisfied: 3/83 (3.6%); regret having surgery: 3	3/83 (3.6%); no	response: 6	6/83	fracture: 1/301 (0.33%)			
metatarsal osteotomy using	(7.2%).				Pain 2nd metatarsal: 4/301			
fluoroscopy for visualisation and	Would you recommend this surgery to others?	? Yes: 78/83 (9	4.0%): no: 4	1/83 (4.8%):	(1.32%)			
no internal fixation (all performed	no response = 1/83 (1.2%).	(0	,,	,,	Intraoperative bur breakage:			
by the first author).		1/301 (0.33%)						
	For people in pain before surgery, how would		Osteomyelitis: 0/301 (0%)					
Follow-up: 8.3 months (mean) range: 2–39 months	surgery)? No pain: 70/83 (84.3%); decreased 0/83 (0%); increased pain: 1/83 (1.2%); no res	vel of pain:	Avascular necrosis: 0/301 (0%)					
Conflict of interest: None reported								

Study details	Key efficacy findings			Key safety findings	Comments
Bauer T (2009) <sup>3</sup> Study type: <b>case series</b> Country: France / Spain  Study period: Sept 2005 – Feb 2006  Study population: patients with mild to moderate hallux valgus	(Median values given for all but last outcome)	Pre- operative (n = 189	1 year Post- operative	Complex regional pain syndrome (type II): 5 patients  Deep vein thrombosis: 3 patients	5.3% (10/189) feet lost to follow-up Multicentre study (5 hospitals)
	AOFAS  1 <sup>st</sup> MTP joint :range of	feet) 52 90	(n = 179 feet) 93 75	Severe postoperative first MTP joint stiffness requiring arthrolysis: 2 patients	Assessment conducted by each
deformity  n = <b>168</b> (189 feet)	motion  1 <sup>st</sup> MTP joint : dorsiflexion	degrees 70 degrees	degrees 60 degrees	No nonunions, osteonecrosis or recurrence of hallux valgus deformities.	site investigator (i.e. no independent assessment of outcomes).
Age: 55 years (median)	1 <sup>st</sup> MTP joint : plantar flexion Hallux valgus angle	20 degrees 28	15 degrees		outcomes).
Sex: 97.6% (164/168) female  Patient selection criteria: all patients who had not undergone	Intermetatarsal angle	degrees 13 degrees	10 degrees		
Patient selection criteria: all patients who had not undergone prior surgery for hallux valgus, had painful mild to moderate deformity, hallux valgus angle ≤40 degrees, first intermetatarsal angle ≤ 15 degrees and no local of systemic conditions (e.g. sepsis, neuropathy or severe arthritis)	Distal metatarsal articular angle Metatarsal index: M1 < M2 Metatarsal index: M1 =	15 degrees 67% (127/189) 23%	8 degrees 70% (125/179) 25%		
Technique: Percutaneous Akin distal first metatarsal osteotomy using fluoroscopy for visualisation. No internal fixation used. Procedure performed with patients under locoregional anesthesia with either popliteal block, ankle block or distal	M2 Metatarsal index: M1 > M2	(43/189) 10% (19/189)	(45/179) 5% (9/179)		
metatarsal block.  Follow-up: 13 months (median)	Not congruous MTP joint  87% (156/179) patients w				
Conflict of interest: None reported.	outcome of the procedure	at final follov	v-up.		

Study details	Key efficacy findin	gs			Key safety findings	Comments
Portaluri (2000) <sup>4</sup>					Complications	In 64 feet (35.2%)
Study type: case series		Preoperative mean (SD)	Postoperative mean (SD)	Correction mean (SD)	Early accidental removal of Kirschner wire: 2/182 (1.1%)	additional procedures were required to correct
Country: Italy	IMA (degrees)	14 (5)	7 (3)	7 (5)	Superficial infection: 8/182	other conditions.
Study period: Dec 1996 – Feb 1999	MTP angle (degrees)	27 (9) (range: 11–53)	10 (7) (range: 0–31)	16 (8) (range: 0–45)	(4.4%) Deep infection: 0/182 (0%) Kirschner wire decubitus:	Preoperative pain at
Study population: patients with painful hallux valgus deformity of the first metatarsal joint	PASA (degrees)  Sesamoids (degrees)	14 (6) (range: 2–27) 3 (0.6)	7 (5) (range: 0–18) 1 (1.5)		2/182 (1.1%) Intolerance to strapping: 2/182 (1.1%) Circulation disease	MTP bursa caused by:  - shoe wearing friction: 155/182
n = <b>143</b> (182 feet)	All measurements w	vere significantly diff	erent postoperative	ly	(ischaemia of the big toe): 0/182 (0%)	(85%)  - moderately painful
Age: 42.8 years (mean), SD 14.7 Sex: 128/143 = 89.5% female	At follow-up, all pati metatarsalgia of the				Necrosis of first metatarsal head: 0/182 (0%)	metatarsalgia of the central rays: 58/182 (32%)
Inclusion criteria: none stated	134/143 (94%) succ surgery. The remain					- painful 5th ray: 12/182 (7%)
Technique: percutaneous distal osteotomy (Bösch technique) using fluoroscopy for visualisation and Kirschner wire for fixation.	in all cases.	bility and unrestricte	d ambulation was a	within 6 months of achieved within 45 days tarsal head at follow-up:		- pronation syndrome: 4/182 (2%).
Follow-up: 16.4 months (mean), SD 2.4	Neutral: 74/182 (419 Dorsiflexed: 2/182 (	1%)				
Conflict of interest: none reported	Lateral displacemer Satisfaction:	t rate: 54% +/- 22 (p	oostoperative), 33%	+/- 20 (follow-up)		
		Patient	E	xaminer	]	
	Very satisfied	127/143 (8	39%) 1:	23/143 (86%)	1	
	Partly satisfied	16/143 (11	(%)	0/143 (14%)	11	
	Unsatisfied	0 (0%)	0	(0%)	71	

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 find	lings			Key safety findings	Comments	
Lui et al (2008) <sup>5</sup>					Complications	Preoperatively, all patients complained	
		Preoperative	Postoperative	Р	Recurrence of hallux valgus:		
Study type: retrospective case series		mean (SD)	mean (SD)	value	2/94 (2.1%) (one foot had first	of bunion pain and difficulty wearing shoes; 25/83 (30.1%) complained of first MJP pain with	
Country: China	Hallux valgus	33 (7)	14 (5)	<0.05	tarsometatarsal hypermobility and was treated with		
Study period: July 2001 – Sept 2005	angle (degrees)	(range: 20-58)	(range: 4-30)		endoscopic soft tissue procedure and arthroscopic		
Study population: patients with hallux valgus	IMA (degrees)	14 (3)	9 (2)	<0.05	Lapidus arthrodesis; the other	joint line tenderness.	
deformity needing surgical correction		(range: 10-26)	(range: 5-18)		one was revised with Scarf		
	Distal	9 (6)	6 (5)	NS	osteotomy).		
n = <b>83</b> (94 feet)	metatarsal	(range: 0-28)	(range: 0-23)		Hallux varus: 1/94 (1.1%) developed 1 year after		
Age: 45.6 years (mean) range: 14-89 years	angle (degrees)				surgery and was treated with		
Sex: 75/83 = 90.4% female	Sesamoid	5 (1)	3 (1)	<0.05	extensor hallucis longus		
	position	(range: 2–7)	(range:1–5)	<0.03	transfer.		
Inclusion criteria: only patients with manual correction	ROM of 1st	71	69		Skin impingement pain by the knot of the medial capsular		
of the 1,2-IMA and percutaneous screw fixation were included. Patients with first metatarsal osteotomy were excluded. Patients with adjuvant procedures	MJP (degrees)	(range: 40– 130)	(range: 15–130)		placation suture: 1/94 (1.1%) treated by removal of knot and fixation screw 8 weeks after		
e.g. arthroscopic Lapidus arthrodesis) were also				<u>-</u>	surgery.		
excluded.	Postoperative sco	ores:			Symptomatic stiffness of 1st		
	AOFAS pain scor	e (out of 40): 37 m	nean (SD 6)		MJP with motion of 15°: 1/94		
Technique:) soft tissue distal procedure using arthroscope for visualisation and screw for fixation.	Functional capaci	ty score (out of 45	): 43 mean (SD 3)		(1.1%) treated with		
artifioscope for visualisation and screw for fixation.	Hallux valgus alig	nment score (out	of 15): 13 mean (SD	arthroscopic release.			
Follow-up: 30.45 months (mean) range: 24–74	Overall score (out	t of 100): 93 mean	(SD 8)		Breakage of screw before removal: 1/94 (1.1%)		
months	Patients satisfied	with procedure: 90	0/94 (95.7%)				
Conflict of interest: none ('authors report no conflict of interest')	Patients dissatisfi	ed with procedure rrence, patient with	: 4/94 (4.3%) includi h stiffness of 1st MJ				

Study details	Key efficac	y findings				Key safety findings	Comments
Sanna and Ruiu (2005) <sup>6</sup> Study type: <b>case series</b>		Preoperative mean	Postoperative mean	Mean correction		No non-union or necrosis of head of 1st MTP reported.	Follow-up: 36/83 (43.4%) of patients lost to
Country: Italy				achieved		Persistent stiffness:	follow-up
Study period: Jan 2001 – Dec 2002	IMA (degrees)	15 (range: 10–23)	9.1	5.9		1/47 (2.1%) Recurrence of hallux	Other surgical
Study population: patients with hallux valgus	1st MJP angle (degrees)	32 (range: 14–55)	12.5	19.5		valgus: 1/47 (2.1%) Superficial infection: 4/47 (8.5%) Pressure sore of the	procedures were conducted for 10/83 (12%) including 8 for hammer deformity of 2 <sup>nd</sup>
n =83 (90 feet)	PASA	15.6	3	12.5			
Age: 58.9 years (mean)		(range: 0-39)				Kirschner wires: 3/47 (6.4%)	
Sex: not reported		, ,	L			Wire loosening: 3/47	toe, 1 claw toe deformity and 1
Inclusion criteria: not reported  Technique: percutaneous linear distal osteotomy Using fluoroscopy for visualisation and Kirschner wire for fixation.	movement of Excellent (5) Good (49–5) Fair (24–48)	. ,	tarsal pain , degr			(6.4%) Loss of wire 1 week after surgery: 1/47 (2.1%) Persistent skin paresthesia: 1/47	Civinini-Morton syndrome.
Follow-up: 30.5 months (mean) range : 25–46 months	Poor (0–23   Patient satis Very satisfie	faction:				(2.1%)	
Conflict of interest: none reported	Partially sati						

Study details	Key efficacy findings								Key safety findings	Comments
Magnan et al (2005) <sup>7</sup>	Total postoperative A	OFAS pair	score	(N = 82) ou	ut of 40	D: 36.3 (n	nean), S	D 6.2	Complications	Conservative
Study type: case series	AOFAS Postoperati score	ve Pain				Number of patients			Deep infection at osteotomy site: 1/118	treatment (wearing
Country: Italy	No pain		83 (70	0%)	56				(0.8%) (treated with intravenous antibiotics	comfortable or modified shoes,
Study period: 1996 – 2001	Mild, occasional	Mild, occasional		2%)	17				and resolved in 2	use of insoles
	Moderate		9 (7.6	5%)	7				weeks)	and skin care)
Study population: patients with painful mild-moderate	Severe, constant		0	(	0				Superficial skin irritation	for at least 1 year had failed
hallux valgus	Functional capacity (I	N=82) out o	of 45: 3	8.1 (SD 5.1	1)				from Kirschner wire: 2/118 (1.7%)	for all patients
n = <b>82</b> (118 feet) Age: 56.3 years (mean), SD 13.1 years, range 17–79 years	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.								Permanent numbness of the hallux: 3/118	prior to surgery. All patients complained of pain in the area
Sex: 77/82 = 94% female	Total AOFAS score (	out of 100):	: 88.2 (ı	mean), SD	12.9, ı	range 40	-100		Nonunions: 0	ons: 0 of the first
GGX. 117/02 = 3470 Terriale	Patient satisfaction: 107/118 (91%) satisfied and 11/118 (9%) dissati								Progressive recurrence of hallux valgus wih	metatarsal head, mainly die to
Inclusion criteria: patients must have been followed for more than 2 years.		Preopera mean (SI		Postoperative mean (SD)			pain and severe limitation in walking:	pressure from footwear. One		
•	IMA (degrees)	12.3 (3)		7.3 (2.7)		5.1 (3)			1/118 (0.8%)	patient had an
Technique: percutaneous distal osteotomy using		(range 10-20)		(range 4-	-16)				Limited motion of 1st	ulcerated bunion and 64/188
fluoroscopy for visualisation and Kirshner wire for	HA angle	31.5 (10.	2)	13.7 (6.7	·)	17.8 (9	.7)		MJP (<30°): 8/118 (6.8%)	(54%) had pain
fixation.	(degrees)	(range 18	3–42)	(range 7-	-25)				Hallux varus: 0	under the lesser metatarsals prior
Follow-up: 35.9 months (mean), SD 10.9, range 24-	Distal metatarsal	14.2 (6.4	)	6.7 (4.6)						to surgery.
78 months	articular angle (degrees)	(range 3-	22)	(range 0-	–15)					
	Sesamoid position	2 (0.8)		0.4 (0.6)						
Conflict of interest: none ('the authors did not receive	All outcomes are sign	nificantly dif	ferent p	postoperati	vely (p	< 0.05)				
grants or outside funding in support of their research or preparation of the manuscript')	Plantar displacement of 1st metatarsal: plantar angulation: 58/118 (49%); dorsiflexion of the head: 14/118 (12%); and neutral: 46/118 (39%).									

Study details	Key efficacy finding	ngs			Key safety findings	Comments
Bosch (2000) <sup>8</sup>					Complications	114 feet
		Preoperative	Postoperative		Deep infection: 4/98	originally
Study type: case series		mean	mean		(4.1%)	operated on between 1984–
Country: Austria	Hallux valgus	36° (range: 14–54°)	19° (range: 7–40°)			1987. Loss to
Study period: Dec 1984-Feb 1987 (follow-up: 1994-	angle				Bone healing delayed	follow-up = 14%
1995)	Intermetatarsal angle	13° (range: 6–18°)	10° (range: 3–18°)		more than 6 weeks: 4/98 (4.1%). Resection of the dorsomedial edge	(16/114).
Study population: patients with painful hallux valgus with metatarsus primus varus.	67% (66/98) had a	preoperative hallux valgu	of the metatarsal was necessary to ease pressure discomfort in 2			
n = <b>64</b> (98 feet)	81% (52/64) were s	satisfied with the cosmeti	c result and 95% (61/64) ha	ad no pain	cases.	
Age: 49 years (mean), (range: 17-78)	at follow up.		, , , , , , , , , , , , , , , , , , , ,			
Sex: 60/64 = 94% female					Recurrence of hallux valgus requiring a further procedure: 1/98	
Inclusion criteria: no age limits.					(1%)	
Technique: percutaneous distal osteotomy (Bösch technique) using fluoroscopy for visualisation and Kirschner wire for fixation.					Lengthening of the extensor tendon required: 1/98 (1%)	
Follow-up: 8 years 9 months (mean)					No cases of hallux varus, pseudarthrosis or	
Conflict of interest: none reported					necrosis.	

Study details	Key efficacy find	lings	Key safety findings	Comments		
Siclari A (2009) <sup>9</sup> Study type: <b>case series</b>		Preoperative mean	Postoperative mean	p value	Pain to the medial side of great toe: 1 patient (resolved when	
Country: Italy Study period: Jan 2003 – Aug 2006	Total AOFAS score (mean)	45	90.6	< 0.001	Kirschner wire removed) Superficial infection: 1	
Study population: patients with painful hallux valgus	AOFAS pain score (mean)	13.5	37.4	< 0.001	patent (resolved with oral antibiotics)	
deformity	AOFAS function score (mean)	29.3	39.7	< 0.01	Radiographically assessed	
n = <b>49</b> (59 feet) Age: 54.6 years (mean) Sex: 87.8% (43/49) female	AOFAS alignment score (mean)	1.5	13.4	< 0.005	complications: Malunion: 2 patients Nonunion: 2 patients	
Patient selection criteria: patient with first intermetatarsal angle < 25 degrees and hallux valgus angle < 40 degrees.	1st MTP angle (mean)  1st intermetatarsal	27.9 degrees 16.5 degrees	12.3 degrees 9.3 degrees	< 0.005 < 0.005	No recurrences of hallux valgus.	
Technique: combination of percutaneous distal osteotomy and arthroscopic lateral release (if patient had a congruent joint) with patients under epidural anaesthesia. Kirschner wire used for fixation	angle (mean) Hallux valgus angle (mean)	28.1 degrees	11 degrees	< 0.005		
Follow-up: 31.5 months (mean)						
Conflict of interest: none						

Study details	Key efficacy findings	Key safety findings	Comments
Giannini et al (2003) <sup>10</sup>	AOFAS score (out of 100):	No serious	
	Mean: 81 points	complications (e.g. avacular necrosis of the	
Study type: case series	Excellent: 64.8% (35/54)	metatarsal head or	
Country: Italy	Good: 18.5% (10/54)	nonunion of the	
Study period: NR	Fair: 9.2% (5/54)	osteotomy)	
	Poor: 7.4% (4/54)		
Study population: patients with mild to moderate reducible deformity with a hallux angle up to 40 degrees and intermetatarsal angle up to 20 degrees.	(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)	Skin inflammation around Kirschner wire outlet at the tip of the great toe: 5.5% (3/54)	
n =37 (54 feet)	All osteotomies healed well with callus evidence after an average of 3 months	Deep vein thrombosis: 2.7% (1/37)	
Age: 48 years (mean), range: 10-70 years	(on radiographic evaluation). In 9.2% (5/54) of patients, radiographic healing of	, ,	
Sex: 34/37 = 92% female	the osteotomy occurred more than 4 months after surgery.	Transfer metatarsalgia with plantar callosities	
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.	Patient satisfaction: 7.4% (4/37) not satisfied with the procedure, 92.6% (33/37) satisfied.	under the 2nd and 3rd metatarsal heads: 7.4% (3/54)	
Technique: minimally invasive linear distal metatarsal osteotomy (SERI technique – simple, effective, rapid, inexpensive). Fluoroscopy is not used and Kirschner wire for fixation			
Follow-up: 36 months (mean), range 22–52 months			
Conflict of interest: none reported			

Study details	Key efficacy findings						Key safety findings	Comments
Lin et al (2009) <sup>11</sup>							Complications	
Study type: case series		Preoperative mean (SD)	)	Follow-up mean (SD)	Correction mea (SD)	n p	Stiffness: 2/47 (4.3%) Pin tract infection: 6/47	
Country :Taiwan	Hallux	26 (4.9)		14.2 (6.7)	11.8 (5.8)	<0.001	(12.8%)	
Study period: Sept 2005 – Dec 2006	valgus angle	(range 18–36	6.9)	(range 0-26.3)	(range 3.5–24.5	5)	Deep infection: 1/47 (2.1%) healed when	
Study population: patients with hallux valgus	First IMA	11.6 (1.6)	7)	5.3 (2.3)	6.3 (2.1)	<0.001	Kirschner wire was removed 3 weeks	
deformities		(range 8–14.	.7)	(range 0.1–10.3)	(range 2.2–11.4	+)	postoperatively;	
n = <b>31</b> (47 feet)	AOFAS s	cores	Mea	an (SD), range			however, the deformity recurred.	
Age: 40.8 years (mean), range 13–63 years	Pain (out	of 40)	35.7	7 (5), 30–40				
Sex: 27/31 = 87.1% female	Function	(out of 45)	43.6	6 (2.3), 40–45			No episodes of nonunion, malunion,	
		it (out of 15)		4 (3), 8–15			overcorrection, transfer	
Inclusion criteria: painful primary mild–moderate hallux valgus deformity with a 1st metatarsal angle <=	Total (out of 100) 92.7 (6.2), 78–100						metatarsalgia or osteonecrosis.	
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.	Patient opinion: 28/31 (90.3%) patient were willing to undergo the same operation again.						Osteorieorosis.	
Technique: minimally invasive distal metatarsal osteotomy (modified from Magnan et al (2006) <sup>14</sup> ). Fluoroscopy is not used and Kirschner wire is used for fixation.								
Follow-up: 23.7 weeks (mean), range 16-68 weeks								
Conflict of interest: none reported								

Study details	Key efficacy findings				Key safety findings	Comments
Maffulli et al (2005) <sup>12</sup>					Complications	
Study type: case series		Preoperative mean (SD)	Postoperative mean (SD)	p-value	Superficial infection: 1/21 (4.8%) managed	
Country: UK	Hallux valgus	32 (12)	14.1 (4.7)	0.04	with oral antibiotics and	
Study period: not reported	angle (degrees)	(range 28-42)	(range 7.5–22)		bed rest for 5 days.	
,	DMAA (degrees)	13.1 (6.2)	7 (4.2)	0.03		
Study population: patients with hallux valgus		(range 5.5-21.5)	(range 5-12)			
	1st IMA	11.5 (4)	7.5 (3)	0.04	04	
n = <b>15</b> (21 feet)	(degrees)	(range 10-17)	(range 3-11)			
Age: 46.5 years (mean), SD 12, range 28-64 years	Sesamoid	2 (0.8)	0.5 (0.6)	0.03		
Sex: 100% female	position		(range 0-1)			
the IMA is up to 20°. Exclusion criteria: severe deformity of the IMA >20°, severe degenerative disease or stiffness of the MJP and severe instability of the metatarsocuneiform or MJP.  Technique: minimally invasive distal metatarsal subcapital osteotomy . Fluoroscopy is not used and Kirschner wire used for fixation.						
Follow-up: 25 months (mean), SD 3.2 months						
Conflict of interest: none reported						

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
Study details  Kadakia et al (2007) <sup>13</sup> Study type: prospective case series  Country: USA  Study period: June 2005 – Oct 205  Study population: patients with mild–moderate hallux valgus deformities  n =13 (assumed 13 feet)  Age: 52 years (mean), range 13–63 years)  Sex: 12/13 = 92.3% female	Hallux valgus angle (degrees) IMA (degrees) Dorsal anguation (degrees)	Preoperative mean  25 (range: 16–33)  10.3 (range: 7–14) 0	First postoperative mean (2 week follow-up)  5 (range: -1–12)  4.8 (range: 1–10)  10.8 (range: 6–15)	Final follow up mean (6 week follow-up)  12 (range: 1–24)  6.4 (range: 2–10)  15.9 (range: 10–22)	Complications Osteonecrosis: 1/13 (7.7%) Nonunion with no evidence of radiographic healing at 27 weeks: 1/13 (7.7%) Superficial cellulitis that resolved with oral antibiotics: 1/13 (7.7%) Deep infection: 0 Recurrent hallux valgus (final angle >15°: 5/13 (38.5%). (One was treated with revision chevron osteotomy)	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".  Conservative management including shoe modifications, orthotic intervention or both failed in all patients.  Concomitant procedures included 1 hallux metatarsophalangeal lateal 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.
Inclusion criteria: hallux valgus angle <40°. Patients with rheumatoid arthritis, diabetes, prior hallux surgery or hypermobility were eligible.  Technique: percutaneous distal metatarsal osteotomy. Fluoroscopyis not used and Kirschner wire used for fixation (based on the technique described by Giannini et al (2003) <sup>10</sup> ).  Follow-up: 130 days (mean), range 50–207 days  Conflict of interest: none reported	Both the hallu postoperative compared witl IMA: p < 0.00 final follow-up  Radiographic three radiogra	h postoperatively (	d the IMA are signoreoperatively, an hallux valgus angulation was signification by the properatively (p < li>Ilus noted at osterativents (92.3%) ha	nificantly different d at final follow-up lle: p < 0.0001; icantly different at < 0.0197).	osteotomy) Dorsal malunion: 9/13 (69.2%) Hallux varus: 0	

#### Validity and generalisability of the studies

- All the studies presented in this overview are case series.
- Different techniques were employed across the studies, in particularly 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

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- 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?

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## 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	Case series	84/136 (61.8%) excellent 48/136 (35.3%) good	Insufficient detail in English abstract
valgus. [Chinese]. Chung-Kuo Hsiu Fu Chung Chien Wai Ko Tsa Chih/Chinese Journal of Reparative & Reconstructive Surgery 20:50-52.	n = 136 (263 feet)  Follow-up: 19 months (mean)	3/136 (2.2%) fair 1/136 (0.7%) poor	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	Case series n = 64	Mean correction of 5° in the intermetartarsal angle and 8° degrees in the PASA. Transfer metatarsalgia occurred in 25%	Insufficient detail in English abstract
Traumatologia 47:406-416.	Follow-up: NR	of cases.	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	Case series	Positive results (very good, good and moderate were obtained in 90% of cases and	Insufficient detail in English abstract
toe. [Italian]. Minerva Ortopedica e Traumatologica 56:127-133.	Follow-up: NR	93% of patients were satisfied.	Larger studies included in table 2
Zorzi R, Pessina R, Confalonieri N et al. (2004) Mini-invasive technique (percutaneous distal osteotomy) in	Case series	87.5% patients said they would undergo percutaneous distal osteotomy again.	Insufficient detail in English abstract
abduct-valgus hallux treatment: Outcome in 42 treated patients. [Italian]. Minerva Ortopedica e Traumatologica 55:73-78.	n = 40 Follow-up: NR		Larger studies included in table 2
Martinez-Nova A, Sanchez- Rodriguez R, Leal-Muro A et al. (2008) Percutaneous distal soft tissue release-akin procedure, clinical and podobarometric assessment with	Case series  n = 26 (30 feet)  Follow-up: 12.1	Improvement in the AOFAS rating scale score from 68.7 to 88.1, HAA from 25.4° to 11.4°, and in the 1st intermetatarsal angle from	Larger studies included in table 2
the BioFoot in-shoe system: a preliminary report. Foot Ankle Spec. 1: 222–230.	months (mean)	12.0° to 9.2°	
Ruffer M, Martini F, Pfeil J. (2006) The operative treatment of the	Case series	Preoperative MPA = 32° (mean)	Insufficient detail in English abstract
juvenile Hallux valgus by minimally invasive modified Kramer osteotomy. [German]. Fuss und Sprunggelenk	n = 15	Postoperative MPA = 13° (mean)	Larger studies
4:240-246.	Follow-up: NR	Preoperative IMA = 12° (mean)	included in table 2
		Postoperative IMA = 5° (mean) Conclude that a modified Kramer procedure is effective	
		in correcting hallux valgus	

Article	Number of patients/follow-up	Direction of conclusions	Reasons for non- inclusion in table 2
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. Chirurgia Degli Organi di Movimento 92:145-148.	Case series  n = 14 (16 feet)  Follow-up: 4 years and 4 months (mean), range 4–6 years	Pain at metatarsal bunion relived in all patients, 7 cases of metatarsalgia before surgery and 1 after surgery. Radiographic results:  • Metatarsal phalangeal angle reduced from 28° to 13.3° (mean).  • Intermetatarsal angle reduced from 13.5° to 7.4° (mean).  • PASA reduced from 13.8° to 4.1°.  • Sesamoid bone position reduced from 3–4 to 2 (mean)  • Costa Bertani angle reduced from 130° to 124° (mean)  All patients satisfied with the treatment.	Larger studies included in table 2
Van Enoo RE, Cane EM. (1986) Minimal incision surgery. A plastic technique or a cover-up? Clinics in Podiatric Medicine & Surgery 3:321- 335.	Case report  n = 6  Follow-up: NR	All successful procedures. No complications reported.	Larger studies included in table 2
Town FC Colordo M (4004) First	•	Dragon aratica IMAA ACO	I aman atualiaa
Toepp FC, Salcedo M. (1991) First metatarsal closing base wedge osteotomy using real-time fluoroscopy. Clinics in Podiatric Medicine & Surgery 8:137-151.	Case report	Preoperative IMA: 16°	Larger studies included in table 2
	n = 1	Proporative IMA: 4°	
		Preoperative HA angle: 23°	
	F-11	No complications reported.	
	Follow-up: 15 years	15-year examination revealed excellent hallux range of motion and no recurrence of hallux valgus deformity.	

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

Guidance	Recommendations
Interventional procedures	Metatarsophalangeal joint replacement of the hallux. NICE interventional procedures guidance 140 (2005)
	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 the Institute's <i>Information for the public</i> 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.

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

Database	Date searched	Version/files
Cochrane Database of	28/07/09	Issue 3, 2009
Systematic Reviews – CDSR		
(Cochrane Library)		
Database of Abstracts of	28/07/09	N/A
Reviews of Effects – DARE		
(CRD website)		
HTA database (CRD website)	28/07/09	N/A
Cochrane Central Database of	28/07/09	Issue 3, 2009
Controlled Trials – CENTRAL		
(Cochrane Library)		
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 metaRegister of Controlled Trials mRCT
- · 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

- 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