# Interventional procedure overview of minimally invasive percutaneous surgical techniques with internal fixation for correcting hallux valgus

# Contents

Indications and current treatment	3
What the procedure involves	3
Outcome measures	4
Evidence summary	5
Population and studies description	6
Procedure technique	
Efficacy	
Safety	47
Validity and generalisability	51
Existing assessments of this procedure	Error! Bookmark not defined.
Related NICE guidance	
Interventional procedures	
Technology appraisals	Error! Bookmark not defined.
Medical technologies	Error! Bookmark not defined.
NICE guidelines	Error! Bookmark not defined.
Professional societies	53
Evidence from patients and patient organisations	Error! Bookmark not defined.
Company engagement	
References	53
Methods	
Other relevant studies	

IP overview: Minimal invasive percutaneous surgical techniques with internal fixation for correcting hallux valgus

#### **Table 1 Abbreviations**

Abbreviation	Definition
AOFAS HMI	American Orthopaedic Foot and Ankle Society Hallux
score	Metatarsophalangeal Interphalangeal score
CI	Confidence interval
DMAA	Distal metatarsal articular angle
HV	Hallux valgus
HVA	Hallux valgus angle
IMA	Intramedullary angle
MICA	Minimally invasive Chevron-Akin
MD	Mean difference
MOXFQ	Manchester-Oxford Foot Questionnaire
MIS	Minimally invasive surgery
MTP	Metatarsophalangeal joint
00	Open Chevron
PECA	Percutaneous Chevron-Akin
POO	Percutaneous oblique osteotomy
PROMs	Patient-reported outcome measures
RCT	Randomised controlled trial
ROM	Range of motion
RR	Relative risk
SA	Scarf Akin
SF-36 MCS	Short form (36) mental health component summary score
SF-36 PCS	Short form (36) physical component summary score
SD	Standard deviation
SMD	Standardised mean difference
VAS	Visual analogue scale

IP overview: Minimal invasive percutaneous surgical techniques with internal fixation for correcting hallux valgus

# Indications and current treatment

Hallux valgus (HV) is more commonly known as a bunion. The big toe is deviated towards the other toes resulting in a bony protrusion. This deviation occurs at the first metatarsal phalangeal joint. The small sesamoid bones found beneath the first metatarsal also become displaced as the first metatarsal bone drifts away from its normal position, weakening the big toe. Symptoms include damage to the skin over the bunion, pain and weakness of the forefoot when walking, cosmetic concerns, and difficulty with footwear.

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

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

# Unmet need

Clinical experts suggest that people with increased frailty, severe HV deformity (defined as HVA 40 degrees or more or IMA 20 degrees or more, or both), poor IP overview: Minimal invasive percutaneous surgical techniques with internal fixation for correcting hallux valgus

soft tissues, high risk of wound healing complications and pain management issues may benefit from percutaneous minimally invasive procedures to treat this condition.

## What the procedure involves

Surgical correction of HV using percutaneous minimally invasive percutaneous techniques with internal fixation is done as a day case under local or general anaesthesia and in supine position. Low-dose X-ray monitoring or endoscopic images are used. One or more small incisions are made close to the hallux metatarsophalangeal joint of the affected toe. The bunion is then removed and the metatarsal is divided surgically (osteotomy). Motorised high torque low speed burrs and surgical jigs aid the complex reduction and fixation steps of the procedure and implant insertion. Temporary wires may be used to toggle the separated parts of the divided bone into the desired position. The bone fragments are then stabilised using plates, specialised screws, or wires. The temporary wires used for toggling pieces of bone are removed. The small incisions are closed and a dressing is applied. After surgery, a dressing or plaster may be used to support the foot in the corrected position until the divided bone heals. People are usually allowed to put weight on the foot immediately.

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

## **Outcome measures**

The main outcomes included patient-reported outcome measures: improvement in function and pain, quality of life, patient satisfaction; complications, recurrence rate and reoperations; hallux joint angle correction and maintenance (radiological IP overview: Minimal invasive percutaneous surgical techniques with internal fixation for correcting hallux valgus

measures), radiation exposure time. The measures used are detailed in the following paragraphs.

## **MOXFQ** score

The MOXFQ is a validated measure of health-related quality of life. It has 3 domains: pain, walking or standing, and social interaction, with a maximum score of 100 in each domain. Higher scores signify poorer quality of life.

## **AOFAS HMI score**

The AOFAS HMI score is the most commonly used patient-reported outcome measure for first MTP fusion (arthrodesis). It consists of subjective and objective variables classified into 3 major categories: pain, function, and alignment. The scores are divided into categories:

- 90 to 100 excellent
- 75 to 89 good
- 50 to 74 fair
- less than 50 points poor.

A minimal clinically important difference of 19 points was suggested by Kaufmann (2019).

## VAS score

The VAS score is used to assess the intensity of pain. The range of the VAS score was from 0 to 10, with higher scores signifying 'worst pain'.

IP overview: Minimal invasive percutaneous surgical techniques with internal fixation for correcting hallux valgus

# **Evidence summary**

## Population and studies description

This interventional procedures overview is based on 1,975 patients from 2 metaanalyses, 3 RCTs and 3 retrospective cohort studies (1 with propensity score matching) and 3 case series. Of these 1,975 patients, 680 patients had the minimally invasive percutaneous surgical technique with internal fixation (636 MIS Chevron osteotomy procedures, 44 fourth generation MIS transverse osteotomy Akin procedures, 47 Lapidus tarsometatarsal [TMT] fusion), and 303 had open osteotomy procedures (163 with open scarf Akin osteotomy, 140 with open Chevron osteotomy), 44 open Lapidus TMT fusion and 901 had MIS Reverdin Isham osteotomy (with no fixation). This is a rapid review of the literature, and a flow chart of the complete selection process is shown in <u>figure 1</u>. This overview presents 11 studies as the key evidence in <u>table 2</u> and <u>table 3</u>, and lists 39 other relevant studies in <u>table 5</u>.

The countries where the procedures were carried out include Romania, Helsinki, Australia, Singapore, China, Austria, Switzerland, and the UK. The population is comprised of patients above 18 years with hallux valgus deformity:

- mild deformity: HVA 15° to 20° or IMA 9° to 14°, or both
- moderate deformity: HVA 20° to 40° or IMA 14° to 20°, or both
- severe deformity: HVA 40° or above, or IMA 20° or above, or both.

The study designs include systematic review and meta-analyses, RCTs, retrospective cohort studies and case series. The follow up periods range from 1 to 5 years.

The meta-analysis comparing third generation PECA osteotomy with open scarf akin osteotomy (traditional open surgery) included only 3 studies (1 RCT and 2

IP overview: Minimal invasive percutaneous surgical techniques with internal fixation for correcting hallux valgus

IP 782/2 [IPGXXX]

cohort studies) with short term follow up (Ferreira 2021). Another meta-analysis compared 2 MIS techniques, MIS distal Chevron-Akin osteotomy (1 study) with MIS Reverdin-Isham osteotomy (no fixation, 14 studies). The quality of the included studies on MIS Reverdin-Isham osteotomy were low and only 7 studies were used in the meta-analysis. The MIS distal Chevron-Akin osteotomy was done by a single surgeon in 1 centre (Kaufmann 2021).

Two small RCTs (Dragosloveanu 2022, Kaufmann 2019 and 2022) compared third generation percutaneous MICA and open approaches for Chevron osteotomy (another traditional open surgery). Follow up in these studies ranged from 1 year (Dragosloveanu 2022) to 5 years (Kaufmann 2019 and 2022). All surgeries in both RCTs were done by a single foot and ankle surgeon. 17% (8/47) of patients dropped out of 1 RCT (2 were lost to follow up and 6 declined continuing in the study; Kaufmann 2019 and 2022). Another small RCT compared MIS scarf osteotomy with open scarf osteotomy. All procedures were done by a single foot and ankle surgeon in both groups. Lesser toe deformities were also treated in 50% of patients in both groups (Torrent 2021).

Two small retrospective cohort studies (Guo 2021, Tay 2022) compared percutaneous MICA and open chevron osteotomy. One of the small retrospective cohort studies compared percutaneous oblique osteotomy and internal fixation with open chevron osteotomy (Guo 2021) in 112 people. The retrospective propensity matched cohort study of 60 patients compared MICA with open scarfakin osteotomy (Tay 2022).

Two case series (1 retrospective and 1 prospective study) assessed third generation MIS procedures (MICA and PECA). The retrospective study of 92 patients (126 consecutive feet) had more than 60 months follow up. The study was adequately powered and validated clinical outcome measures were used. But it lacked validated preoperative clinical PROMS. A 40% loss to follow up for

IP overview: Minimal invasive percutaneous surgical techniques with internal fixation for correcting hallux valgus

radiographs at final follow up was reported (Lewis 2023a). The prospective case series was large (230 patients [333 feet]) and had 2 years follow up. All procedures were done by a single surgeon and validated measures were used to assess PROMs. In-depth analysis of adverse events were reported. There was a lack of long-term radiographic follow up (Lewis 2021).

One small prospective case series of 50 patients with a wide range of HV deformities reported on a fourth generation (META) MIS technique with short follow-up period. All procedures were done by a single surgeon (Lewis 2023b).

A retrospective study compared MIS TMT fusion (Lapidus procedure) with the open Lapidus procedure in a single-surgeon practice. The follow-up period was shorter in the MIS group compared with the open procedure (Vieira Cardoso 2022).

Half of the studies are observational studies with some source of bias. Nonvalidated outcome measure tools, such as the AOFAS and VAS were used in most studies.

Table 2 presents study details.

IP overview: Minimal invasive percutaneous surgical techniques with internal fixation for correcting hallux valgus

#### Figure 1 Flow chart of study selection



IP overview: Minimal invasive percutaneous surgical techniques with internal fixation for correcting hallux valgus

## Table 2 Study details

Study no.	First author, date country	Patients and sex (female: male) or gender (women: men) as reported by the study	Age	Study design	Inclusion criteria	Intervention	Follow up
1	Ferreira GF, 2020 Australia, Singapore, and Switzerland	N=235 feet with hallux valgus PECA group n=102 (89:13) Open SA osteotomy group n=133 (120:13)	PECA Mean 48 to 54 years open SA osteotomy mean 48 to 54 years	Systematic Review and meta- analysis (n=3 studies including 2 cohort studies and 1 RCT)	Hallux valgus diagnosis and surgical treatment by the open SA osteotomy and PECA techniques.	PECA osteotomy and open SA osteotomy	6 months
2	Kaufmann G, 2021 Austria	N=950 patients MIS/percutaneous chevron osteotomy: 49 patients (57 feet) (52:5) MIS Reverdin- Isham osteotomy: 901 patients (1033 feet) (774: 60; 4 studies did not report).	MIS chevron osteotomy Mean 53 years MIS Reverdin- Isham group range from 12.5 to 61.5 years	Systematic review and meta- analysis 14 studies (7 included in meta- analysis).	Articles in English or Spanish, assessing MIS/percutaneous chevron distal /oblique osteotomy, MIS Reverdin-Isham method, with a minimum follow up of 6 months and presenting results in terms of clinical or	MIS distal chevron osteotomy (1 case series of 49 patients-57 feet with mild to moderate HV deformity) 45 feet had phalangeal Akin osteotomy compared with MIS Reverdin- Isham method.	MIS chevron osteotomy mean follow up 58.9 (range 39.0 to 85.4) months. MIS Reverdin- Isham method minimum

IP overview: Minimal invasive percutaneous surgical techniques with internal fixation for correcting hallux valgus

Study no.	First author, date country	Patients and sex (female: male) or gender (women: men) as reported by the study	Age	Study design	Inclusion criteria	Intervention	Follow up
					radiological data were included.		6 to 60 months.
3	Dragosloveanu S, 2022 Romania/Helsinki	N=50 patients with moderate hallux valgus Percutaneous MIS chevron osteotomy group n=24 (24:0) OC osteotomy group n=26 (24:2)	MIS chevron osteotomy: 49±15 years OC osteotomy: 55±15 years	RCT	Patients older than 20 years old, when conservative treatment had failed, with moderate valgus deformity (HVA between 20 and 40 degrees and an IMA between 11 and 16 degrees)	Percutaneous MIS chevron osteotomy (MIS group) compared with OC osteotomy (OC group)	1 year
4	Kaufmann G, 2019, 2020 Austria	N=47 patients with hallux valgus MIS chevron osteotomy n=25 feet (21:4) OC n=22 feet (19:3)	MIS chevron: 54±15.2 years OC: 47±14.3 years	RCT	Adults with hallux valgus who were scheduled to have distal chevron osteotomy between January 2012 and August 2013. In all nonoperative treatment had failed before surgery.	Percutaneous/MIS chevron osteotomy compared with OC osteotomy	9 months (mean, 67.1 ± 6.1 months): 47 feet 5 years: 39 feet

Study no.	First author, date country	Patients and sex (female: male) or gender (women: men) as reported by the study	Age	Study design	Inclusion criteria	Intervention	Follow up
5	Tay A, 2022 Singapore	N=60 patients with symptomatic hallux valgus MICA osteotomy group n=30 (21:9) Open SA osteotomy n=30 (26:4)	MICA: mean 51.7 years Open SA osteotomy: mean 52.7 years	Retrospective propensity score matched cohort Study	Patients who had primary, unilateral MICA osteotomy for symptomatic hallux valgus between 2016 and 2018 for persistent painful bunion with or without metatarsalgia after conservative treatment for at least 3 months.	MICA osteotomy screw compared with open SA osteotomy (control) Other concomitant procedures were also done in a few cases.	24 months
6	Guo CJ, 2021 China	N=112 feet (99 patients with hallux valgus) MIS percutaneous oblique osteotomy (POO) group n=48 feet (41 patients; 45:3) OC osteotomy group n=64 feet (58 patients; 61:3)	MIS (POO) group: mean 60.9±12.2 years OC group: mean 60.6±9.69 years	Retrospective cohort study	Patients above 18 years with painful HV and failed conservative treatment; and HV correction had operative treatment via POO or open chevron osteotomy techniques.	Intervention: percutaneous oblique osteotomy (POO) and Control: OC osteotomy Akin osteotomy done in 50 (15 in POO and 35 in OC group) Weil osteotomy in 39 (16 in POO and 23 in OC group).	2 years

Study no.	First author, date country	Patients and sex (female: male) or gender (women: men) as reported by the study	Age	Study design	Inclusion criteria	Intervention	Follow up
7	Lewis T, 2023a Australia, 3 centres	N=92 patients with hallux valgus deformity (126 feet) (87:5) Included for analysis (n=53, 78 feet [51:2])	Mean age: 60.4±11.5	Retrospective observational study	People aged over 16 presenting with a painful hallux valgus deformity (HVA more than 15 degrees) who had isolated primary third- generation PECA with at least 60 months' follow up.	PECA by a single surgeon. No additional concomitant procedures were done.	Mean follow-up was 66.8±5.9 (range 60 to 88) months
8	Lewis T 2023b UK 2 centres	N=44 patients with hallux valgus deformity (n=47 feet [38:6])	Mean 55.4±15.7 years	Prospective case series	People aged 16 and over, who had primary correction of hallux valgus, of all radiological severities and congruent and incongruent deformities, with first TMT joint instability or a diagnosis of generalised hyper-mobility, who had additional forefoot procedures.	Fourth-generation MIS only in 40% patients 60% had additional concomitant procedures (23 lesser toe proximal and distal interphalangeal joint deformity corrections, 3 bunionette corrections at little toe, 1 K-wire fixation for	Mean 1.3±0.4 years (range 1.0 to 2.3).

Study no.	First author, date country	Patients and sex (female: male) or gender (women: men) as reported by the study	Age	Study design	Inclusion criteria	Intervention	Follow up
						dislocated second toe, and 1 case of lesser metatarsal distal osteotomies for metatarsalgia in rheumatoid arthritis).	
9	Lewis T (2021)	N=230 patients (333 feet with hallux valgus deformity [214:16]) Mild: HVA 15 to less than 20 degrees and IMA 9 to 14 degrees 7.8% (n=25) Moderate: HVA 20 to less than 40 degrees and IMA 14 to less than 20 degrees 65.5% (n=209) Severe HVA 40 degrees or more and IMA 20	Mean age 55 years (range, 23.5 to 84.9 years)	Prospective case series	Patients over 16 who had primary correction of hallux valgus (of any deformity severity) were included. Patients who had additional forefoot procedures (such as hammer-toe correction or distal metaphyseal metatarsal osteotomy) were included.	Third-generation MICA by a single surgeon. 69 patients (138 feet) had bilateral procedures on same day.	Mean follow up was 2.5 years (range, 2.0 to 5.5 years)

Study no.	First author, date country	Patients and sex (female: male) or gender (women: men) as reported by the study	Age	Study design	Inclusion criteria	Intervention	Follow up
		degrees or more 26.6% (n=85)					
10	Torrent J, 2021 Spain	N=58 patients MIS SA osteotomy group n=30 (28:2) Open SA osteotomy group n=28 (28:2)	MIS SA osteotomy: mean 60.7 years Open SA osteotomy: mean 64.2 years	RCT	Indication of scarf osteotomy as the treatment for HV deformity, failed conservative treatment for at least 6 months.	Minimally invasive scarf osteotomy compared with open scarf osteotomy	21 (range, 12 to 38) months
11	Vieira Cardoso D 2022 Switzerland	N=91 patients MIS Lapidus procedure N=47 (43:4) Open Lapidus procedure N=44 (38:6)	MIS group mean 58 years Open group mean 62 years	Retrospective cohort study	Patients over 18 who had MIS (between 2018 to 2019) or open first TMT fusion surgical procedure (between 2015 to 2017) to treat moderate to severe hallux valgus deformities were reviewed.	MIS TMT fusion (Lapidus procedure) compared with open TMT fusion (Lapidus procedure)	MIS group mean 29 (range, 14 to 47) months Open group mean 82 (range, 31 to 82) months

## Table 3 Study outcomes

First author, date	Efficacy outcomes	Safety outcomes
Ferreira GF, 2020	Clinical outcomes	Complications (3 studies)
	Pain (assessed using VAS)	(PECA [n=102] versus open SA [n=133]), RR
	Day 1 after surgery (2 studies)	1.51 (95% CI 0.80 to 2.86, p=0.36, I <sup>2</sup> =3%)
	(PECA [n=54] versus open SA [n=83]), SMD -1.68 points (95% CI -2.09 to -1.27, p<0.01, l <sup>2</sup> =87%)	PECA group reported complications with the screws, in some cases being necessary to
	At last clinical visit (3 studies)	remove them (actual number not reported). In
	(PECA [n=102] versus open SA [n=133]), SMD -0.14	metatarsalgia and wound complications.
	points (95% CI -0.49 to 0.20, p=0.81, I <sup>2</sup> =0%)	Radiation exposure time (assessed using the
	<b>Function</b> (assessed using AOFAS score at 6 months) (n=3 studies)	mean fluoroscopy duration in seconds; 2 studies).
	PECA [n=102] versus open SA [n=133]), SMD 4.97 points (95% CI 3.55 to 6.39, p=0.14, I <sup>2</sup> =48%,	PECA group [n=54] versus open SA group [n=83]). Exposure to radiation was higher in the PECA group (SMD 35.53 seconds, 95% CI 31.75
	Radiological outcomes	to 35.31, p<0.01, l <sup>2</sup> =87%)
	Difference in HVA (3 studies)	
	(PECA [n=102] versus open SA [n=133]), SMD -0.80 degrees (95% CI -1.07 to -0.52, p=0.03, l <sup>2</sup> =70%)	
	Difference in IMA (3 studies)	
	(PECA [n=102] versus open SA [n=133]), SMD -0.53 degrees (95% CI -0.93 to -0.13, p<0.01, l <sup>2</sup> =93%)	
Kaufmann 2021	Radiographic outcomes	
Austria	MIS distal chevron osteotomy (1 study)	
	IMA (degrees)	
	Preoperative=13.3	
	• 6 weeks=6.2	

IP overview: Minimal invasive percutaneous surgical techniques with internal fixation for correcting hallux valgus

First author, date	Efficacy outcomes	Safety outcomes
	• 12 weeks=6.2	
	• 9 months=5.9	
	Mean 58.9 months=6.1	
	HVA (degrees)	
	Preoperative=29.9	
	• 6 weeks=8.9	
	• 12 weeks=8.1	
	• 9 months=7.7	
	• Mean 58.9 months=8.4	
	DMAA (degrees)	
	Preoperative=20.9	
	• 6 weeks=8.7	
	• 12 weeks=7.6	
	• 9 months=5.5	
	• Mean 58.9 months=6.8	
	MIS Reverdin Isham osteotomy	
	IMA (degrees)	
	Mean postoperative IMA=11.6	
	Three studies reported a correction of 3 degrees and 3 studies less than 3 degrees.	
	In the meta-analysis of 7 studies, mean postoperative IMA was 11.6 degrees.	

First author, date	Efficacy outcomes	Safety outcomes
	Sufficient correction of IMA was not achieved with the MIS Reverdin-Isham osteotomy.	
	MIS distal chevron osteotomy versus MIS Reverdin Isham osteotomy Radiographic outcomes (HVA, IMA, and DMAA) were statistically significantly better with the MIS distal chevron osteotomy than with the MIS Reverdin-Isham osteotomy in mild to moderate hallux valous deformity correction (p<0.05).	
	Clinical outcomes	
	<u>VAS (0-10)</u> • Preoperative=5.6	
	• 6 weeks=1.4	
	• 12 weeks=0.8	
	<ul><li>9 months=0.9</li><li>Mean 58.9 months=0.5</li></ul>	
	<u>AOFAS (0-100)</u>	
	Preoperative=64.4	
	• 6 weeks=84.2	
	• 12 weeks=90.2	
	• 9 months=92.2	
	• Mean 58.9 months=95.3	

First author, date	Efficacy outcomes	Safety outcomes
	<ul> <li><u>ROM of the first MTP joint (degrees)</u></li> <li>Preoperative=1.5</li> <li>6 weeks=1.1</li> <li>12 weeks=1.4</li> <li>9 months=1.5</li> <li>Mean 58 9 months=1.6</li> </ul>	
	<ul> <li>Mean Sole months – 1.6</li> <li><u>MIS Reverdin Isham osteotomy</u> Improved AOFAS and VAS scores were seen in studies.</li> <li>ROM was reported in 3 Reverdin-Isham studies and showed a slight reduction.</li> <li><u>MIS distal chevron osteotomy versus MIS Reverdin</u> <u>Isham osteotomy</u></li> <li>Clinical outcomes were comparable with both</li> </ul>	
	Recurrence (radiographic analysis)MIS distal chevron osteotomy (in 1 study at 58.9months follow-up)IMA >10 degrees (n=2 feet)HVA >20 degrees (n=5 feet)Reverdin Isham osteotomyA significant number of the Reverdin-Isham studiesshowed radiographic recurrence for IMA and HVA.	

First author, date	Efficacy outcomes	Safety outcomes
Dragosloveanu S, 2022	<ul> <li>Clinical outcomes</li> <li>Pain (assessed using VAS)</li> <li>Preoperative: MIS osteotomy group=7.6 ± 1.2, OC osteotomy group=7.1 ± 1.8; p=0.257</li> <li>Discharge: MIS=2.5 ± 0.8, OC=4.5 ± 1.4; p&lt;0.001</li> <li>3 weeks: MIS=1.4 ± 0.5, OC=2.8 ± 0.9; p&lt;0.001</li> <li>6 weeks: MIS=0.4 ± 1, OC=2.0 ± 0.8; p&lt;0.001</li> <li>6 months: MIS=0.2 ± 0.8, OC=0.8 ± 0.6; p=0.004</li> <li>12 months: MIS=0.2 ± 0.6, OC=0.4 ± 0.7; p=0.285.</li> <li>Function (AOFAS score)</li> <li>Preoperative: MIS=85.6 ± 4.1, OC=79.4 ± 3.6; p=0.125.</li> </ul>	Screw removal (after 3 months, because of soft tissue irritation, pain caused by screw prominence) MIS osteotomy group: 12.5% (3/24) OC osteotomy group : 3.8% (1/26) Metatarsalgia after 6 months OC group 3.8% (1/26) Average radiological exposure time MIS group (15.5 ± 5.6 seconds) versus OC group (1.8 ± 3.8 seconds) (p<0.001).
	<ul> <li>Radiological outcomes</li> <li>HVA</li> <li>Preoperative: MIS=32.5 ± 2.5, OC=31.9 ± 4.3; p=0.553</li> <li>6 months: MIS=9.6 ± 2.4, OC=9.5 ± 1.8; p=0.867</li> <li>12 months: MIS=8.8 ± 3.1, OC=8.9 ± 2.3; p=0.896.</li> <li>IMA</li> </ul>	

First author, date	Efficacy outcomes	Safety outcomes
	<ul> <li>Preoperative: MIS=15.1 ± 1.8, OC=15.6 ± 1.9; p=0.345</li> </ul>	
	<ul> <li>6 months: MIS=7.9 ± 1.4, OC group=7.6 ± 1.1; p=0.401</li> </ul>	
	<ul> <li>12 months: MIS=7.2 ± 1.8, OC=6.4 ± 1.5; p=0.093.</li> </ul>	
Kaufmann 2019, 2020	Clinical outcomes	Adverse events
	Pain (assessed by VAS, median)	MIS group:
	<ul> <li>Preoperative: MIS osteotomy group=5, OC osteotomy group=6, p=0.829</li> </ul>	Screw removal (because of soft tissue irritation and pain by K wire) 48% (12/25) feet.
	• 6 weeks: p=0.95	
	• 12 weeks: MIS group=1, OC group=1, p=0.144	OC group:
	• 9 months: MIS group=1, OC group=0, p=0.744	Screw removal (1 because of local pain and soft
	• 5 years: MIS group=0, OC group=0, p=0.322	tissue irritation and another because of patient wish $0\%$ (2/22) of fact
	Function (AOFAS score, median)	Holly, your $p=1$
	<ul> <li>Preoperative: MIS group=65, OC group=66.5, p=0.932</li> </ul>	
	<ul> <li>12 weeks: MIS group=85, OC group=83.5, p=0.237</li> </ul>	
	• 9 months: MIS group=85, OC group=90, p=0.943	
	• 5 years: MIS group=95, OC group=95, p=0.235	
	Radiological outcomes	
	IMA	
	<ul> <li>Preoperative: MIS group=14, OC group=15.15, p=0.201</li> </ul>	

First author, date	Efficacy outcomes	Safety outcomes
	• 12 weeks: MIS group=7.7, OC group=7.4, p=0.898	
	• 9 months: MIS group=6.8, OC group=5.85, p=0.502	
	• 5 years: MIS group=7.4, OC group=6	
	ниа	
	• Preoperative: MIS group=26.4, OC group=28.25, p=0.957	
	• 12 weeks: MIS group=8.8, OC group=9.15, p=0.873	
	• 9 months: MIS group=6.9, OC group=8.5, p=0.839	
	<ul> <li>5 years: MIS group=9.8, OC group=10.3, p=0.967</li> </ul>	
	DMAA	
	• Preoperative: MIS group=22.5, OC group=24.5, p=0.247	
	• 12 weeks: MIS group=7.1, OC group=8.2, p=0.322	
	• 9 months: MIS group=4.1, OC group=5.5, p=0.061	
	• 5 years: MIS group=5.9, OC group=7.5, p=0.396	
	ROM of the first MTP joint	
	Preoperative p=0.910	

First author, date	Efficacy outcomes	Safety outcomes
	Less than 30 degrees: MIS group=4%, OC group=4.5%	
	<ul> <li>31 to 75 degrees: MIS group=40%, OC group=50%</li> </ul>	
	<ul> <li>More than 75 degrees: MIS group=56%, OC group=45.5%</li> </ul>	
	<u>6 weeks follow up p=0.075</u>	
	<ul> <li>Less than 30 degrees: MIS group=8%, OC group=32%</li> </ul>	
	<ul> <li>31 to 75 degrees: MIS group=88%, OC group=64%</li> </ul>	
	<ul> <li>More than 75 degrees: MIS group=4%, OC group=4.5%</li> </ul>	
	<u>12 weeks follow up p</u> =0.653	
	<ul> <li>Less than 30 degrees: MIS group=0%, OC group=9.1%</li> </ul>	
	<ul> <li>31 to 75 degrees: MIS group=84%, OC group=73%</li> </ul>	
	<ul> <li>More than 75 degrees: MIS group=16%, OC group=18%</li> </ul>	
	<u>9 months follow up</u> p=0.910	
	<ul> <li>Less than 30 degrees: MIS group=0%, OC group=5%</li> </ul>	
	<ul> <li>31 to 75 degrees: MIS group=60%, OC group=67%</li> </ul>	

First author, date	Efficacy outcomes	Safety outcomes
	<ul> <li>More than 75 degrees: MIS group=33%, OC group=35%</li> </ul>	
	<u>5 years follow up p=0.496</u>	
	<ul> <li>Less than 30 degrees: MIS group=0%, OC group=0%</li> </ul>	
	<ul> <li>31 to 75 degrees: MIS group=37%, OC group=50%</li> </ul>	
	<ul> <li>More than 75 degrees: MIS group=63%, OC group=50%</li> </ul>	
	Patient satisfaction	
	9 months	
	<ul> <li>Very satisfied: MIS group=62.5%, OC group=70%, p=0.736</li> </ul>	
	• Satisfied: MIS group=25%, OC group=15%	
	• Don't know: MIS group=4.2%, OC group=0%	
	• Not satisfied: MIS group=8.3%, OC group=15%	
	5 years	
	• Very satisfied: MIS group=89%, OC group=70%	
	<ul> <li>poor satisfaction: n=2 in the OC group, (1 developed partial osteonecrosis of the lateral metatarsal head, and 1 had a recurrence off hallux valgus).</li> </ul>	
	Recurrence:	
	MIS group	
	Recurrence of HVA less than 25 degrees, 8% (2/25)	
	OC group	

First author, date	Efficacy outcomes	Safety outcomes
	Recurrence of HVA less than 25 degrees, 9% (2/22)	
	Recurrence of hallux valgus with an HVA of more than 30 degrees, n=1.	
Tay A, 2022	Clinical outcomes	Open SA osteotomy group
	Pain (assessed using VAS score, mean)	Readmission on day 10 for acute myocardial
	<ul> <li>Preoperative: MICA group=5.5, open SA group=5.6; p=0.958</li> </ul>	infarction (treated medically) n=1
	• Early post operative: MICA=2.0±2.0, open SA=3.4±2.6; p=0.029	
	• 6 months: MICA=1.2, open SA group=1.2; p=0.990	
	• 24 months: MICA=1.1, open SA group=0.5; p=0.290	
	Function (assessed using AOFAS, mean)	
	• Preoperative: MICA=54.3, open SA=53.2; p=0.800	
	• 6 months: MICA=79.8, open SA=79.3; p=0.920	
	• 24 months: MICA=83.3, open SA=86.5; p=0.432	
	Quality of life	
	SF-36 MCS, mean	
	<ul> <li>Preoperative: MICA=56.8 SD 10.6, open SA=54.8 SD 10.3; p=0.462</li> </ul>	
	• 6 months: MICA=55.3, open SA=55.9; p=0.820	
	• 24 months: MICA=56.0 SD 10.7, open SA=55.2 SD 11.1; p=0.756	
	SF-36 PCS	

First author, date	Efficacy outcomes	Safety outcomes
	<ul> <li>Preoperative: MICA=40.9 SD 9.3, open SA=43.9 SD 9.7; p=0.215</li> </ul>	
	<ul> <li>6 months: MICA=50.5 SD 9.1, open SA=48.9; p=0.550</li> </ul>	
	<ul> <li>24 months: MICA=50.6 SD 9.1, open SA=51.9 SD 7.1; p=0.538</li> </ul>	
	Radiological outcomes	
	HVA, mean (degrees)	
	<ul> <li>Preoperative: MICA=23.5, open SA=23.7; p=0.915</li> </ul>	
	• 24 months: MICA=7.7, open SA=9.3; p=0.375	
	IMA (degrees)	
	<ul> <li>Preoperative: MICA=13.5, open SA=13.6; p=0.899</li> </ul>	
	• 24 months: MICA=7.5, open SA=7.8; p=0.134	
	Patient satisfaction	
	<ul> <li>6 months: MICA=87% (26/30), open SA=73% (22/30), p=0.197</li> </ul>	
	<ul> <li>24 months: MICA=80% (24/30), open SA=87% (26/30), p=0.488</li> </ul>	
Guo CJ, 2021	Quality of life	Complication rate
	Clinical foot specific (MOXFQ score) Walking/standing score	POO group 8.3% (4/48) versus OC group 12.5% (8/64), p=0.48
	Preoperative: POO group=50.3 ± 8.59. OC	POO group:
group=49.8 ± 10.4; p=0.24	Screw removal (because of irritation after 3 months) n=1	

First author, date	Efficacy outcomes	Safety outcomes
	<ul> <li>2 years: POO group=13.5 ± 7.83, OC group=15.2 ± 8.08; p=0.23</li> </ul>	Revision surgery (on day 6 because of screw displacement after weight bearing) n=1
	Social interaction score	Paraesthesia of the medial of first metatarsal n=1
	<ul> <li>Preoperative: POO group=56.9 ± 10.7, OC group=58.6 ± 9.22; p=0.41</li> </ul>	Stiffness of the first MTP joint n=1
	<ul> <li>2 years: POO group=13.3 ± 10.9, OC group=17.6 ± 16.8; p=0.40</li> <li>Pain score</li> <li>Preoperative: POO group=51.6 ± 9.87, OC group=40.8 ± 10.4; p=0.46</li> </ul>	<b>OC group:</b> Wound problem n=1 Screw irritation n=2 Second metatarsalgia n=2
	<ul> <li>group=49.8 ± 10.4, p=0.16</li> <li>2 years: POO group=15.8 ± 13.3, OC group=22.7 ± 17.3; p=0.06</li> </ul>	Paraesthesia of the medial of first metatarsal n=1 Stiffness of the first MTP joint n=2
	Clinical outcomes	
	Function (assessed using AOFAS HMI)	
	<ul> <li>Preoperative: POO group=46.4 ± 10.1, OC group=43.7 ± 15.1; p=0.64</li> </ul>	
	<ul> <li>1 year: POO group=86.5 ± 10.7, OC group=88.2 ± 10.8; p=0.4</li> </ul>	
	<ul> <li>2 years: POO group=85.2 ± 13.8, OC group=79.5 ± 23.7; p=0.66.</li> </ul>	
	Pain (assessed using VAS score)	
	<ul> <li>Preoperative: POO group=7.63 ± 1.06, OC group=7.29 ± 1.42, p=0.07</li> </ul>	
	<ul> <li>2 weeks: POO group=2.00 ± 0.98, OC group=5.51 ± 1.45, p=0.00</li> </ul>	

First author, date	Efficacy outcomes	Safety outcomes
	• 1 year: POO group=2.00 ± 0.99, 2.56 ± 2.88, p=0.53	
	<ul> <li>2 years: POO group=1.55 ±1.11, 2.56 ± 2.88, p=0.37</li> </ul>	
	Compared with preoperative scores, both groups showed statistically significant improvement in all the domains at 2 year follow-up (p<0.001), but no statistically significant difference was noted between the groups.	
	Radiologic outcomes	
	HVA (degrees)	
	<ul> <li>Preoperative: POO group=35.9 ± 10.0, OC group=34.3 ± 8.85; p=0.38</li> </ul>	
	<ul> <li>1 year: POO group=12.5 ± 2.22, OC group=14.1 ± 6.78; p=0.12</li> </ul>	
	<ul> <li>2 years: POO group=17.9 ± 9.31, OC group=14.8 ± 7.83; p=0.06</li> </ul>	
	IMA (degrees)	
	<ul> <li>Preoperative: POO group=13.2 ± 3.31, OC group=13.7 ± 2.53; p=0.46</li> </ul>	
	<ul> <li>1 year: POO group=7.61 ± 1.63, OC group=6.89 ± 3.06; p=0.14</li> </ul>	
	<ul> <li>2 years: POO group=6.94 ± 1.53, OC group=6.97 ± 2.95; p=0.95</li> </ul>	
	Compared with preoperative outcomes, both groups demonstrated statistically significant differences in the HVA and IMA at the final follow-up (p<0.05).	
Lewis T, 2023a	Radiological outcomes (n=78 feet)	Reoperations (for removal of prominent screws)

First author, date	Efficacy outcomes	Safety outcomes
	IMA, (mean degrees)	4% (5/126) in patients who had more than 60
	Preoperative=12.8 ±2.9	months follow up.
	• 6 months=5.9 ±2.4	
	• More than 60 months=6.0 ±2.6 (p<0.001)	
	HVA, (mean degrees)	
	Preoperative=28.2 ±8.1	
	• 6 months=6.7 ±4.6	
	• More than 60 months=7.8 ±5.1 (p<0.001)	
	Clinical outcomes (n=78 feet)	
	Quality of life	
	Clinical foot specific (MOXFQ score) at more than 60 months	
	Walking/standing=6.8±17.7	
	Social interaction=11.2 ±20.1	
	Pain=11.8 ±19.6	
	Index=10.1±17.0	
	General health related QOL (EuroQoL-5D-5L: EQ- VAS score) at ≥60-months=92.0±10.2	
	VAS-pain scores at ≥60-months=6.3±14.9	
	<b>Recurrence</b> (HVA more than 15 degrees at final follow-up radiographs)=8% (6/78)	
	Of these, only 1 foot (1.3%) had an HVA more than 20 degrees and 3 of the 6 feet had a severe preoperative deformity (HVA more than 40 degrees).	

First author, date	Efficacy outcomes	Safety outcomes
	Patient satisfaction (at 60 months and over followup )77% reported 'highly satisfied'27% reported 'satisfied'	
Lewis T 2023b	Clinical outcomes	Complications
	<b>MOXFQ (n=47 feet)</b> (scale from 0 to 100, 0 best possible score).	Superficial infections (treated with antibiotics) n=1
	Pain Preoperative mean=53.7±23.0	First metatarsal lateral wall fracture (asymptomatic) n=1
	Postoperative (12 month) mean= $15.0\pm20.4$ (p<0.001)	Prominent screw removal (3 akin, 2 metatarsal) n=5
	Walking/standing	Scar revision (because of prominent bone swarf)
	Preoperative mean=53.9±25.1	
	Postoperative (12 month) mean=13.6±20.5 (p<0.001)	
	Social interaction	
	Preoperative mean=52.1±22.4	
	Postoperative (12 month) mean=9.9±15.3 (p<0.001)	
	Index	
	Preoperative mean=53.4±21.0	
	Postoperative (12 month) mean=13.1±17.5 (p<0.001)	
	EuroQoI-5D-5L (scale from 0 to 100, 100 best possible score) VAS	

First author, date	Efficacy outcomes	Safety outcomes
	Preoperative mean=69.8±17.8	
	Postoperative (12 month) mean=84.1±15.0 (p<0.001)	
	Index	
	Preoperative mean=0.556±0.237	
	Postoperative (12 month) mean=0.799±0.233 (p<0.001)	
	VAS pain (scale 0 to 100, 0 best possible score)	
	Preoperative mean=45.6±23.3	
	Postoperative (12 month) mean=14.7±21.0 (p<0.001)	
	<b>Recurrence of deformity</b> (between 6 week and 6 months HVA increased from 11 to 17 degrees): n=1; No progression between 6 months and 2 years noted.	
	Radiological outcomes (final follow up at 1.5 years [SD 0.5], n=42 feet)	
	HVA (degrees)	
	Preoperative 32.7±8.8	
	Final follow-up 7.9±5.0	
	Change –24.8±8.2, p<0.001	
	IMA (degrees)	
	Preoperative 14.0±3.6	
	Final follow-up 4.2±2.5	

First author, date	Efficacy outcomes	Safety outcomes
	Change –9.8±3.6, p<0.001	
	DMAA (degrees) Preoperative 18.5±6.4 Final follow-up 5.6±3.5 Change _12.9±6.1, p<0.001	
Lewis T 2021	Clinical outcomes	Adverse events
	PROMS in 87.7% (292/333); (200 patients, 292 feet)	Overall adverse-event rate 21.3%
	MOXFQ score (mean±SD) Walking and standing Preoperative $38.7 \pm 23.4$ 24 months $6.5 \pm 14.6$ (change $-32.2 \pm 25.5$ , p<0.001) Social interaction Preoperative $48.0 \pm 22.3$ 24 months $6.6 \pm 13.5$ (change $-41.3 \pm 24.7$ , p<0.001) Pain Preoperative $44.5 \pm 21.0$ 24 months $9.4 \pm 15.8$ (change $-35.1 \pm 23.7$ , p<0.001) Index Preoperative $42.8 \pm 19.8$ 24 months $7.4 \pm 13.2$ (change $-35.4 \pm 21.9$ , p<0.001) EQ-5D-5L Index (mean±SD) Preoperative $0.75 \pm 0.14$	Grade III (needing surgical intervention or unplanned hospital admission) rate 7.8% ( Osteotomy site displacement: bone-screw interface failure (fracture/screw cutout) 1.8% (n=6) Osteotomy site displacement: delayed union/malunion/non-union 1.2% (n=4) Symptomatic prominent screw(s) 2.4% (n=8) Prominent bone 1.2% (n=4) Deep infection needing surgical debridement and washout 1.2% (n=4) All cause screw removal rate 6.3% (n=21) Grade II (treatable and no surgical intervention needed) Additional intraoperative fixation (for example, Kirschner wire, additional screw) 1.8% (n=6)

First author, date	Efficacy outcomes	Safety outcomes
	24 months 0.90 ± 0.13 (change 0.17 ± 0.16, p<0.001)	Symptomatic osteotomy site displacement 0.3% (n=1)
		Symptomatic delayed union 1.5% (n=5)
	EQ-VAS (mean±SD)	Transfer metatarsalgia/sesamoid pain 0.9%
	Preoperative 83.5 ± 14.9	(n=3)
	24 months 84.2 ± 16.9 (change 0.8 ± 18.5, p=0.563)	Intraoperative conversion to open surgery 0.6% (n=2)
	VAS-pain (mean ± SD)	
	Preoperative $31.4 \pm 22.7$	Grade I (minor complications)
	24 months 8.4 ± 16.4 (change -22.9 ± 26.4, p<0.001)	Delayed wound healing 0.6% (n=2)
		Superficial cellulitis (treated with oral antibiotics) 4.5% (n=15)
	Radiographic outcomes (in 95.8% 222/230	Transient neurapraxia 0.9% (n=3)
	IMA (degrees mean+SD)	Flexor hallucis longus tendon injury 1.5% (n=5)
	Preoperative $15.3 \pm 3.6$	
	6 weeks 5.7 $\pm$ 3.2 (mean deformity correction 9.6 $\pm$ 3.8, p<0.001)	
	HVA (degrees, mean±SD)	
	Preoperative $32.9 \pm 10.2$	
	6 weeks 8.7 $\pm$ 5.2 (mean deformity correction 24.1 $\pm$ 9.7, p<0.001	
	Recurrence	
	Symptomatic recurrence of hallux valgus deformity 0.9% (n=3)	
Torrent J, 2021	Radiological outcomes	Complications

First author, date	Efficacy outcomes	Safety outcomes
	HVA, degrees; mean (range)	MI Group:
	• Preoperative: MIS scarf group=32.9 (21 to 48), open scarf group=33.3 (25 to 45); p=0.764	Screw removal because of irritation and screw prominence/dorsal protrusion 3.3% (1/30)
	• Final follow-up: MIS scarf group=12.7 (4 to 19), open scarf group=10.5 (3 to 19); p=0.08	Recurrences of HVA (no revision surgery) 7% (2/30)
	IMA, degrees; mean (range)	Open Group:
	<ul> <li>Preoperative: MIS scarf group=15.3 (13 to 19), open scarf group=14.7 (11 to 19); p=0.212</li> </ul>	Hypertrophic scar formation 7% (2/28) Radiation exposure, mean
	<ul> <li>Final follow-up: MIS scarf group=7.3 (3 to 12), open scarf group=7.5 (4.5 to 12); p=0.793</li> </ul>	MIS scarf 34 versus open scarf 2.4 mGy/cm <sup>2</sup> (p<0.001).
	DMAA, degrees; mean (range)	
	<ul> <li>Preoperative: MIS scarf group=10.7 (1 to 20), open scarf group=10.7 (2 to 21); p=0.991</li> </ul>	
	• Final follow up: MIS scarf group=2.8 (1 to 6), open scarf group=3 (1 to 8); p=0.803.	
	Clinical outcomes	
	Function (assessed by AOFAS), mean	
	<ul> <li>Preoperative: MIS scarf group=41 (IQR 10), open scarf group=39 (IQR 14)</li> </ul>	
	<ul> <li>Final follow-up: MIS scarf group=84 (IQR 16), open scarf group=82 (IQR 15)</li> </ul>	
	In both groups, there was a statistically significant improvement at follow up compared with preoperative scores (p<0.001). There were no statistically significant differences between groups.	
	Pain (assessed by VAS scores), mean (range)	

First author, date	Efficacy outcomes	Safety outcomes
	24 hours: MIS scarf group=2.3 (0 to 7), open scarf group=3.7 (0 to 8); p=0.03.	
	Mean operative time, minutes	
	<ul> <li>MIS=16.7 (range 12 to 25)</li> <li>Open=26.1 (range 21 to 34)</li> </ul>	
Vieira Cardoso 2022	Radiographic outcomes	Overall complications
	<ul> <li><u>HVA (mean, degrees)</u></li> <li>Preoperative: MIS group=34.4 ± 9.0, open group=37.4 ± 6.3, p=0.091</li> <li>Postoperative: MIS group=14.5 ± 8.0, open group=11.9 ± 6.2, p=0.084</li> <li><u>IMA (mean, degrees)</u></li> <li>Preoperative: MIS group=15.8 ± 4.6, open group=17.2 ± 4.9, p=0.141</li> <li>Postoperative: MIS group=6.4 ± 3.2, open group=4.8 ± 3.6, p=0.034.</li> </ul>	<ul> <li>5 in MIS group versus 12 in open group (p=0.42)</li> <li>Wound healing complications:</li> <li>0 in MIS group versus 4 in open group (p=0.051)</li> <li>Non-union (needed revision):</li> <li>0 in MIS group versus 4 in open group (p=0.051)</li> <li>Neurovascular complications</li> <li>3 in MIS group versus 1 in open group (p=0.617)</li> <li>Deformity recurrence (needed revision)</li> <li>2 in MIS group versus 3 in open group (p=617)</li> <li>Hardware-related pain</li> <li>8 in the MIS group versus 9 in the open group</li> </ul>
	<ul> <li><u>DMAA (mean, degrees)</u></li> <li>Preoperative: MIS group=20.4 ± 12.7, open group=24.0 ± 10.5, p=0.131</li> <li>Postoperative: MIS group =10.3 ± 7.7, open group=11.0 ± 5.3, p=0.187.</li> </ul>	<b>Surgery for hardware removal</b> 6 in the MIS group (at mean 33.5 months), 3 in the open group (at mean 85 months, p = 0.487).

IP 782/2 [IPGXXX]

## **Procedure technique**

All studies detailed their procedure technique with variations in surgical technique, implants placed and additional surgery. The most common approach used in 6 studies (Dragosloveanu 2022, Kaufmann 2019 and 2021, Guo 2021, Tay 2022, Lewis 2023a) was the third generation MIS percutaneous distal chevron osteotomy (also known as MICA/PECA techniques). It is an extraarticular metatarsal osteotomy that involves sliding manoeuvre of the first metatarsal head and internal fixation with at least 1 or 2 screws. Different screws were used in studies (such as headless cannulated screws with flat and square ends, and fully threaded MICA screws with a chamfered head design). MICA procedure with a new generation MICA screw was used in 1 of the studies (Tay 2022). Different fixation methods in different zones (such as dorsal-to-plantar) were used in studies. POO was used in 1 study to avoid excessive shortening of the first metatarsal and provide intrinsic stability (Guo 2021).

A fourth generation MIS surgery with a distal metaphyseal extra-articular transverse and akin osteotomy (META), combined with 3D reduction manoeuvre and fixed using 2 screws for early weightbearing and biomechanical stability was used in 1 study (Lewis 2023b).

MIS scarf osteotomy is another third generation extra-articular osteotomy used in 2 studies (Ferreira 2021, Torrent 2021), in which the osteotomy is fixed with 1 or 2 headless screws introduced through a dorsal percutaneous approach. The procedure was done under a midfoot nerve block and no tourniquet with the use of intraoperative fluoroscopy.

MIS Reverdin Isham osteotomy is another specific MIS hallux valgus correction technique used in 1 study as a comparator (Kaufmann 2021). This procedure involves an intra-articular medial based closing wedge osteotomy of the metatarsal head without addressing the IMA and without any internal fixation. IP overview: Minimal invasive percutaneous surgical techniques with internal fixation for correcting hallux valgus

Two main traditional techniques assessed as comparators in included studies were OC osteotomy and open SA osteotomy. In OC osteotomy, a V shaped osteotomy was done through a 4 to 5 cm incision. In open SA osteotomy a Z-shaped diaphyseal osteotomy of the first metatarsal was usually done and needs fixation with 2 screws.

Another technique, the Lapidus procedure either as a MIS or open procedure was reported in 1 study. This involves removing the cartilage from the first tarsometatarsal joint (TMT) and the medial cuneiform, correcting the deformity and fusing of the bones by hardware.

In most of the studies, some patients had additional adjunct procedures such as Akin or Weil osteotomy together with hallux valgus correction.

## Efficacy

#### Functional improvement

Five studies on MIS techniques (PECA or MICA) compared with open SA or OC osteotomy showed similar functional improvement at follow up, which ranged from 6 months to 5 years.

#### MICA or PECA compared with OC osteotomy

The RCT of 47 patients reported that the functional AOFAS score improved from baseline for both the MIS and OC osteotomy groups. The median score improved from 65 at baseline to 95 at 5 years in the MIS group, and from 66.5 to 95 in the OC osteotomy group. The difference between the groups was not statistically significant at any of the follow-up intervals (Kaufmann 2019, 2020).

The retrospective cohort study of 112 feet (99 patients) reported that the AOFAS HMI scores improved significantly in POO and OC osteotomy groups postoperatively (p<0.001). There was no statistically significant difference IP overview: Minimal invasive percutaneous surgical techniques with internal fixation for correcting hallux valgus

between the groups at 1 year (86.5  $\pm$  10.7 for POO and 88.2  $\pm$  10.8 for OC, p=0.40) and 2 years follow up (85.2  $\pm$  13.8 for POO and 79.5  $\pm$  23.7 for OC, p=0.66; Guo 2021).

The systematic review of 3 studies (n=235 feet) comparing PECA with open SA osteotomy reported that the mean difference in the AOFAS score between the groups was small (4.97 points 95% CI 3.55 to 6.39, p=0.14,  $I^2$ =48%) at 6 months follow up (Ferreira 2021).

The RCT of 50 patients reported improvements in the AOFAS score for both MIS and OC osteotomy groups. There were no statistically significant differences between the groups, either before surgery (MIS group  $65.7 \pm 3.8$  compared with OC group  $61.4 \pm 4.5$ ; p=0.134), or at 6 months follow up (MIS group  $85.6 \pm 4.1$  compared with OC group  $79.4 \pm 3.6$  p=0.125; Dragosloveanu 2022).

#### MIS scarf osteotomy compared with open scarf osteotomy

The RCT of 58 patients compared MIS scarf osteotomy (n=30) with open scarf osteotomy (n=28). It reported that in both groups the AOFAS scores showed a significant improvement at final follow up (mean 21 months) compared with preoperative scores (MIS scarf group from 41 to 84 and open scarf group from 39 to 82, p<0.001) without significant differences between groups (Torrent 2021).

#### Pain improvement

Six studies on MIS techniques (PECA or MICA) compared with open SA or OC osteotomy showed similar improvement in pain at follow up, which ranged from 6 months to more than 5 years.

#### MICA or PECA compared with OC osteotomy

The RCT of 47 patients reported that VAS pain score improved from baseline for both the MIS and OC osteotomy groups but was not significantly different

between the groups at any of the follow-up intervals (6 weeks [p=0.95], 12 weeks IP overview: Minimal invasive percutaneous surgical techniques with internal fixation for correcting hallux valgus

[p=0.14], 9 months [0.74]), and 5 years (p=0.32) follow up (Kaufmann 2019 and 2020).

In the retrospective observational study of 92 patients (126 feet) who had treatment with PECA, an analysis of data in 53 patients (78 feet) reported a mean postoperative VAS pain score (ranging from 0 to 10, where 0 is the best possible score) of 6.3 SD 14.9 at more than 60-month follow up (Lewis 2023a).

In the prospective case series of 233 patients (333 feet), the quality-of-life PROMs analysed in 200 patients (n=292 feet) reported that the VAS pain score improved from 31.4 SD 22.7 preoperatively to 8.4 SD 16.4 at 24 months follow up (p<0.001; Lewis 2021).

The propensity matched cohort study of 60 patients compared MICA with open SA osteotomy. It reported that the first 24-hour postoperative VAS score was significantly lower in the MICA group compared with the open SA group (2.0 SD 2.0 compared with 3.4 SD 2.6, p=0.029). But there was no significant difference in clinical or radiological outcomes between the groups at 6 months (p=0.990) and 24 months (p=0.290; Tay 2022).

The retrospective cohort study of 112 feet (99 patients) reported that the VAS scores in the POO group during the follow-up period were 2.00 SD 0.98 at 2 weeks, 2.00 SD 0.99 at 1 year and 1.55 SD 1.11 at 2 years. In the OC group the VAS scores were 5.51 SD 1.45 at 2 weeks, 2.56 SD 2.88 at 1 year and 2.56 SD 2.88 at 2 years. The VAS scores between POO and open groups showed no statistically significant difference at 1-year (p=0.53) and 2-year (0.37) follow up. But the POO group showed statistically significantly lower VAS scores 2 weeks after surgery (p<0.001; Guo 2021).

The RCT of 50 patients found significant improvements in the VAS scores for MIS and OC osteotomy groups. The VAS showed significantly better

IP overview: Minimal invasive percutaneous surgical techniques with internal fixation for correcting hallux valgus

postoperative results for the MIS group at discharge (2.5 SD 0.8 compared with 4.5 SD 1.4, p<0.001), 3 weeks (1.4 SD 0.5 compared with 2.8 SD 0.9, p<0.001), 6 weeks (0.4 SD 1 compared with 2.0 SD 0.8, p<0.001), and 6 months (0.2 SD 0.8 compared with 0.8 SD 0.6, p=0.004). At 12 months, the pain level was comparable between both groups (0.2 SD 0.6 compared with 0.4 SD 0.7, p=0.285; Dragosloveanu 2022).

The systematic review of 3 studies (n=235 feet) compared PECA with open SA osteotomy. It reported that the mean difference in the VAS pain scale (ranging from 1 to 10) between the groups was -1.68 points (95% CI -2.09 to -1.27, p<0.01,  $I^2$ =87%; 2 studies) 1 day after surgery. The mean difference at last clinical visit decreased between the groups (SMD-0.14 points, 95% CI -0.49 to 0.20, p=0.81,  $I^2$ =0%; 3 studies; Ferreira 2021).

#### MIS scarf osteotomy compared with open scarf osteotomy

The RCT of 58 patients comparing MIS scarf osteotomy (n=30) with open scarf osteotomy (n=28) reported that the mean postoperative VAS for pain at 24 hours was significantly lower in the MIS scarf group compared with the open scarf group (2.3 compared with 3.6, p=0.03; Torrent 2021).

#### Range of motion

The RCT of 47 patients reported no significant differences in range of motion of the first metatarsophalangeal joint (categorised into 3 classes: less than 30 degrees, 30 to 70 degrees, and more than 75 degrees) between the MIS and OC osteotomy groups at all follow-up periods (6 weeks, p=0.075; 12 weeks, p=0.653; 9 months, p=0.910; and 5 years, p=0.496; Kaufmann 2019 and 2020).

#### Quality of life

Two studies on MIS techniques (MICA or POO) compared with open SA or OC osteotomy showed similar improvement in quality of life at follow up.

IP overview: Minimal invasive percutaneous surgical techniques with internal fixation for correcting hallux valgus

IP 782/2 [IPGXXX]

A retrospective cohort study of 112 feet (99 patients) compared POO and OC osteotomy. It reported that the clinical foot-specific postoperative MOXFQ scores in all domains (walking or standing, social interaction and pain) significantly improved in both groups. But there was no significant difference in the improvement of any domain between POO and open groups at 2-year follow up (Guo 2021).

The propensity matched cohort study of 60 patients compared MICA and open SA osteotomy. It reported improvement in both the mean SF-36 PCS scores (from 40.9 SD 9.3 to 50.6 SD 9.1, p<0.001) and the mean SF-36 MCS scores (from 56.8 SD 10.6 to 56.0  $\pm$  10.7, p<0.001) at 24 months follow up in the MICA group. The scores also improved for the scarf osteotomy group (mean SF-36 PCS from 43.9 SD 9.7 to 51.9 SD 7.1, p<0.001; and mean SF-36 MCS from 54.8 SD 10.3 to 55.2 SD 11.1, p<0.001). But the scores were not significantly different between the groups (PCS p=0.538, MCS p=0.756; Tay 2022).

In the retrospective observational study of 92 patients (126 feet) who had treatment with PECA, an analysis of data in 53 patients (78 feet) reported that the clinical foot-specific mean MOXFQ index score (where 0 is the best possible score) at more than 60-month follow-up was 10.1. The mean general health-related quality of life PROM (assessed using EuroQoL-5D-5L: EQ-VAS, where 100 is the best possible score) at more than 60 month follow-up was 92.0 (Lewis 2023).

In the prospective case series of 233 patients (333 feet), the quality-of-life PROMs was analysed in 200 patients (n=292 feet). It reported significant improvement in MOFXQ scores in each domain (reduced from 44.5 SD 21.0 preoperatively to 9.4 SD 15.8 at 24 months for pain (p<0.001), from 38.7 SD 23.4 to 6.5 SD 14.6 for walking and standing (p<0.001), and from 48.0 SD 22.3 to 6.6 SD 13.5 for social interaction (p<0.001); EQ-5D-5L score improved from

IP overview: Minimal invasive percutaneous surgical techniques with internal fixation for correcting hallux valgus

preoperative mean 0.75 SD 0.14 to 0.90 SD 0.13 at 24 months (p<0.001) with the exception of the EQ-VAS (from preoperative score mean 83.5 SD 14.9 to 84.2 SD 16.9 at 24 months, p=0.563; Lewis 2021).

In the prospective case series of 50 patients who had fourth generation MIS with metaphyseal extraarticular transverse and akin osteotomy (META) there was a significant improvement in all MOXFQ domain scores, with the index domain improving from 53.4 to 13.1 (p<0.001). There was also a statistically significant improvement in general health-related quality of life EQ-5D-5L index and EQ-VAS scores (p<0.001; Lewis 2023).

#### Patient satisfaction

Two studies on MIS techniques (MICA or POO) compared with open SA or OC osteotomy showed similar patient satisfaction rates at follow up.

In the RCT of 47 patients, patient satisfaction (measured using a scale ranging from very satisfied to not satisfied) was comparable in both MIS and OC osteotomy groups at 9 months follow up (very satisfied: 62.5% compared with 70%, p=0.736). At 5 years, 89% of the patients in the MIS and 70% in the OC osteotomy group were very satisfied. Two patients in OC osteotomy group, reported poor satisfaction. One of these patients had developed partial osteonecrosis of the lateral metatarsal head, and 1 had a recurrence of hallux valgus (Kaufmann 2019 and 2020).

The propensity matched cohort study of 60 patients comparing MICA and open SA osteotomy reported that satisfaction rates were similar at 6 months (MICA group 87% [26/30]) compared with the open SA group 73% [22/30], p=0.197) and 24 months follow up (MICA group 80% [24/30] compared with the open SA group 87% [26/30], p=0.488; Tay 2022).

IP overview: Minimal invasive percutaneous surgical techniques with internal fixation for correcting hallux valgus

In the retrospective observational study of 92 patients (126 feet) who had treatment with PECA, an analysis of data in 53 patients (78 feet) reported that at more than 60 months follow up, 77% patients were highly satisfied and 23% patients were satisfied with the procedure (Lewis 2023).

#### Recurrence

In the RCT of 37 patients comparing MIS chevron osteotomy with OC osteotomy, 8% (2/25) of patients in the MIS group (25) and 9% (2/22) of patients in the OC group had recurrence of hallux valgus with an HVA of less than 25 degrees. One patient in the OC group had recurrence of hallux valgus with an HVA of more than 30 degrees (Kaufmann 2019 and 2021).

The prospective case series of 230 patients (333 feet) reported symptomatic recurrent HV after the procedure in 3 feet (0.9%). Two of these were because of under-correction by the chevron osteotomy and failure of the akin osteotomy screw because of cutout. The third was because of soft tissue stretching over a prolonged time (Lewis 2021).

In the retrospective observational study of 92 patients (126 feet) who had treatment with PECA, an analysis of data in 53 patients (78 feet) reported a radiographic recurrence rate (defined as HVA more than 15 degrees) of 8% (6/78 feet) at more than 60 months follow up. Of these, only 1 foot had an HVA more than 20 degrees and 3 of the 6 feet had a severe preoperative deformity (HVA more than 40 degrees; Lewis 2023).

Recurrences of HVA (no revision surgery) was reported in 7% (2/30) of patients in the MIS scarf osteotomy group in the RCT of 58 patients (Torrent 2021).

In the retrospective cohort study of 91 patients who had TMT Lapidus procedure, deformity recurrence (needing revision) was reported in 2 patients in the MIS group and 3 patients in the open group (p=0.617; Vieira Cardoso 2022). IP overview: Minimal invasive percutaneous surgical techniques with internal fixation for correcting hallux valgus

#### Hallux joint angle correction

There are normal for X-ray measurements: HVA less than 15 degrees; IMA less than 9 degrees; and DMAA less than 10 degrees.

Nine studies on MIS techniques (MICA/PECA/META) reported statistically significant improvement in HVA, IMA and DMAA from preoperative values at follow up. Six of these studies compared MIS techniques (PECA or MICA) with open SA or OC osteotomy and showed similar radiographic correction.

#### MICA or PECA compared with OC osteotomy

A systematic review of 3 studies (n=235 feet) compared PECA osteotomy (n=102) with open SA osteotomy (n=133). It reported that the final mean difference in the HVA was 0.80 degrees (95% CI -1.07 to -0.52, p=0.03,  $I^2$ =70%) and the mean difference in the IMA was 0.53 (95% CI -0.93 to -0.13, p<0.01,  $I^2$ =93%), at the last radiographic evaluation (Ferreira 2021).

A RCT of 50 patients comparing percutaneous MIS chevron osteotomy (n=26) with OC osteotomy (n=26) reported improvements in both groups regarding the IMA and HVA at 12 months follow up. But, it did not find any statistically significant differences between the groups (IMA: 7.2 SD 1.8 compared with 6.4 SD 1.5; p=0.093; HVA: 8.8 SD 3.1 compared with 8.9 SD 2.3; p= 0.896; Dragosloveanu 2022).

A RCT of 47 patients comparing MIS chevron osteotomy (n=25) with OC osteotomy (n=22) reported statistically significant correction of the hallux deformity using both techniques. The IMA improved from 14 to 6.8 degrees in the MIS group and from 15.1 to 5.8 degrees in the OC group. The HVA improved from 26.4 to 6.9 degrees in the MIS group and from 28.3 to 8.5 degrees in the OC group. No statistically significant differences were seen between the groups

IP overview: Minimal invasive percutaneous surgical techniques with internal fixation for correcting hallux valgus

at all follow-up periods (6 weeks, 12 weeks, 9 months and at 5 years; Kaufmann 2019 and 2020).

A propensity matched cohort study of 60 patients comparing MIS chevron akin osteotomy (MICA) with open SA osteotomy reported that HVA improved from 23.5 to 7.7 degrees postoperatively, and IMA improved from 13.5 to 7.5 degrees postoperatively for the MICA group. For the open SA osteotomy group, HVA improved from 23.7 to 9.3 degrees postoperatively, and IMA improved from 13.6 to 7.8 degrees postoperatively. There was no statistically significant difference between the groups (Tay 2022).

A retrospective cohort study of 112 feet (99 patients) compared percutaneous oblique osteotomy (POO) and OC osteotomy. It reported that the HVA in the POO group reduced from 35.9 SD 10.0 degrees preoperatively to 12.5 SD 2.22 degrees at 1 year (p<0.05) and to 17.9 SD 9.31 degrees at 2 years follow up (p<0.05). In the OC group, HVA decreased from 34.3 SD 8.85 degrees preoperatively to 14.1 SD 6.78 degrees at 1 year (p<0.05) and 14.8 SD 7.83 degrees at 2 years follow up (p<0.05). Similar results were reported for IMA at follow-up periods (p<0.05). When comparing both groups, HVA (at 1 year, p=0.12 and 2 years, p=0.06) and IMA (at 1 year, p=0.14 and 2 years, p=0.95) showed similar results (Guo 2021).

In a retrospective observational study of 92 patients (126 feet) who had treatment with PECA, an analysis of data in 53 patients (78 feet) reported a change in HVA from mean 28.2 degrees preoperatively to 7.8 degrees at more than 60 months follow up (mean change -20.3 SD 7.0; p<0.001) and change in the IMA from mean 12.8 degrees preoperatively to 6.0 degrees at more than 60 months follow up (mean change -6.8 SD 3.0, p<0.001; Lewis 2023).

In a prospective case series of 233 patients (333 feet), radiographic outcomes analysed in 200 patients (n=319 feet) reported significant reduction in the IMA IP overview: Minimal invasive percutaneous surgical techniques with internal fixation for correcting hallux valgus

(from mean preoperative 15.3 SD 3.6 to 5.7 SD 3.2 degrees at 6 weeks, p<0.001) and HVA (from mean preoperative 32.9 SD 10.2 to 8.7 SD 5.2 at 6 weeks, p<0.001; Lewis 2021).

In a prospective case series of 50 patients who had fourth generation MIS with metaphyseal extraarticular transverse and akin osteotomy (META) there was a significant improvement in HVA (32.7 to 7.9 degrees, p<0.001), IMA (14.0 to 4.2 degrees, p<0.001) and DMAA (18.5 to 5.6 degrees, p<0.001) at mean follow up of 1.53 SD 0.51 years (Lewis 2023).

#### MIS scarf osteotomy compared with open scarf osteotomy

A RCT of 58 patients comparing MIS scarf osteotomy (n=30) with open scarf osteotomy (n=28) reported that radiologic measurements were similar in both groups at final follow-up (mean 21 months: HVA p=0.08, IMA p=0.79, and DMAA p=0.80) but showed significant improvement from preoperative measures (Torrent 2021).

# MIS distal chevron osteotomy compared with MIS Reverdin-Isham osteotomy

A systematic review and meta-analysis comparing MIS distal chevron osteotomy with MIS Reverdin-Isham osteotomy reported that radiographic outcomes were significantly better in the MIS chevron osteotomy group (IMA p<0.05, HVA and DMAA p<0.05; Kaufmann 2021).

#### MIS Lapidus procedure compared with open Lapidus procedure

A retrospective cohort study of 91 patients comparing first tarsometatarsal (TMT) fusion (Lapidus procedure) using MIS (n=47) and open (n=44) techniques reported that radiographic outcomes (IMA, HVA, DMAA) significantly improved from preoperative measures at postoperative follow up (mean 29 months for MIS and 82 months for open group). When compared between both the groups, the

IP overview: Minimal invasive percutaneous surgical techniques with internal fixation for correcting hallux valgus

IMA was significantly lower in the open group (4.8 SD 3.6 degrees compared with 6.4 SD 3.2 degrees, p<0.05; Vieira Cardoso 2022).

## Safety

#### Complications

The systematic review of 3 studies (n=235 feet) comparing PECA with open SA osteotomy reported a higher rate of complications in the PECA group (RR 1.51, 95% CI 0.80 to 2.86, p=0.36, l<sup>2</sup>=3%). Complications with the screws were reported in the PECA group, some of which were removed (actual number not reported). Complications in the open SA group included metatarsalgia and wound complications (Ferreira 2021).

The propensity matched cohort study of 60 patients comparing MICA and open SA osteotomy reported that there were no complications in either group. All cases achieved complete fusion of the osteotomy at the last radiological evaluation (Tay 2022).

The retrospective case study of 112 feet (99 patients) reported there was no statistical significance between the POO and OC osteotomy group in terms of complications rates (8.3% [4/48] compared with 12.5% [8/64], p=0.48; Guo 2021).

The prospective case series of 230 patients (n=333 feet) reported an overall complication rate of 21% at 24 months follow up. Grade 3 complications needing intervention or hospital admission were reported in 7.8% (n=26) of patients. These include hardware problems (prominent screws in 8, bone screw interface failure [fracture/screw cutout] in 6), delayed union or malunion, or no union, in 4, prominent bone in 4, deep infection in 4 cases. Grade 2 complications needing no additional intervention or hospital admission were reported in 6% (n=20) of patients. These include additional intraoperative fixation in 6, intraoperative IP overview: Minimal invasive percutaneous surgical techniques with internal fixation for correcting hallux valgus

conversion to open surgery in 2, symptomatic osteotomy site displacement in 1, symptomatic delayed union in 1, transfer metatarsalgia in 3, and recurrence in 3 cases (Lewis 2021).

The RCT of 58 patients comparing MIS scarf osteotomy with open scarf osteotomy reported that there were no major complications in either group (Torrent 2021).

The retrospective study of 91 patients who had first TMT fusion (Lapidus procedure) using MIS or open techniques reported that overall complications were higher in the open group compared with the MIS group, but this was not significantly different (5 in MIS group compared with 12 in the open group, p=0.42; Vieira Cardoso 2022).

#### Metatarsalgia

Metatarsalgia after 6 months was reported in 1 patient in the OC osteotomy group (n=26) in the RCT of 50 patients. Shortening of the first metatarsal during the osteotomy could be the reason for this complication (Dragosloveanu 2022). Two cases of second metatarsalgia were also reported in the OC osteotomy group (n=64 feet) in the retrospective cohort study of 99 patients (with 112 feet; Guo 2021).

#### Reoperations and hardware removal

Soft tissue irritation and pain caused by screw prominence (needing hardware removal after 3 months) was reported in 13% (3/24) of patients in the MIS osteotomy group compared with 1 patient in the OC osteotomy group (n=26) in the RCT of 50 patients. Authors state that the reason for tissue irritation could be the oblique insertion and slight protrusion of the screw head (Dragosloveanu 2022).

IP overview: Minimal invasive percutaneous surgical techniques with internal fixation for correcting hallux valgus

IP 782/2 [IPGXXX]

In the RCT of 47 patients, substantial soft-tissue irritation caused by the Kirschner wire needing removal was reported in 64% (16/25) of patients in the MIS group, whereas screw removal was needed in 18% (4/22) of patients in the OC osteotomy group. In response to these results, authors recommended using a cannulated oblique-headed compression screw for fixation during MIS chevron osteotomy (Kaufmann 2019 and 2020). Screw removal because of irritation after 3 months was reported in 1 patient in the POO group (n=41 patients, 48 feet) in the retrospective cohort study of 99 patients (Guo 2021).

Screw removal because of irritation and screw prominence or dorsal protrusion was reported in 1 patient in the MIS scarf osteotomy group (n=30) in the RCT of 58 patients (Torrent 2021).

Reoperations for removal of prominent screws were reported in 4% (5/126) of patients at more than 60 months follow up in the retrospective observational study of 92 patients (126 feet) who had treatment with PECA (Lewis 2023a). The all-cause screw-removal rate needing revision was 6.3% (n=21 feet) in the case series of 230 patients (n=333 feet) at 2 years follow up (Lewis 2021).

One patient in the POO group (n=41) had a revision surgery at day 6 because of screw displacement after initial weight-bearing on the first day after surgery in the retrospective cohort study of 99 patients (Guo 2021).

Surgery for hardware removal was reported in 6 patients in the MIS group (at mean 33.5 months) and 3 patients in the open group (at mean 85 months, p=0.487) in the retrospective study of 91 patients who had the TMT Lapidus procedure (Vieira Cardoso 2022).

#### Wound complications and non-union

Wound healing and non-union rates were higher in the open group compared with the MIS group in the retrospective study of 91 patients who had the TMT IP overview: Minimal invasive percutaneous surgical techniques with internal fixation for correcting hallux valgus

Lapidus procedure (wound healing: 0 in the MIS group compared with 4 in the open group, p=0.051; non-union (needing revision): 0 in MIS group compared with 4 in the open group, p=0.051; Vieira Cardoso 2022).

#### **Exposure to radiation**

The systematic review of 3 studies (n=235 feet) compared the percutaneous chevron akin (PECA) with open SA osteotomy. It reported that exposure to radiation during the surgical procedure was higher in the PECA group, with a mean of 35.53 seconds (95% CI 31.75 to 35.31, p<0.01,  $I^2$ =87%; Ferreira 2021).

The RCT of 50 patients reported that the average radiological screen time was significantly longer for the MIS group (15.5 SD 5.6 seconds) compared with the OC osteotomy group (1.8 SD 3.8 seconds; p<0.001; Dragosloveanu 2022).

The RCT of 58 patients comparing MIS scarf osteotomy with open scarf osteotomy reported that radiation exposure was 14 times higher in the MIS scarf group compared with the open scarf group (mean 34 mGy/cm<sup>2</sup> compared with 2.4 mGy/cm<sup>2</sup>, p<0.001; Torrent 2021).

#### Other events

Other events such as paraesthesia of the medial of first metatarsal (n=1), stiffness of the first MTP joint (n=1), flexor hallucis longus (FHL) tendon injury (n=5), superficial cellulitis (n=15), delayed wound healing (n=2) and transient neurapraxia (n=3) were reported in the MIS groups in the included studies. Neurovascular complications and hardware-related pain were reported in both the MIS and open technique groups in the retrospective study of 91 patients who had first TMT Lapidus procedure (Vieira Cardoso 2022). One of the patients in the OC osteotomy group had developed partial osteonecrosis of the lateral metatarsal head (Kaufmann 2019 and 2021).

IP overview: Minimal invasive percutaneous surgical techniques with internal fixation for correcting hallux valgus

#### Anecdotal and theoretical adverse events

Expert advice was sought from consultants who have been nominated or ratified by their professional society or royal college. They were asked if they knew of any other adverse events for this procedure that they had heard about (anecdotal), which were not reported in the literature. They were also asked if they thought there were other adverse events that might possibly occur, even if they had never happened (theoretical).

They listed the following anecdotal adverse events:

• patient dissatisfaction because of recurrent deformity.

They listed the following theoretical adverse events:

- avascular necrosis of the metatarsal head
- non-union due to the large corrections
- tendon damage
- complex regional pain syndrome.

Five professional expert questionnaires for this procedure were submitted. Find full details of what the professional experts said about the procedure in the <u>specialist advice questionnaires for this procedure</u>.

## Validity and generalisability

 Studies on percutaneous techniques with internal fixation only have been considered in this overview of evidence. Variation in osteotomy techniques, hardware/cutting tools, insertion aids, fixing devices (screws, wires, sutures) were reported as they have been changed with time. Studies compared different MIS procedures to different conventional open surgical procedures. Few small RCTs performed compared different surgical procedures.

• Follow-up in studies ranged from 1 to 5 years. IP overview: Minimal invasive percutaneous surgical techniques with internal fixation for correcting hallux valgus

- In all studies correction was indicated after failure of conservative treatment with progressive deformity.
- Studies included patients with mild (HVA 15 to less than 20 degrees, IMA 9 to 14 degrees), moderate (HVA 20 to less than 40 degrees, IMA 14 to less than 20 degrees) and severe (HVA 40 degrees or more or IMA 20 degrees or more) hallux valgus deformity. Small case series for correction of severe hallux valgus deformity also demonstrated deformity correction and significant improvements in clinical outcomes 3 years following surgery (these studies are included in table 5).
- There is a learning curve with percutaneous hallux valgus surgery. There is some published evidence suggesting that adequate training and experience is required (these studies are in table 5).
- Procedures were done only by consultant trauma and orthopaedic surgeons sub-specialising in foot and ankle surgery.
- Patients who have this procedure should be entered into the national BOFAS Registry via the Adult Foot and Ankle pathway. This dataset collects PROMS on both open and MIS techniques for hallux valgus correction. One specialist adviser stated that 18% (137/766) of procedures logged onto the database were minimally invasive metatarsal osteotomies.

# **Related NICE guidance**

## Interventional procedures

- NICE's interventional procedures guidance on <u>Synthetic cartilage implant</u> insertion for first metatarsophalangeal joint osteoarthritis (hallux rigidus) IPG 727 (2022) (Recommendation: special arrangements)
- NICE's interventional procedures guidance on <u>Metatarsophalangeal joint</u> <u>replacement of the hallux</u> IPG 140 (Nov 2005) (Recommendation: normal arrangements)

IP overview: Minimal invasive percutaneous surgical techniques with internal fixation for correcting hallux valgus

# **Professional societies**

- British Orthopaedic Association (BOA)
- British Orthopaedic Foot & Ankle Society (BOFAS)
- The Royal College of Podiatry
- British Society of Rheumatology
- The Society of Chiropodists & Podiatrists
- The British Chiropody and Podiatry Association
- Association of Foot and Ankle Physiotherapists & AHPs.

# **Company engagement**

NICE asked companies who manufacture a device potentially relevant to this procedure for information on it. NICE received 1 completed submission. This was considered by the IP team and any relevant points have been taken into consideration when preparing this overview.

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IP overview: Minimal invasive percutaneous surgical techniques with internal fixation for correcting hallux valgus

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# Methods

NICE identified studies and reviews relevant to minimally invasive percutaneous surgical techniques with internal fixation for correcting hallux valgus from the medical literature. The following databases were searched between the date they started to 30.06.2023: MEDLINE, EMBASE, Cochrane Library and other databases. Trial registries and the internet were also searched (see the <u>literature search strategy</u>). Relevant published studies identified during consultation or

resolution that are published after this date may also be considered for inclusion. IP overview: Minimal invasive percutaneous surgical techniques with internal fixation for correcting hallux valgus

The following inclusion criteria were applied to the abstracts identified by the literature search.

- Publication type: clinical studies were included with emphasis on identifying good quality studies. Abstracts were excluded if they did not report clinical outcomes. Reviews, editorials, and laboratory or animal studies, were also excluded and so were conference abstracts, because of the difficulty of appraising study methodology, unless they reported specific adverse events that not available in the published literature.
- Patients with hallux valgus.
- Intervention or test: minimally invasive percutaneous surgical techniques with internal fixation.
- Outcome: articles were retrieved if the abstract contained information relevant to the safety, efficacy, or both.

If selection criteria could not be determined from the abstracts the full paper was retrieved.

Potentially relevant studies not included in the main evidence summary are listed in the section on other relevant studies.

Find out more about how NICE selects the evidence for the committee.

#### Table 4 literature search strategy

Databases	Date searched	Version/files
MEDLINE (Ovid)	30/06/2023	1946 to June 29, 2023
MEDLINE In-Process (Ovid)	30/06/2023	1946 to June 29, 2023
MEDLINE Epubs ahead of print (Ovid)	30/06/2023	June 29, 2023
EMBASE (Ovid)	30/06/2023	1974 to 2023 June 29
EMBASE Conference (Ovid)	30/06/2023	1974 to 2023 June 29
Cochrane Database of Systematic	30/06/2023	Issue 6 of 12, June 2023
Reviews – CDSR (Cochrane Library)		

IP overview: Minimal invasive percutaneous surgical techniques with internal fixation for correcting hallux valgus

Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane Library)	30/06/2023	Issue 6 of 12, June 2023
International HTA database (INAHTA)	30/06/2023	-

Trial sources searched

- Clinicaltrials.gov
- ISRCTN
- WHO International Clinical Trials Registry

Websites searched

- National Institute for Health and Care Excellence (NICE)
- NHS England
- 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 translated for use in the other sources.

Ovid MEDLINE(R) <1946 to June 29, 2023>

- 1 Hallux Valgus/ 3918
- 2 (Hallux\* adj4 (valgus\* or abduct\*)).tw. 3505
- 3 (Metatars\* adj4 primus\* adj4 varus\*).tw. 159
- 4 Bunion/ 180
- 5 Bunion\*.tw. 832
- 6 (Toe\* adj4 (deformit\* or malform\*)).tw. 802
- 7 or/1-6 5308
- 8 Osteotomy/ 33240
- 9 Osteotom<sup>\*</sup>.tw. 34209
- 10 8 or 9 45382
- 11 Percutaneous\*.tw. 148195
- 12 10 and 11 593
- 13 Surgical Procedures, Minimally Invasive/ 29683
- 14 (Minimal\* adj4 invasive\* adj4 (surg\* or tech\* or procedur\* or incision\* or correct\* or treat\* or therap\* or method\*)).tw. 49147

IP overview: Minimal invasive percutaneous surgical techniques with internal fixation for correcting hallux valgus

15 (Bosch adj4 (surg\* or tech\* or procedur\* or incision\* or correct\* or treat\* or therap\* or method\*)).tw. 28

16 (Minimally adj4 invasive adj4 Chevron adj4 Akin).tw. 27

17 (MICA adj4 (surg\* or tech\* or procedur\* or incision\* or correct\* or treat\* or therap\* or method\*)).tw. 235

18 (Percutaneous adj4 Chevron adj4 Akin adj4 Osteotom\*).tw.

19 (PECA adj4 (surg\* or tech\* or procedur\* or incision\* or correct\* or treat\* or therap\* or method\*)).tw. 27

20 (Metaphyseal adj4 Extra adj4 Articular adj4 Transverse adj4 Akin adj4 Osteotom\*).tw. 1

21 (MÉTA adj2 (surg\* or tech\* or procedur\* or incision\* or correct\* or treat\* or therap\* or method\*)).tw. 10810

22 (distal adj4 (metatarsal or chevron) adj4 osteotom\*).tw. 422

23 (Minimal adj4 invasive adj4 scarf adj4 osteotom\*).tw. 0

24 Arthroscopy/ 28167

25 Arthroscop<sup>\*</sup>.tw. 30771

26 fracture fixation, internal/ 41317

27 "internal fixation".tw. 18321

28 (Osteosynthes\* or Osteo synthes\*).tw. 11999

29 (SERI adj4 (surg\* or tech\* or procedur\* or incision\* or correct\* or treat\* or therap\* or method\*)).tw. 26

30 or/12-29 161683

31 7 and 30 769

32 (PROstep or (MICA adj4 implant\*)).tw. 9

33 31 or 32 778

34 Animals/ not Humans/ 5100269

35 33 not 34 777

36 limit 35 to ed=20130101-20230630 424

IP overview: Minimal invasive percutaneous surgical techniques with internal fixation for correcting hallux valgus

# Other relevant studies

Other potentially relevant studies to the IP overview that were not included in the main evidence summary (tables 2 and 3) are listed in table 5.

Article	Number of patients and follow up	Direction of conclusions	Reason study was not included in main evidence summary
Alimy AR, Polzer H, Ocokoljic A et al. (2023) Does Minimally Invasive Surgery Provide Better Clinical or Radiographic Outcomes Than Open Surgery in the Treatment of Hallux Valgus Deformity? A Systematic Review and Meta-analysis. Clinical orthopaedics and related research. 481, 6, 1143-1155.	Systematic Review and Meta-analysis 7 studies (395 feet), consisting of 6 RCTs and 1prospective comparative study, were included. MIS versus open surgery.	This meta-analysis found that hallux valgus treated with minimally invasive surgery did not result in improved clinical or radiologic outcomes compared with open surgery. Methodologic shortcomings of the studies in this meta-analysis likely inflated the apparent benefits of minimally invasive surgery, such that in reality it may be inferior to the traditional approach.	Includes a variety of techniques, such as the Bosch and SERI osteotomy, mini-SCARF and MICA osteotomy.
Bia A, Guerra-Pinto F, Pereira BS et al. (2018) Percutaneous osteotomies in hallux valgus: a systematic review. J Foot Ankle Surg; 57:123–130.	Systematic review n=18 studies (1534 procedures for percutaneous HV surgery on 1397 patients). 14 were level IV, 2 were level III, and 2 were level II.	Overall, the average angle correction of the HV deformity improved postoperatively. Regarding the complications, although some investigators revealed no major complications, others described deformity recurrence in 7.8%, stiffness of the first metatarsophalangeal joint in 9.8%, malunion in 4% to 8.7%, and infection rates ranging from 1.9% to 14.3%.	Different types of MIS - mainly those with temporary or no fixations were included in the analyses.

IP overview: Minimal invasive percutaneous surgical techniques with internal fixation for correcting hallux valgus

Boksh K, Qasim S, Khan K, Tomlinson C, Mangwani J. (2018) A Comparative Study of Mini-Scarf Versus Standard Scarf Osteotomy for Hallux Valgus Correction. J Foot Ankle Surg. 57(5):948-951.	N=37 Prospective non- randomised study 16 mini-scarf versus traditional 21 scarf osteotomy 12 weeks post-operative follow-up.	The medial sesamoid position had improved in all patients, with similar satisfaction between the 2 procedures (p = .43). The results of the present study have shown that the mini- scarf osteotomy for mild to moderate hallux valgus is as effective as the standard approach, with the potential benefit of a smaller scar and less soft tissue disruption.	Higher level evidence included in table 2.
Brogan K, Lindisfarne E, Akehurst H, et al. (2016) Minimally invasive and open distal chevron osteotomy for mild to moderate hallux valgus. Foot Ankle Int; 37:1197–1204.	Retrospective cohort study N=81 feet 49 minimally invasive versus and 32 open distal chevron osteotomies. Follow-up 24 months	Clinical and radiologic postoperative scores in all domains were substantially improved in both groups but there was no statistically significant difference in improvement of any domain between open and MIS groups. There were no significant differences in complications between the two groups.	Larger and higher quality studies included in table 2.
Brogan K, Voller T, Gee C et al. (2014) Third-generation minimally invasive correction of hallux valgus: technique and early outcomes. International Orthopaedics (SICOT) 38:2115–2121.	Case series N=45 feet underwent a third- generation MIS distal chevron osteotomy 6 month follow-up	There were significant improvements in all three domains of the MOXFQ (p<0.001) There was also significant improvement in all radiographic parameters (p<0.001). Mean HVA decreased from 30.54° to 10.41°, and the mean IMA decreased from 14.55° to 7.11°. Shortening of the first metatarsal had no effect on clinical outcomes. There was a very low rate of complications.	Higher quality studies included in table 2.
Caravelli S, Mosca M, Massimi S et al. (2018) Percutaneous treatment of hallux valgus: What's	Systematic review 4 papers, a total of 464 hallux valgus	There are different aspects that the foot and ankle non- experienced surgeon must consider about percutaneous surgery:	Different types of MIS - mainly those with temporary

the evidence? A systematic review. Musculoskelet Surg 102:111–117	has been treated with a properly percutaneous distal first metatarsal osteotomy.	limitation of the tools, radio- exposure, lack of direct visual control of the osteotomy and higher costs and patient risk due to surgical time.	fixations were included in the analyses.
Castellini JLA, Grande Ratti MF, Gonzalez DL. (2022) Clinical and Radiographic Outcomes of Percutaneous Third- Generation Double First Metatarsal Osteotomy Combined With Closing-Wedge Proximal Phalangeal Osteotomy for Moderate and Severe Hallux Valgus. Foot & Ankle International 43(11) 1438–1449	Retrospective case series N= 156 percutaneous double first metatarsal osteotomy (PEDO) and first phalanx osteotomy in 128 patients. median follow-up was 22.6 months.	Clinical and radiographic parameters improved significantly, with a minimum of 12 months of follow-up in moderate and severe hallux valgus. The satisfaction rate was 97% in the total sample. Recurrence rate (HVA ≥20 degrees) was 7.7%. Hallux varus (HVA<0 degrees) occurred in 5.8%, acute osteomyelitis in 1.3%, partial avascular necrosis in 0.6%, screw removal in 0.6%, and reoperation in 1.9%. No non-union was observed.	Higher level evidence included in table 2.
Frigg A, Zaugg S, Maquieira G, Pellegrino A. (2019) Stiffness and range of motion after minimally invasive chevron-akin and open scarf-akin procedures. Foot Ankle Int. 40(5):515– 25.	Prospective cohort (non- randomised, comparative) study N=48 PECA versus 50 open Scarf Akin technique. Follow-up 2 years.	MICA showed no advantages over scarf other than a shorter scar. The observed gain in extension could be related to the increased shortening of the first metatarsal because of the size of the burr.	Study included in systematic review added to table 2.
Lu J, Zhao H, Liang X et al. (2020) Comparison of Minimally Invasive and Traditionally Open Surgeries in Correction of Hallux Valgus: A Meta-Analysis. The journal of foot and	Meta-analysis N=11 studies with 1166 patients treated with MIS and 1035 patients treated with	The pooled data (OR 6.28, 95% CI 3.20 to 12.32, $Z =$ 5.35, $p < .01$ ) indicated that patients treated with MIS had a significantly higher rate of excellent-good radiographic angular results than did patients treated with open surgery.	Different types of MIS - mainly those with temporary fixations were included in the analyses.

ankle surgery. 59, 4, 801-806.	traditionally open surgery.	However, the incidences of complications (OR 0.67, 95% Cl 0.24 to 1.91, Z = 0.75, p = .45), recovery time (standard mean difference $-3.09$ , 95% Cl $-$ 7.98 to 1.80, Z = 1.24, p = .22), and patient-reported satisfaction (OR 2.76, 95% Cl 0.72 to 10.65, Z = 1.48, p = .14) were similar between patients with hallux valgus treated with MIS and patients treated with open surgery.	
Fukushi JI, Tanaka H, Nishiyama T et al (2022) Comparison of outcomes of different osteotomy sites for hallux valgus: A systematic review and meta-analysis. Journal of Orthopaedic Surgery 30(2) 1–8.	Systematic review and meta-analysis of RCTs. N=10 studies with a total of 793 feet in the qualitative synthesis.	For the management of mild to moderate HV deformity, we found no significant clinical and radiological differences between patients treated with scarf and chevron osteotomies. Further controlled trials comparing different sites of osteotomies for moderate to severe HV deformity are needed.	Only one RCT with percutaneous technique included. All other studies are open/mini osteotomies.
Di Giorgio L, Touloupakis G, Simone S et al. (2013) The Endolog system for moderate-to-severe hallux valgus. Journal of Orthopaedic Surgery; 21(1):47-50.	Case series N=25 patients underwent minimally invasive surgery using the Endolog system. Mean follow- up 18.2 months.	The mean hallux valgus angle (HVA), the intermetatarsal angle (IMA), and the proximal articular set angle (PASA) and the mean AOFAS score improved significantly after surgery (all p<0.0001). Periosteal reaction was noted by week 4, and callus formation after 3 months. There were no delayed or non-union or other complications.	Higher quality studies included in table 2.
Harrasser N, Hinterwimmer F, Baumbach SF et al. (2023) The distal	Case control study n=55 MICA procedures	Fixation of the first MTH with a single bicortical screw in MICA with moderate lateralization of	Variation of the MICA procedure

metatarsal screw is not always necessary in third-generation MICA: a case-control study. Arch Orthop Trauma Surg.143(8):4633- 4639.	(50 patients with hallux valgus deformities) 22 with two screws (MICA2), 33 with one screw (MICA1) 12 months follow-up	MTH shows stable anchoring and good clinical results. The routine use of a second metatarsal screw can be omitted.	
Holme TJ, Sivaloganathan SS, Patel B et al. (2020) Third-Generation Minimally Invasive Chevron Akin Osteotomy for Hallux Valgus. Foot & Ankle International, 41(1) 50–56.	Case series N=40 patients undergoing third- generation MICA Follow up 12 months.	At 12 months, the MOXFQ score improved and the AOFAS score improved, with 70% of patients reporting excellent outcomes and 30% good ones. Hallux valgus angles improved from 32 degrees to 12 degrees, and intermetatarsal angles improved from 13 degrees to 7 degrees. There were 4 cases of Akin screw removal for soft tissue irritation. There were no other complications, including recurrence.	Higher quality studies included in table 2.
Jowett CRJ, Bedi HS. (2017) Preliminary Results and Learning Curve of the Minimally Invasive Chevron Akin Operation for Hallux Valgus. J Foot Ankle Surg. 56(3):445-452.	Case series n=78 consecutive feet underwent minimally invasive Chevron Akin (MICA) for symptomatic hallux valgus. Follow-up mean of 25 (range 18 to 38) months.	The mean AOFAS score improved from 56 preoperatively to 87 postoperatively ( $p < 0.001$ ). The mean hallux valgus and intermetatarsal angles preoperatively were 29.7° and 14.0°. The postoperative angles were 10.3° and 7.6° ( $p < 0.001$ ). The patients were satisfied in 87% of cases (92/106). The incidence of reoperation was 14% (15/106). They display a steep associated learning curve, and the learning	Learning curve Higher level evidence included in table 2.

		curve is comparable to that for open hallux valgus surgery.	
Karry LK-L, Siu-Wah K, Yuen-Hon C. (2015) Percutaneous Chevron Osteotomy in Treating Hallux Valgus: Hong Kong Experience and Mid-Term Results. Journal of Orthopaedics, Trauma and Rehabilitation 19 (1), 25-30.	Case series N= 23 percutaneous chevron osteotomies with screw fixation in 20 patients. Follow-up 18 months	At 18 months, the mean hallux valgus angle (HVA) was corrected from 31.68° to 14.39°, mean intermetatarsal angle (IMA) from 13.77° to 7.98° and mean American Orthopaedic Foot and Ankle Society (AOFAS) score from 59.26 to 88.35. There were 4 cases of medial plication stitch impingement and 4 cases with screw impingement but no other complications.	Higher quality studies included in table 2.
Lai MC, Rikhraj IS, Woo YL et al. (2018) Clinical and radiological outcomes comparing percutaneous chevron- akin osteotomies vs open scarf-akin osteotomies for hallux valgus. Foot Ankle Int; 39(3):311–7.	Retrospective analysis of prospective data. 29 feet had PECA and 58 feet had open Scarf Akin osteotomies. Follow-up 24 months.	Both groups showed comparable clinical and radiological outcomes at 24 months. The percutaneous group demonstrated less pain and shorter length of operation. there were no complications in percutaneous group, but 3 wound complications were reported in the open group.	Higher quality studies included in table 2. Study included in systematic review added to table 2.
Lee M, Walsh J, Smith MM et al. (2017) Hallux valgus correction comparing percutaneous chevron/Akin (PECA) and open SCARF/Akin osteotomies. Foot Ankle Int; 38:838–846.	Prospective RCT N=50 25percutaneo us Chevron/Akin (PECA) versus 25 open SCARF/Akin osteotomies Follow-up 6 months.	Both groups showed significantly improved clinical and radiological results. The PECA group showed significantly lower pain level (visual analogue scale) in the early postoperative phase. No serious complications were observed in either group.	Study included in systematic review added to table 2.
Lewis TL, Robinson PW, Ray R et al. (2023) The Learning	Retrospective review of the first 58	Technical proficiency was reached after 38 cases. Operation time and	Studies reporting similar

Curve of Third- Generation Percutaneous Chevron and Akin Osteotomy (PECA) for Hallux Valgus. The Journal of Foot & Ankle Surgery 62, 162–167.	consecutive PECA cases of a single surgeon.	radiation exposure significantly decreased after this transition point ( $p < .05$ ). There was no difference in complication rate or radiographic deformity correction regardless of position along the learning curve ( $p > .05$ ). In conclusion, the mean number of cases required to reach technical proficiency in third generation PECA is 38 cases. The complication rate does not correlate to the number of cases performed.	outcome included in table 2.
Lewis TL, Ray R, Robinson P, Dearden PMC, Goff TJ, Watt C, Lam P. Percutaneous Chevron and Akin (PECA) Osteotomies for Severe Hallux Valgus Deformity With Mean 3-Year Follow- up. Foot Ankle Int. 2021 Oct;42(10):1231- 1240.	Retrospective review of 50 patients (59 feet) with HVA >40 degrees or IMA >20 degrees had PECA. Mean follow- up 3.1 years.	Mean postoperative MOXFQ index score was 15.1. There was a statistically significant improvement ( $P < .001$ ) in both IMA and HVA after surgery (IMA 17.5-5.1 degrees; HVA 44.1-11.5 degrees). 76.8% reporting they were highly satisfied. The hallux valgus recurrence rate was 7.5%.	Studies with longer follow- up included in table 2.
Lewis TL, Ray R, Gordon DJ. (2022) Minimally invasive surgery for severe hallux valgus in 106 feet. Foot Ankle Surg. 28(4):503-509.	Case series N=106 feet (78 patients) had MICA with screw fixation. Follow-up 2 years	At 2 years follow-up, the MOXFQ score significantly improved for the Pain, Walking and Standing and Social Interaction domains from 39.2 to 7.5, 38.2 to 5.9 and 48.6 to 5.5, respectively ( $p < 0.001$ ). Pre- and 6 week post- operative radiographic data was available for all 106 feet. Mean IMA improved from 18.2° to 6.3° ( $p <$ 0.001) whilst mean HVA improved from 45.3° to 10.9° ( $p < 0.001$ ). The	Studies with longer follow- up included in table 2.

		complication rate was 18.8% and the screw removal rate was 5.6%.	
Lewis TL, Ray R, Gordon DJ. (2002) Time to maximum clinical improvement following minimally invasive chevron and Akin osteotomies (MICA) in hallux valgus surgery. Foot Ankle Surg. 28(7):928- 934.	Case series N=202 feet had third- generation MICA Follow-up 2 years	Most of the PROM improvement with MICA is gained by 6 months post- operatively but further significant improvement can be seen up to 2 years. Those patients who have not improved at 6 months, are likely to do so with time.	Larger studies with longer follow- up included in table 2.
Liszka H, Gądek A. (2020) Percutaneous Transosseous Suture Fixation of the Akin Osteotomy and Minimally Invasive Chevron for Correction of Hallux Valgus. Foot Ankle Int. 241(9):1079- 1091.	103 minimally invasive chevron (MIC) Akin osteotomies, with screw stabilization (group A, n=54), and percutaneous transosseous suture (group B, n=49). Follow-up 1 year	The minimally invasive chevron osteotomy with transosseous suture stabilization of the Akin osteotomy was a safe method with good functional results that were comparable to the outcomes achieved when using screw fixation.	Variation of the procedure.
Lucas y, Hernandez J, Golanó P et al. (2016) Treatment of moderate hallux valgus by percutaneous, extra- articular reverse-L chevron (PERC) osteotomy. Bone Joint J; 98-B:365–373.	Prospective case series N=38 patients who underwent 45 extraarticular reverse-L Chevron (PERC) osteotomies. Mean follow- up of 59.1 months (45.9 to 75.2).	The AOFAS score increased from 62.5 (range, 30 to 80) preoperatively to 97.1. There was a statistically significant decrease in the hallux valgus angle and the intermetatarsal angle. With a mean preoperative hallux valgus and intermetatarsal angle of 26 degrees and 11 degrees, respectively, these patients presented mainly mild deformities.	Larger and higher quality studies included in table 2.
Miranda MAM, Martins C, Cortegana IM et al.	Systematic review	The mean angle correction of HV deformity improved	different surgical

IP overview: Minimal invasive percutaneous surgical techniques with internal fixation for correcting hallux valgus

(2021) Complications on Percutaneous Hallux Valgus Surgery: A Systematic Review. 60, 3, 548-554.	16 studies were included and 1157 procedures reported for percutaneous HV on 1246 patients.	postoperatively. Reported complications vary among the studies. The highest complication rate was joint stiffness in 18.47% of cases, followed by HV recurrence and shortening of M1, both in 15.2%, material intolerance in 10.1%, osteoarthritic changes in 9.1%, infection in 7.6% and transfer	approaches, and fixation devices used those with temporary fixation or no fixation were also included.
Malagelada F. Minimally invasive surgery for hallux valgus: a systematic review of current surgical techniques. Int Orthop 2018;43:625– 637	Systematic review N=23 studies 2279 procedures in 1762 patients	metatarsalgia in 5.4%. There is some evidence that Chevron and Akin showed the most potential for improvement of the HVA and the Endolog for the IMA. An overall complication rate of 13% was obtained among studies. Randomized controlled trials and long- term follow up are needed to assess the efficacy of MIS techniques.	Different surgical techniques assessed- Bosch, MIS Chevron- Akin, Reverdin- Isham, Endolog system, and techniques involving distal soft tissue release and fixation
Maffulli N, Longo UG, Marinozzi A et al. (2011) Hallux valgus: effectiveness and safety of minimally invasive surgery. A systematic review. Br Med Bull 97: 149-167.	Systematic review	Given the limitations of the case series, extensive clinical heterogeneity, it is not possible to determine clear recommendations regarding the systematic use of minimally invasive surgery for hallux valgus correction, even though preliminary results are encouraging. Studies of higher levels of evidence, concentrating on large adequately powered randomized trials, should be conducted.	Different MIS techniques were included.

Mikhail CM, Markowitz J, Di Lenarda L, Guzman J, Vulcano E. (2022) Clinical and Radiographic Outcomes of Percutaneous Chevron-Akin Osteotomies for the Correction of Hallux Valgus Deformity. Foot Ankle Int. 43(1):32-41.	Retrospective cohort study N=248 patients (274 feet) had minimally invasive chevron-Akin (MICA). Follow-up 12.9 months.	The mean preoperative intermetatarsal angle (IMA) and hallux valgus angle (HVA) were 13.4 and 29.1 degrees, respectively. The postoperative IMA and HVA were 4.9 and 8.9 degrees, respectively. The mean Foot Function Index (FFI) score part A was 92 preoperatively and 43 postoperatively. Patient satisfaction was 91.6%. The mean postoperative 5 mg oxycodone pill consumption was 2.2.	Higher level evidence included in table 2.
Neufeld SK, Dean D, Hussaini S. (2021) Outcomes and Surgical Strategies of Minimally Invasive Chevron/Akin Procedures. Foot Ankle Int. 42(6):676- 688.	Retrospective analysis treating surgeon's first 94 MICA procedures. Average patient follow- up was 11.2 months.	The MICA osteotomy was a safe and reproducible technique, associated with rapid improvement in pain scores, early weightbearing, and significant deformity correction. Complication rates and patient satisfaction scores were similar between the first and second half of patients ( $P > .05$ ), suggesting the learning curve was not a factor.	Similar outcomes reported in studies added to table 2.
Palmanovich E, Ohana N, Atzmon R et al. (2020) MICA: A Learning Curve. <u>The</u> <u>Journal of Foot and</u> <u>Ankle Surgery</u> . 59 (4), 781-783	Case series N= 50 patients using the minimally invasive Chevron and Akin procedure over the course of 3 years.	Results showed that surgery duration decreased from >2 hours in the first cases to a mean of 45 minutes in the third year. This learning curve plateaued by the 21st patient. The number of intraoperative fluoroscopy u sed decreased substantially over the first 27 surgeries, at which point the learning curve plateaued. In summary, it took about 27 procedures for an	Larger studies included in table 2.

		inexperienced surgeon to acquire the skill of performing minimally invasive Chevron and Akin osteotomy.	
Palmanovich E, Ohana N, Tavdi A, et al. (2023) A modified minimally invasive osteotomy for hallux valgus enables reduction of malpositioned sesamoid bones. Arch Orthop Trauma Surg. 143(10):6105-6112.	N=53 patients open chevron osteotomy (n = 19), minimally invasive V- shaped osteotomy (n = 18), and a modified straight minimally invasive osteotomy (n = 16). Postoperative follow-up.	When compared to open chevron and V-shaped osteotomies, the modified osteotomy resulted in significantly lower postoperative sesamoid position scores ( $3.74 \pm$ $1.48$ , $4.61 \pm 1.09$ , and $1.44 \pm$ 0.81, respectively, P < 0.001). Furthermore, the mean change in postoperative sesamoid position score was greater (p < 0.001).	Modified MIS osteotomy technique Higher level studies included in table 2.
Siddiqui NA, Mayer BE, Fink JN. (2021) Short-Term, Retrospective Radiographic Evaluation Comparing Pre- and Postoperative Measurements in the Chevron and Minimally Invasive Distal Metatarsal Osteotomy for Hallux Valgus Correction. The Journal of Foot & Ankle Surgery, 60 (6), 1144–1148.	Retrospective radiographic review of chevron (n=30) and MIDMO (n=31) osteotomies Mean follow- up was 26.6 months for chevron and 18.7 months for MIDMO osteotomies.	Postsurgical retrospective radiographic review demonstrated chevron and MIDMO procedures provide comparable radiographic correction of IMA, HAA, and TSP.	Higher quality studies included in table 2.
Slullitel G, López V, Álvarez V et al. (2022) Refined Minimally Invasive Distal First Metatarsal Osteotomy for Moderate Hallux Valgus Treatment: The BC Procedure. J Foot	Prospective case series N= 63 patients who underwent the modified distal	The mean AOFAS score improved from a median of 47.4 points preoperatively to a median of 88 points postoperatively (p < .05). First MTPJ ROM did not change from preoperative period (mean 32.5°) to the	Higher level evidence included in table 2.

Ankle Surg.61(5):1052-1055	metatarsal osteotomy (DMO) BC technique for mild and moderate hallux valgus. Mean follow- up was 36.5 (range 23.4- 59.8) months.	postoperative period (mean $31.8^{\circ}$ ) (p > .65). All osteotomies went on to bony healing in the 6-week follow-up visit. Fifty-two (82%) of patients were either very satisfied or satisfied with the procedure (p < .05).	
Singh MS, Khurana A, Kapoor D, et al. (2020) Minimally invasive vs open distal metatarsal osteotomy for hallux valgus - A systematic review and meta- analysis. J Clin Orthop Trauma. 11(3):348- 356.	Systematic review and meta- analysis. N= 9 studies were included.	Most available studies are either randomized control trials, or prospective cohort studies providing good level of evidence. Radiological analysis showed similar correction with both MIS and open osteotomies. In functional analysis results were different with open techniques providing better results in terms of AOFAS score. (p < 0.0001). VAS score and complication rate were similar in both groups.	Different MIS techniques were included in the analysis (Bosch, SERI/Kramm er, mini scarf, percutaneous Chevron +Akin)
Toepfer A, Strässle M. (2022) 3rd generation MICA with the "K- wires-first technique" - a step-by-step instruction and preliminary results. BMC Musculoskelet Disord. 18;23(1):66.	Case series N=50 consecutive MICAs in 47 patients were performed with the K- wires-first technique. 12 months follow-up.	There was one intraoperative conversion to an open surgical bunion correction corresponding to a 2% conversion rate respectively (1/50). On 3 feet (2 patients), removal of the Chevron screws was performed after 7, 9, and 12 months due to prominent and disturbing screw heads at the level of the medial cortex, accounting for a revision rate of 6% (3/50). The IMA decreased after MICA by a mean of 10.8° from 16.2° to 5.4° and the HVA by a mean of 22.1° from 30.6° to 8.5°.	Modified MICA technique

		demonstrating MICA's high potential for correction.	
Toepfer A, Strassle M. (2022) The percutaneous learning curve of 3rd generation minimally- invasive Chevron and Akin osteotomy (MICA). Foot and Ankle Surgery 28 1389–1398.	Case series N= first 50 consecutive MICA procedures with the "K- wires-First technique".	Although the learning curve of 3rd generation MICA is flat and requires specific training and intensive practice, the rate of complications is not elevated compared to other percutaneous hallux valgus techniques. The learning curve showed a continuous improvement regarding surgery time and use of fluoroscopy. After 40 procedures, the surgery time consistently dropped under 45 min and required less than 100 fluoro-shots. The modified surgical technique may help reduce Chevron screw mal- positioning when using large C-arm fluoroscopy for this procedure.	Learning curve Studies reporting similar outcomes included in table 2.
Trnka HJ, Krenn S and Schuh R. (2013) Minimally invasive hallux valgus surgery: a critical review of the evidence. Int Orthop 37(9): 1731- 1735.	Systematic review N=21 papers (1750 patients).	The majority of papers are level IV studies. Reported complications seem to be less than one may see in one's own clinical practice. This possible bias may be related to the fact that most studies are published by centres performing primarily minimally invasive hallux valgus surgery.	Different MIS techniques were included in the analysis.
Trnka HJ, (2021) Percutaneous, MIS and open hallux valgus surgery. EFORT Open Rev;6:432-438.	Review	Review distinguishes the first, second and third generation minimal incision surgery techniques and reports that minimally invasive and percutaneous hallux valgus correction lead to similar clinical and radiological results as the open chevron or SCARF	Review

		osteotomies. Third generation minimally invasive Chevron osteotomies present similar clinical and radiological outcomes. Training is vital to avoid unnecessary complications and to minimize the surgeon's learning curve.	
Vernois J, Redfern DJ.(2016) Percutaneous surgery for severe hallux valgus. Foot Ankle Clin; 21:479–493.	Case series N=100 feet treated with a percutaneous Chevron osteotomy.	Radiological analysis revealed a correction of the intermetatarsal angle from 14.5° to 5.5° at the last follow-up. The mean hallux valgus angle was corrected from 33.7° preoperatively to 7.3° at the last follow-up. Patient-reported satisfaction rate was 95% good/excellent results.	Higher level evidence included in table 2.
Yousaf A, Saleem J, Al-Hilfi L et al. (2023) Third-Generation Minimally Invasive Chevron Akin Osteotomy for Hallux Valgus: Three-Year Outcomes. Indian Journal of Orthopaedics. 57:1105–1111	Cohort study N=33 patients underwent third- generation MICA surgery. Follow-up 3 years.	Third-generation MICA demonstrates promising patient satisfaction scores post-operatively, and we have shown these improvements are sustained over a minimum three-year follow-up period.	Higher quality studies included in table 2.