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Hallux valgus: effectiveness and safety of minimally invasive surgery. A systematic review

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Minimally invasive techniques for hallux valgus correction include arthroscopy, percutaneous and minimum incision surgery. In the last few decades, several techniques have been increasingly used. We performed a comprehensive search of CINAHL, Embase, Medline, HealthSTAR and the Cochrane Central Registry of Controlled Trials, from inception of the database to 4 January 2010, using various combinations of the keywords terms 'Bosch', 'PDO', 'percutaneous distal osteotomy', 'SERI', 'percutaneous', 'minimal incision', 'minimum incision', 'minimally invasive', 'less invasive', 'mini-invasive', 'hallux valgus', 'bunion', 'surgery', 'arthroscopy', 'metatarsal' 'forefoot'. Only articles published in peer reviewed journals were included in this systematic review. Several new techniques are available for minimally invasive correction of the hallux valgus. Minimally invasive correction of the hallux valgus may provide better outcome for patients who would not recover well from traditional open approaches, because of decreasing recovery and rehabilitation times, as surgical exposure and deep tissue dissection are smaller and gentler to the soft tissues. Data are lacking to allow definitive conclusions on the use of these techniques for routine management of patients with hallux valgus. Given the limitations of the current case series, especially the 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 to help answer these questions.

Keywords: hallux valgus/percutaneous surgery/minimally invasive/minimum incision/less invasive/arthroscopy

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Introduction

Hallux valgus is a common disorder of the forefoot, with deviation of the great toe (hallux) towards the midline of the foot and prominence of the head of the first metatarsal, the medial eminence. Hallux valgus is associated with increasing age, female sex and osteoarthritidess.[1] Conservative management may include footwear modification, and the use of insoles or toe spacers. However, its value has been questioned.[2] Patients in whom conservative measures fail to relieve symptoms may be candidates for surgery.[3]

Surgical correction of hallux valgus rebalances the first ray, correcting the various features of the deformity.[3] While several well-established surgical methods are available for hallux valgus (more than 130 different operative methods),[3] consensus regarding the best management has yet to be established.[4,5] In 2004, a systematic review of the published literature concluded that there was no compelling evidence of advantages of any of these methods over any other particular type of surgery.[4]

Minimally invasive trauma and orthopaedic surgery is increasingly common.[6–23] These techniques have the theoretical advantage of decreasing recovery and rehabilitation times, because surgical exposure and deep soft tissue dissection are less extensive and possibly gentler.[6–20] These techniques hold the promise to provide better clinical outcome for patients who would not recover well from traditional open approaches.[18,24]

Minimally invasive hallux valgus techniques include arthroscopy, percutaneous and minimum incision osteotomies. With the advance of foot and ankle arthroscopy, distal soft tissue procedures (lateral soft tissue release and medial capsular placation) have been performed endoscopically.[25–28] The advantages of arthroscopic procedures are better assessment of sesamoid reduction and the potential to minimize the risk of overcorrection. However, arthroscopic hallux valgus correction is technically demanding, is time-intensive and carries the potential risk of digital nerve injury.[25–28]

Percutaneous and minimum incision osteotomies for the management of patients with hallux valgus have received increasing recognition because of the perceived efficacy comparable to traditional open approaches but with purported less cost and higher patient satisfaction.[24]

Percutaneous surgery is performed through the smallest possible working incision (usually 1–3 mm long) without direct visualization of the underlying target structures, using a mini-blade for soft tissue incision, and a power rotatory bur for bony procedures under

intra-operative fluoroscopy.[24,29,30] This kind of surgery has also inappropriately been referred as 'blind' or 'closed' surgery.

Minimally incision surgery is performed through the smallest incision necessary to perform the procedure (usually 1–3 cm long) using a traditional scalpel blade for soft tissue incision and power saw blades for bony procedures under direct visualization of the structures, and may or may not require intra-operative fluoroscopy.[24]

This systematic review assesses the efficacy and safety of minimally invasive surgery (arthroscopy, percutaneous and minimum incision surgery) for the management of patients with hallux valgus.

Literature search and data extraction

Two reviewers (U.G.L. and A.M.) independently identified studies, in any language, by a systematic search of CINAHL, Embase, Medline, HealthSTAR and the Cochrane Central Registry of Controlled Trials, from inception of the database to 4 January 2010, using various combinations of the keywords terms 'Bosch', 'PDO', 'percutaneous distal osteotomy', 'simple, effective, rapid, inexpensive (SERI)', 'percutaneous', 'minimal incision', 'minimum incision', 'minimally invasive', 'less invasive', 'mini-invasive', 'hallux valgus', 'bunion', 'surgery', 'arthroscopy', 'metatarsal' 'forefoot'. All articles relevant to the subject were retrieved, and their bibliographies hand searched for further references in this context. We considered publications in any language. Reviewers scanned the bibliographies of all retrieved studies and other relevant publications, including reviews and meta-analyses, for additional relevant articles. We contacted the Group of Research and Study into Minimally Invasive Surgery of the Foot and Ankle (GRECMIP) (http://grecmip.com/) to inquire about any additional unpublished trials or trials in progress.

Two reviewers (U.G.L. and A.M.) screened the titles and abstracts of identified citations independently and in duplicate and acquired the full text of any article that either judged potentially eligible. These reviewers independently applied eligibility criteria to the methods section of potentially eligible trials. Eligible studies had to report on patients with hallux valgus managed by minimally invasive surgery. Only articles published in peer-reviewed journals were included in this systematic review. We resolved disagreements by discussion.

Three reviewers (U.G.L., A.M. and V.D.) extracted data from each eligible study independently and in triplicate. Data included personal information, methodology, details on interventions and reported outcomes.

Among eligible studies, we found substantial diversity in the types of employed technique for the correction of the deformity. Two

experienced foot and ankle surgeons (N.M. and V.D.) grouped the participants into the three surgical categories of minimally incision, percutaneous and arthroscopic surgery. For the clinical and radiographical outcomes, we presented data in the original units of measurement.

We planned to use Review Manager (RevMan.Version 5 forWindows) to calculate the magnitude of treatment effect. However, because only case series were retrieved, no pooling of data was performed.

Quality assessment

To assess the quality of the studies, we planned to use the Coleman methodology score (CMS), which assesses methodology with use of 10 criteria, giving a total score between 0 and 100. A score of 100 indicates that the study largely avoids chance, various biases and confounding factors. The subsections that make up the CMS are based on the subsections of the CONSORT statement (for randomized controlled trials) and are modified to allow for other trial designs.[31]

We modified the Coleman criteria to make them reproducible and relevant for the systematic review of minimally invasive surgery for correction of the hallux valgus. Each study was scored by two reviewers (U.G.L. and A.M.) independently and in duplicate for each of the criteria adopted (listed in Table 1) to give a total CMS between 0 and 100. We resolved disagreements by discussion.

The studies were also assessed by two reviewers (U.G.L. and A.M.) independently and in duplicate with use of the level of evidence rating introduced in the *American Volume of the Journal of Bone and Joint Surgery* in 2003.[32] Again, we resolved disagreements by discussion (Table 2).

Results

Identification and selection of studies

A total of 67 citations were obtained from searches of the various electronic bibliographies. An additional 25 papers were obtained from the reference list of the studies included. The study selection process and reasons for exclusions are summarized in Figure 1. The 26 studies that were included described a total of 2197 operations for minimally invasive surgery on 1830 patients. Of the three studies (Magnan *et al.*[33–35]) with overlapping publication of data, the first publication only was considered.[33] This left 24 studies published from January 1991 to February 2010 to be included in the present investigation.

Table 1 Modified CMS.

Part A: only one score to be given for each of the six sections			
1.	Study size: number of procedures	<30	0
		30–50	4
		51–100	7
		>100	10
2.	Mean follow-up (months)	<12	0
		12–36	4
		37–60	7
		>61	10
3.	Surgical approach	Different approach used and outcome not reported separately	0
		Different approaches used and outcome separately reported	7
		Single approach used	10
4.	Type of study	Case series (level IV)	0
		Case–control study (level III)	5
		Retrospective comparative study (level III)	5
		Prospective comparative study (level II)	10
		Randomized control trial (level I)	20
5.	Descriptions of surgical technique	Inadequate (not stated, unclear)	0
		Fair (technique only stated)	5
		Adequate (technique stated, details of surgical procedure given)	10
6.	Description of postoperative rehabilitation	Described	5
		Not described	0
Part B: scores may be given for each option in each of the three sections if applicable			
1.	Outcome criteria	Outcome measures clearly defined	2
		Timing of outcome assessment clearly stated	2
		Use of outcome criteria that has reported reliability	3
		General health measure included	3
2.	Procedure of assessing outcomes	Subjects recruited	5
		Investigator independent of surgeon	4
		Written assessment	3
		Completion of assessment by patients themselves with minimal investigator assistance	3
3.	Description of subject selection process	Selection criteria reported and unbiased	5
		Recruitment rate reported	
		>90%	5
		<90%	0

Table 2 Level of evidence and Coleman scoring (CMS) for the studies under review.

No	Study	Level of evidence	Type of study	Year of publication	Procedures	Number of patients (feet)	CMS
1	Baietta *et al.*[70]	IV	Case series	2007	Bosch osteotomy	84 (98)	34
2	Barragan-Hervella *et al.*[39]	IV	Case series	2008	Percutaneous	29 (number of feet not specified)	17
3	Bauer *et al.*[36]	IV	Case series	2009	Percutaneous	168 (189)	51
4	Bianchi and Cavenago[71]	IV	Case series	2002	Bosch osteotomy	27 (27)	12
5	Bösch *et al.*[63]	IV	Case series	2000	Mini-incision	64 (98)	45
6	De Giorgi *et al.*[72]	IV	Case series	2003	Bosch osteotomy	24 (27)	11
7	Giannini *et al.*[37]	IV	Case series	2003	Mini-incision	37 (54)	45
8	Giannini *et al.*[38]	IV	Case series	2007	Mini-incision	190 (299)	62
9	Kadakia *et al.*[47]	IV	Case series	2007	Mini-incision	13 (13)	37
10	Leemrijse *et al.*[60]	V	Expert opinion	2008	Percutaneous	Not reported	31
11	Lin *et al.*[40]	IV	Case series	2009	Arthroscopy	31 (47)	31
12	Lostia *et al.*[73]	IV	Case series	2007	Bosch osteotomy	71 (82)	34
13	Lui *et al.*[26]	IV	Case series	2008	Arthroscopy	83 (94)	38
14	Maffulli *et al.*[14]	III	Retrospective comparative study	2009	Mini-incision versus Bosch osteotomy	36 (36) per group	57
15	Maffulli *et al.*[23]	IV	Case series	2005	Mini-incision	15 (15)	36
16	Magnan *et al.*[33]	IV	Case series	2005	Mini-incision	82 (118)	46
17	Markowski *et al.*[74]	IV	Case series	1991	Bosch osteotomy	45 (63)	28
18	Martinez-Nova *et al.*[42]	IV	Case series	2008	Percutaneous	26 (30)	29
19	Portaluri *et al.*[75]	IV	Case series	2000	Mini-incision	156 (197)	39
20	Roth *et al.*[43]	III	Retrospective comparative study	1996	Mini-incision versus Kramer osteotomy	105 (124): subcutaneous group, 88 ft; open group, 36 ft	37
21	Sanna and Ruiu[57]	IV	Case series	2005	Mini-incision	83 (90)	40
22	Siclari and Decantis[41]	IV	Case series	2009	Mini-incision and arthroscopy	49 (59)	38
23	Solarino *et al.*[76]	III	Retrospective comparative study	2006	Bosch versus Hallux splint	80 (80): Bosch group, 40 ft; Hallux splint, 40 ft	40
24	Weinberger *et al.*[77]	IV	Retrospective case series	1991	Percutaneous	204 (301)	35

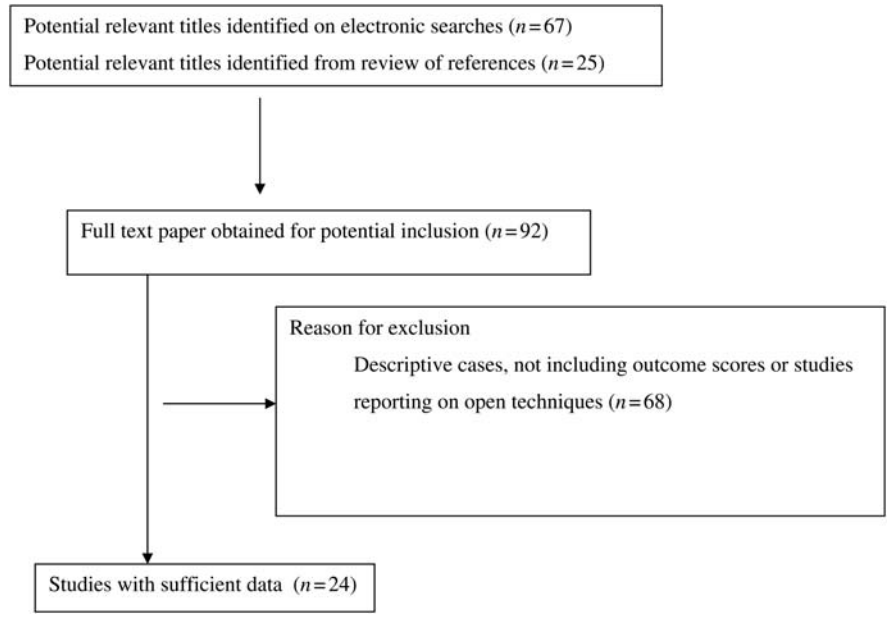

Fig. 1 Details of the investigations excluded and included in the study.

Quality assessment

The mean CMS was calculated for the studies included in the present investigation. The values set by agreement between the two examiners are presented in Table 2. The majority of studies had methodological limitations, with an average CMS of 36.4.

Only 10[14,26,33,36–42] studies used a scoring system to evaluate clinical outcome. All of them used the AOFAS score as scale for clinical outcome measurement. The FAOS score was used in one study.[14] The other article reported generically satisfaction of the patients and on radiographical outcome.

All the studies were level IV studies, with the exception of two level III studies, comparing minimum incision hallux valgus correction versus scarf[14] and Kramer *et al.*[43] osteotomy.

We planned to use Review Manager (RevMan.Version 5 forWindows) to calculate the magnitude of treatment effect. However, since the available studies reported different techniques (different types of hardware, use of a single or two wires), different post-operative immobilization, different end points at different time points, we found that was not serious to pool data together and provide average of pre- and postoperative results. Therefore, data from the available studies are reported in Tables 3 and 4. Overall, the average correction of the hallux valgus angle (HVA) improved from a preoperative value of 29.95 to 16.76°

postoperatively; the average intermetatarsal angle (IMA) improved from a preoperative value of 13.28 to 7.66° postoperatively; the average correction of distal metatarsal articular angle (DMMA) improved from a preoperative value of 14 to 6.45° postoperatively.

Complications, which notoriously are the main concerns for minimally invasive HV correction, are reported in detail in Table 5.

Discussion

Several case series are now available to document outcomes and complications of minimally invasive hallux valgus correction. There were however no randomized controlled trials. Two comparative case–control studies[14,43] reported comparable clinical outcome when comparing minimum incision versus Scarf[14] and Kramer osteotomies.[43]

The studies included in this review were not homogeneous: they differed in study design, type of patients, type and level of hallux deformity, type of surgical procedures and type of outcomes assessed. Not all data from the selected papers were available, and most papers describe low-quality (mainly grade IV level of evidence) case series.

The present investigation has also highlighted increasing number of articles being published in the last few years, indicating growing interest and development in this field. However, there was no evidence of improvement of the quality of the articles in the last years. On the other hand, as the topic has been published on only for a few years, it is to be expected that it is still maturing.

Although minimally invasive surgery for hallux valgus correction has been introduced in the foot surgery community in the 1970s and 1980s,[44,45] and may well be undertaken in 50% of patients requiring forefoot surgery outside the USA,[46] there are no published randomized controlled trials.[47] The remaining non-controlled studies provide no strong scientific evidence in favour of these techniques. However, in the case of minimally invasive surgery for hallux valgus, case series make a useful contribution to the systematic review. Inclusion of case series can increase the evidence base and strengthen the credibility of a review of an emerging health technology. These advantages must be balanced against the risk of bias associated with the lack of a control group, potential publication bias, over-representation of results from specialist centres,[14,36] and overlap of patients across series.[33–35] The published case series represent the experience of centres in a range of different countries and health-care systems.

A limitation of all case series data is that, in the absence of a control group, it is not possible to be certain that any change observed is really an effect of the treatment reported. In the present context, there can be

Table 3 Data from the available studies (part 1).

Study	Mean Follow-up	AOFAS		FAOS score		Duration of surgery	Length of hospital stay
		Preoperative	Postoperative	Preoperative	Postoperative		
Baietta *et al.*[70]	76.2 ± 10.9 months (range: 60–99 months)	Not reported	88.9 ± 11.3 (range: 49–100)	Not reported	Not reported	Not reported	Not reported
Bianchi and Cavenago[71]	6 months	Not reported	Not reported	Not reported	Not reported	Not reported	Not reported
Barragan-Hervella *et al.*[39]	6 months	60.37 (95% CI: 53.87–66.38)	96.62 (95% CI: 94.63–98.70	Not reported	Not reported	Not reported	Not reported
Bauer *et al.*[36]	13 months (range: 12–24 months)	52 (44–60)	93 (82.5–100)	Not reported	Not reported	Not reported	Not reported
Bösch *et al.*[63]	8 years an 9 months (range: 7 years and 6 months to 10 years and 6 months)	Not reported	Not reported	Not reported	Not reported	Not reported	Not reported
De Giorgi *et al.*[72]	19 months	Not reported	Not reported	Not reported	Not reported	Not reported	Not reported
Giannini *et al.*[37]	36 months (range: 22–52 months)	Not reported	81	Not reported	Not reported	Not reported	Not reported
Giannini *et al.*[38]	4 years (range: 2–6 years)	43 (10–75)	88 (52–100)	Not reported	Not reported	Not reported	Not reported
Kadakia *et al.*[47]	130 days (range: 50–207 days)	Not reported	Not reported	Not reported	Not reported	Not reported	Not reported
Leemrijse *et al.*[60]	Not reported	Not reported	Not reported	Not reported	Not reported	Not reported	1.5 day
Lin *et al.*[40]	23.7 weeks, (range: 16 to 68 weeks)	Not reported	92.7 ± 6.2 (78–100)	Not reported	Not reported	Not reported	Not reported
Lostia *et al.*[73]	24.5 months (range: 8–47 months)	42.62 (range: 30–55)	81.32 (range: 63–100)	Not reported	Not reported	Not reported	Not reported
Lui *et al.*[26]	30.45 months (range: 24–74 months)	Not reported	93 ± 8	Not reported	Not reported	Not reported	Not reported
Magnan *et al.*[33]	35.9 ± 10.9 months (range: 24–78 months)	Not reported	88.2 ± 12.9	Not reported	Not reported	Not reported	Not reported
Maffulli *et al.*[23]	25 ± 3.2 months	Not reported	Not reported	Not reported	Not reported	Not reported	Not reported
Maffulli *et al.*[14]	2.5 years; (range: 2.1–3.2 years)	54 ± 10	85 ± 11	264 ± 19 (range: 182–300)	356 ± 28 (range: 302– 402)	19 ± 7.3 min (range: 11–29)	1.1 ± 0.4 (range: 0–2 days)
Martinez-Nova *et al.*[42]	12.1 months	68.7 ± 11.9 (range: 42–85)	88.1 ± 7.8 (range: 72–97)	Not reported	Not reported	Not reported	Not reported
Markowski[74]	16 months (8–32 months)	Not reported	Not reported	Not reported	Not reported	Not reported	Not reported
Portaluri *et al.*[75]	16.4 months (range: 6–27 months)	Not reported	Not reported	Not reported	Not reported	Not reported	Not reported
Roth *et al.*[43]	15.6 months (range: 12–21 months)	Not reported	Not reported	Not reported	Not reported	Not reported	Not reported
Sanna and Ruiu[57]	31.5 (range: 25–46)	Not reported	Not reported	Not reported	Not reported	Not reported	Not reported
Siclari and Decantis[41]	31.48 months (range: 12–48 months)	45 (range: 30–65)	90. 6 (range: 75–100)	Not reported	Not reported	Not reported	Not reported
Solarino *et al.*[76]							
Bosch group: 40 ft	13 months	40	87	Not reported	Not reported	Not reported	Not reported
Hallux Splint: 40 ft	13 months	37	90	Not reported	Not reported	Not reported	Not reported
Weinberger *et al.*[77]	8.3 months (range: 2–39 months)	Not reported	Not reported	Not reported	Not reported	Not reported	Not reported

Table 4 Data from the available studies (part 2).

Study	HVA		IMA		DMAA	
	Preoperative	Postoperative	Preoperative	Postoperative	Preoperative	Postoperative
Baietta *et al.*[70]	28.3 ± 5.7	13.9 ± 3.4	14.0 ± 1.9	8.7 ± 1.2	23.8 ± 5.6	8.6 ± 3.3
Bianchi and Cavenago[71]	28	10	16	7	14	7
Barragan-Hervella *et al.*[39]	Not reported	Not reported	Not reported	Not reported	Not reported	Not reported
Bauer *et al.*[36]	28 (range: 22–32)	14 (range: 10–18)	13 (range: 11–15)	10 (range: 9–12)	15 (range: 11–19)	8 (range: 4–10)
Bösch *et al.*[63]	36 (14–54)	19 (7–4)	13 (6–18)	10 (3–18)	Not reported	Not reported
De Giorgi *et al.*[72]	32°	7.3	15.3	5.8	11.3	4.6
Giannini *et al.*[37]	Not reported	Not reported	Not reported	Not reported	Not reported	Not reported
Giannini *et al.*[38]	33 (18–60)	16 (2–36)	13 (11–24)	7 (0–16)	Not reported	Not reported
Kadakia *et al.*[47]	25 (16–33)	12 (1–24)	10.3 (7–14)	6.4 (2–10)	Not reported	Not reported
Leemrijse *et al.*[60]	Not reported	Not reported	Not reported	Not reported	Not reported	Not reported
Lin *et al.*[40]	26 ± 4.9° (range: 18–36.9°)	14.2 ± 6.7 (range: 0–26.3)	11.6 ± 1.6 (range: 8–14.7)	5.3 ± 2.3 (range: 0.1–10.3)	Not reported	Not reported
Lostia *et al.*[73]	Not reported	Not reported	Not reported	Not reported	Not reported	Not reported
Lui *et al.*[26]	33 ± 7° (range: 20–58°)	14 ± 5 (range: 4–30).	14 ± 3 (range: 10–26)	9 ± 2 (range: 5–18)	9 ± 6 (range: 0–28)	6 ± 5 (range: 0–23)
Magnan *et al.*[33]	31.5 ± 10.2 (18–42)	13.7 ± 6.7 (7–25	12.3 ± 3 (10–20)	7.3 ± 2.7 (4–16)	Not reported	Not reported
Maffulli *et al.*[23]	32 ± 12 (range: 28–42)	14.1 ± 4.7 (range: 7.5–22)	11.5 ± 4 (range: 10–17)	7.5 ± 3 (range: 3–11)	13.1 ± 6.2 (range: 5.5–21.5)	7 ± 4.2 (range: 5–12)
Maffulli *et al.*[14]	27 ± 6°	17 ± 4	15 ± 6	8 ± 3	11 ± 5	7 ± 4
Martinez-Nova *et al.*[42]	25.4 ± 3.9° (range: 16.5–29.9°)	11.4 ± 2.8 (range: 5.2–17.1)	12.0 ± 0.3 (range: 11.4–12.7)	9.2 ± 0.6 (range: 8.1–10.7)	Not reported	Not reported
Markowski *et al.*[74]	36° (range: 24–61°)	19 (range: 5–40)	13	8	Not reported	Not reported
Portaluri *et al.*[75]	27 ± 9 (11–53)	10 ± 7 (0–31)	14 ± 6 (4–26)	7 ± 3 (0–15)	14 ± 6 (2–27)	7 ± 5 (0–18)
Sanna and Ruiu[57]	32 (range: 14–55)	12.5	15 (range: 10–23)	9.1	15.6	3
Siclari and Decantis[41] Roth[43]	27.9 (range: 12–45)	12.3 (range: 2–21)	16.5 (range: 8–25)	9.3 (range: 3–15)	Not reported	Not reported
Subcutaneous group: 88 ft	30° (14–48°)	12.75 (0–28)	12 (4–20)	7.67 (3–14)	Not reported	Not reported
Open group: 36 ft Solarino[76]	29° (15–50°)	12.06 (2–28)	12 (6 ≥ 17)	7.19 (3–14)	Not reported	Not reported
Bosch group: 40 ft	33° (range: 13–60°)	23 (range: 4–30)	13 (range: 7–24)	8 (range: 2–19)	16 (range: 0–38)	6 (range: 0–10)
Hallux Splint: 40 ft	31° (range: 10–0°)	15 (range: 3–32)	15 (range: 8–35)	8 (range: 4–20)	13 (range: 4–28)	8 (range: 0–10)
Weinberger *et al.*[77]	–	–	–	–	–	–

Table 5 Complications.

Study	Number of patietns (feet)	Kirschner wire decubitus	Recurrence of hallux valgus	Pin infection	Skin infammatory reaction	Pulled out the wires	Non-union	Mal union	Delayed union	Complex regional pain syndrome	Osteo necrosis	Hallux varus	Deep infection	Super ficial infection	Transfer metatarsalgia	Deep vein thrombosis	Joint stiffness
Baietta *et al.*[70]	98 (84)	4	2	–	–	–	0	–	–	–	0	–	1	–	5		4
Bianchi *et al.*[71]	27 (27)	2	–	–	–	1	–	–	–	–	–	–	1	1	–	–	–
Barragan-Hervella *et al.*[39]	29 (number of feet not specified)	–	–	–	–	–	–	–	–	–	–	–	–	1	–	–	–
Bauer *et al.*[36]	168 (189)	–	–	–	–	–	–	–	–	5	–	–	3	–	–	–	2
Bösch *et al.*[63]	64 (98)	–	1	–	–	–	0	–	4	–	0	0	4	–	–	–	–
De Giorgi *et al.*[72]	24 (27)	–	–	–	1	–	–	–	1	–	–	–	–	–	–	–	–
Giannini *et al.*[37]	37 (54)	–	–	–	3	–	–	–	5	–	–	–	–	–	4	1	–
Giannini *et al.*[38]	190 (299)	–	24	–	12	–	–	–	–	–	–	1	–	–	–	1	–
Kadakia *et al.*[47]	13 (13)	–	5	–	–	–	1	–	–	–	1	0	–	1	–	–	–
Leemrijse *et al.*[60]	Not reported	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
Lin *et al.*[40]	31 (47)	–	0	6	–	–	0		0	–	0	–	1	–	0	–	2
Lostia *et al.*[73]	71 (82)	–	1	–	–	2	–	–	–	–	0	–	1	–	–	–	–
Lui *et al.*[26]	83 (94)	–	2	–	–	–	–	–	–	–	–	1	–	–	–	–	1
Magnan *et al.*[33]	82 (118)	–	1	–	2	–	0	–	–	–	–	0	1	–	–	–	7
Maffulli[23]	15 (15)	–	–	–	–	–	–	–	–	–	–	–	–	1	–	–	–
Maffulli *et al.*[14]	Mini–inicision group (36)	–	–	–	3	–	–	–	–	–	–	–	–	–	–	–	–
Martinez-Nova *et al.*[42]	26 (30)	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
Markowski *et al.*[74]	45 (63)	–	–	–	–	2	1	–	–	–	–	–	4	–	–	–	–
Portaluri *et al.*[75]	156 197)	2	–	–	–	2	–	–	–	0	–	–	0	8	–	–	–
Roth *et al.*[43]	105 (124)																
	Subcutaneous group 88	–	–	–	–	–	9	–	–	5	1	–	–	13	–	–	–
	Open group 36 ft	–	–	–	–	–	1	–	–	0	0	–	–	3	–	–	–
Sanna and Ruiu[57]	83 (90)	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
and Siclari Decantis[41] Solarino *et al.*[76]	49 (59)	–	0	–	–	–	2	2	–	–	–	–	–	1	–	–	–
	Bosch group: 40 ft	–	–	–	–	–	–	–	3	–	0	–	–	2	–	–	–
	Hallux Splint: 40 ft	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
Weinberger *et al.*[77]	204 (301)	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–

more certainty in interpreting studies of minimally invasive surgery for hallux valgus correction, because the natural history of the condition suggests that hallux valgus does not normally disappear spontaneously for prolonged periods.

We did not use quality features of case series as inclusion or exclusion criteria for our review, because we wanted to include all case series likely to be regarded as relevant by clinicians and because of the absence of standard validated criteria for quality assessment.

With case series, more than other types of studies, authors choose what and when to publish, and journals may be less likely to publish case series without 'interesting' data, such as a large 'treatment effect' or notable complications. In support of the data derived from the case series in this review, the results of this review are similar to those obtained for review of traditional open surgery of hallux valgus surgery.[4]

Bias in this systematic review may be driven by some of the same factors that contribute to publication bias in case series, including, for example, the desire of clinicians to demonstrate their best results and 'advertise' the success of an intervention to which they feel personally committed.[48]

We did not include in the present systematic review articles that are not yet published in peer-reviewed journals. Inclusion of these papers would have reinforced the evidence for the effectiveness and safety of minimally invasive surgery for hallux valgus correction.

Giannini *et al.*[49] performed a prospective randomized study comparing linear distal metatarsal osteotomy with Scarf osteotomy in 40 patients affected by bilateral hallux valgus at 4 years follow-up. All patients were operated bilaterally, and received Scarf osteotomy on one side and SERI osteotomy on the other performed through a 1-cm skin incision under the direct view control. No statistical differences were observed in preoperative HVA, IMA, DMMA in both groups. The average surgical time was 17 min in Scarf and 3 min in SERI ($P < 0.0005$). These operating times are extremely short, and possibly not reproducible by the majority of even-experienced surgeons. No complications were observed in the series, with no wound dehiscence. All osteotomies healed. At 4 year follow-up, no statistical differences were observed in HVA, IMA, DMMA comparing Scarf with SERI. Average AOFAS score was 87 ± 12 in Scarf and 89 ± 10 in SERI ($P = 0.07$), and MFS was 86 ± 7 in Scarf and 90 ± 3 in SERI ($P = 0.08$). The authors concluded that both Scarf and linear distal metatarsal osteotomy techniques resulted effective in the correction of hallux valgus. However SERI, performed with a shorter skin incision, more rapid surgical time, fixed with a less expensive device (one kirshner wire), resulted in better clinical outcome.

Giannini *et al.*[50] also reported on 1000 1000 ft in 641 patients (359 bilateral) with hallux valgus managed by SERI. Inclusion criteria were deformity less than 40° and IMA up to 18°. All patients were checked at an average follow-up of 37 months. All osteotomies healed, delayed consolidation was observed in 25 ft. Slight stiffness was observed in 31 ft. The mean AOFAS score was 48 ± 15 pre-operatively and 89 ± 13 at follow-up. The pre-operative HVA was 32 ± 8, while at follow-up it was 18 ± 8 ($P < 0.005$). Pre-operatively, the IMA was 14 ± 3, while at follow-up it was 6 ± 4 ($P < 0.005$); the pre-operative DMMA was $21 + 9$, while at follow-up was 9 ± 8($P < 0.005$).

Systematic reviews of rapidly developing technologies face a number of challenges, particularly when the technology involved is a therapeutic procedure or a device rather than a medical therapy.[48] In particular, the evidence base includes very few randomized controlled trials. For surgical interventions, it has been estimated that randomized controlled trials are less than 10% of studies, with most of them being retrospective case series.[48,51] Randomized controlled trials are important because they can provide reliable evidence of treatment effects. In contrast, case series rank lower in the hierarchy of evidence, as they are inherently susceptible to bias, and, in the absence of a control group, causal relationships between interventions and outcomes cannot be definitely established. Despite their limitations as evidence, case series for emerging interventions are frequently performed and published. In contrast to randomized controlled trials, such studies are relatively quick and easy to conduct and provide clinicians and patients with some information about the effects of a procedure. Indeed, by the time a technology has developed sufficiently to be evaluated in a randomized controlled trial, evidence from uncontrolled studies may already have convinced clinicians of the effectiveness of the intervention, thus removing the degree of uncertainty (equipoise) that provides the ethical basis for randomizing patients to treatment.[52] Case series may also be useful sources of evidence on safety, because they often have relatively long follow-up and large sample size, and their inclusion criteria may be less strict than those of randomized controlled trials.[48] It follows that, when conducting a systematic review or health technology assessment of a rapidly developing technology, there may be strong arguments in favour of including case series.[53]

Another important issue, when dealing with outcome of hallux valgus correction surgery, is that the numbers of participants in some trials remaining dissatisfied at follow-up is consistently high, even when the HVA and pain had improved.[4] A few of the more recent trials used assessment scores that combine several aspects of the patients outcomes. These scoring systems are useful to the clinician when comparing techniques, but are of dubious relevance to the patient if they do not

address their main concern and such scoring systems have frequently not been validated in a scientifically rigorous fashion.[4] Future research should include patient-focused outcomes, standardized assessment criteria and longer follow-up periods, in the period of 5–10 years.[4]

The main advantages of minimally invasive hallux valgus correction are the shorter surgical times, less soft tissue damages and higher patient acceptance to the approach.[23,24,29,30,33–35,37–39,45,54–68] These features propose minimally invasive surgery as an effective tool for medically compromised patient, such as patients with diabetes mellitus, chronic non-infected, non-healing ulceration secondary to peripheral sensory neuropathy and structural forefoot deformity.[24,29,30]

The clinical results obtained with percutaneous procedures for the correction of mild-to-moderate hallux valgus deformity are comparable to those obtained with other percutaneous distal metatarsal osteotomies and to most series of open surgical procedures.[14,36,43]

Percutaneous techniques must be divided into intra- and extra-articular procedures. Stiffness of the first metatarso-phalangeal joint is one of the most feared complications after hallux valgus surgery. Given the limited scar on the medial side of the first metatarso-phalangeal joint and the extra-articular metatarsal osteotomy, percutaneous procedures theoretically limit the risk of stiffness.[36]

Intra-articular procedures,[36] with extensive bunionectomy, may produce many bony fragments in the joint and capsular tissues, and are potentially a major cause of joint stiffness. If the working area and the joint are not accurately cleaned with rasps and irrigated with normosaline, the remaining bony fragments may induce a florid inflammatory reaction leading to pain, fibrosis and stiffness.

Another important difference in minimally invasive techniques for hallux valgus correction is the fixation used. In the original Bosch technique, the Kirschner wire was uniquely transfixed to the first metatarso-phalangeal joint medial capsule instead of being used to fix the bony capital fragment. Because the Kirschner wire was stabilized proximally, the stiffness of the wire contributed to the lateral translation of the capital fragment. Thus, bunion resection is not necessary in these procedures because the more medial eminence is preserved and results in greater lateral translation of the capital fragment. A limitation of this approach is that the surgeon is often unable to control the magnitude of lateral translation. Considering the fixation, the Kirschner wire is less stable in comparison with screws used in other no lineal distal metatarsal osteotomies. Nevertheless, consolidation of the osteotomy is normally reached in 4–6 weeks.[69]

Advocates against the use of minimally invasive hallux valgus correction report higher rates of complications with these techniques. However, the encountered complications seem to be related more to

improper percutaneous or minimum incision technique[24,29,30] rather than inherent to these techniques themselves.[24,29,30] Improper technique may lead to complications, including thermal injury to skin, delayed- or malunion, neurovascular damages.

Arthroscopic correction of hallux valgus deformity has been proposed to achieve good clinical and imaging results.[25–27] Endoscopic soft tissue procedures employ the same principles as open procedures. All the components of a distal soft tissue procedure (lateral soft tissue release, medial soft tissue plication and resection of medial eminence) can be performed through the small portal wounds under arthroscopic visualization.[25–27] The first metatarso-phalangeal joint can be assessed at the same time and intra-articular pathology can be dealt with accordingly. Arthroscopic correction has the advantages of a minimally invasive approach (e.g. better cosmesis, less soft tissue dissection and less post-operative pain).[25–27] Moreover, the reduction of the sesamoid bones to the corresponding metatarsal grooves can be assessed arthroscopically. As other hallux valgus surgeries, the endoscopic distal soft tissue procedure cannot correct all types of hallux valgus. The contraindications of the endoscopic distal soft tissue procedure are similar to the open procedure (e.g. osteoarthrosis of the first metatarsophalangeal joint).[25–27]

Siclari and Decantis[41] reported on a combination of minimally invasive techniques for the surgical correction of hallux valgus with good short-term follow-up results. Probably, arthroscopy of the metatarsophalangeal joint does not add much to a percutaneous lateral release which would be possible through the small incision needed to introduce the arthroscope. Also, the utility of the arthroscopic synovectomy proposed by the authors has been questioned by the Editor of *Foot and Ankle International*, in an appendix published at the end of the same article.[41] Minimally invasive procedures are controversial, and doubts arise mainly from 'classically' trained orthopaedic surgeons. Some of the concepts of management of hallux valgus using these techniques are not in concert with what is classically described. This, however, reflects the multiplicity of opinions in the general subject of hallux valgus, and there is no real evidence of superiority of one technique over another arising from level I studies. In Continental Europe, these minimally invasive procedures are considered just one alternative to the open procedures, and the recent larger series, where the procedure under study has been performed after the necessary learning curve, provide at least some evidence of the safety and efficacy of the minimally invasive ones.

This document states that the evidence on safety is inadequate. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research. We agree

with this statement, because it is important that full trained surgeons develop these new techniques. In our hands, these techniques provided similar results when compared with the traditional ones.

Conclusion

In a typical systematic review of a rapidly developing technology, such as minimally invasive surgery for the management of hallux valgus, case series contributed substantially to the available evidence base, and their results complemented the absent evidence available from randomized controlled trials. As case series are included in the present review, potential biases must be taken into account, including biases inherent in this study design, overrepresentation of specialist centres with better results than routine clinical practice,[14,36,49,50] publication bias, possible multiple publication of results from the same patients in several papers.

Given the limitations of the case series, especially the 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. Clearly, studies of higher levels of evidence, including large randomized trials, should be conducted to help answer these questions. Future trials should use validated functional and clinical outcomes, adequate methodology, and be sufficiently powered.

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