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Operative versus Non-Operative Management of The Medial Malleolus in Bimalleolar and Trimalleolar Fractures – A Systematic Review

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Abstract

Purpose Ankle fractures are the fifth most common fracture worldwide. Some reviews have shown that non-operative management of isolated medial malleolar fractures has satisfactory outcomes, and more recent studies have suggested the same may apply in bimalleolar and trimalleolar fractures (BTMF). Importantly, non-operative management has the added benefits of avoiding complications including wound infection, and protruding metalwork. This systematic review aims to compare operative and non-operative management of medial malleolar fractures in the context of BTMF. Methods A search syntax of MeSH terms was used to search ScienceDirect, Scopus, Cochrane Library, and PubMed databases. The methodological quality of the included studies was assessed according to the MINORS criteria. Data extracted included patient demographics, operative techniques, functional outcome scores (EQ-5D, OMAS, MOXFQ, VAS, AOFAS return to work/sports) and complication rates Results A total of four studies were included: one randomised-controlled and three prospective study. Two of these directly compared operative and non-operative approaches, while the remaining two reported solely an operative cohort. Of 373 total fractures, 274 were managed operatively and 99 non-operatively. There was no significant difference across all functional scores between operative and non-operative approaches to medial malleolar fractures in the comparative studies. However, there was an association for higher rates of mal/non-union in the non-operative groups (10.5% vs 5.0%). Conclusion Although there is existing belief that operative approach to BTMF would lead to better outcomes, there is currently no evidence that shows operative is superior to non-operative management. Orthopaedic surgeons should consider the morbidity of post-operative complications when deciding the treatment for medial malleolar fractures in BTMF, particularly in the elderly. Further studies need to be performed on this topic before a definitive conclusion can be made

Keywords: Medial malleolus fracture, Operative, Non-operative, Conservative, Bimalleolar fracture, Trimalleolar fracture, Ankle fracture, Outcomes.

INTRODUCTION

Ankle fractures represent one of the most common fractures worldwide [1]. Amongst these, the medial malleolus can be fractured in isolation or in combination with the lateral malleolus and posterior malleolus resulting in bimalleolar and trimalleolar fractures (BTMF) [2]. A Danish study identified that within ankle fractures, the lateral malleolus was most commonly fractured in 55% of cases, followed by trimalleolar fractures at 14%, isolated medial malleolar fractures (IMMF) at 4% and bimalleolar fractures at 10% respectively [3].

A recent epidemiological study looking at 1756 ankles found that 75% of the BTMF occurred in elderly female patients due to low-energy trauma. In contrast, the majority of IMMF result from high-energy trauma and predominantly occur in males [4]. This may explain the unimodal male and bimodal female distribution of ankle fracture injuries [1,5,6].

These findings have important implications for patient management; complications such as wound infection and painful metalwork after open reduction and internal fixation (ORIF) of ankle fractures are more common in elderly patients with vulnerable soft tissues, with incidence rates as high as 39.7% [7] and 23% [8]

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respectively. Furthermore, age has been found to be a significant predictor of increased short-term complications after ORIFs [9]. Traditionally, ORIF is recommended for BTMF due to their inherent instability and the need to obtain an anatomical reduction to maintain long term function. Nonetheless, two recent studies argue that the medial malleolar component of these fractures can be managed non-operatively on a selective basis so long as the lateral or fibular component is stabilised [10, 11]. Although, the evidence analysing the use of non-operative management in BTMF remains sparse, there exists evidence showing that non-operative treatment for IMMF demonstrates satisfactory outcomes [12]. In particular, a previous systematic review looking at 2566 IMMFs concluded that IMMFs with <2mm displacement experience similar outcomes regardless of fixation or non-operative treatment [13]. As such, it may be possible that non-operative treatment versus ORIF of the medial malleolar component in BTMF may demonstrate similar findings.

This systematic review aims to compare the outcomes following operative and non-operative management of medial malleolar fractures in the context of BTMF. To the authors' knowledge, a systematic review on this question has not yet been reported in the literature.

METHODS

Search strategy

This systematic review was carried out following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines [14]. Search syntax consisting of the keywords: "medial malleolus" and "internal fixation" or "conservative" was done across four databases PubMed, ScienceDirect, Scopus and Cochrane Library by three reviewers (WW,A., B,B. and ZZ,L.) on the 10/2/2020. A search syntax with MeSH Terms was generated accordingly to extend our search (Appendix 1).

Selection criteria

Studies that included medial malleolar fractures in the context of BTMF published after year 2000 in English were included. Studies looking solely at isolated medial malleolar fractures, stress fractures, posterior or lateral malleolar fractures were excluded. Studies were excluded whenever they reported outcomes without segregating the fractures into isolated, bimalleolar or trimalleolar fractures, as the authors were unable to extract data according to our inclusion criteria. Other exclusion criteria included paediatric/animal/cadaveric studies, biomechanical studies, case reports/reviews/grey literature, surgical technique studies, books and educational studies.

Once duplicate articles were removed, the titles and abstracts were screened, with articles filtered accordingly to the inclusion and exclusion criteria mentioned above. The remaining articles were read in full by two reviewers (WW, A. and S, J.) to assess suitability for inclusion. If consensus was not achieved, the other reviewers (B,B., ZZ, L. and N, QQX.) were consulted for agreement. Additional appropriate articles were identified through the references of the final articles, if any.

Quality appraisal

The Methodological Index for Non-Randomised Studies (MINORS) was used to assess the quality of the included studies[15]. This was carried out by two reviewers (WW, A. and S, J.).

Data extraction for baseline characteristics and outcomes

Data extraction process was carried out by two reviewers (WW, A. and S, J.). Baseline characteristics such as year, study design, intervention (operative or non-operative), treatment method, number of patients, age and mean follow-up time were tabulated.

The authors aimed to evaluate functional outcomes to compare operative vs non-operative mangements. These were assessed by American Orthopaedic Foot and Ankle Society (AOFAS) score, Olerud-Molander Ankle Score (OMAS), Manchester Oxford-Foot Questionnaire (MOXFQ), EQ-5D, Visual Analogue Scale (VAS) and time to return to baseline function. Complications such as revision surgery, malunion, infection, metalwork removal, malposition, posttraumatic osteoarthritis and deep vein thrombosis (DVT) were also recorded.

RESULTS

Study selection

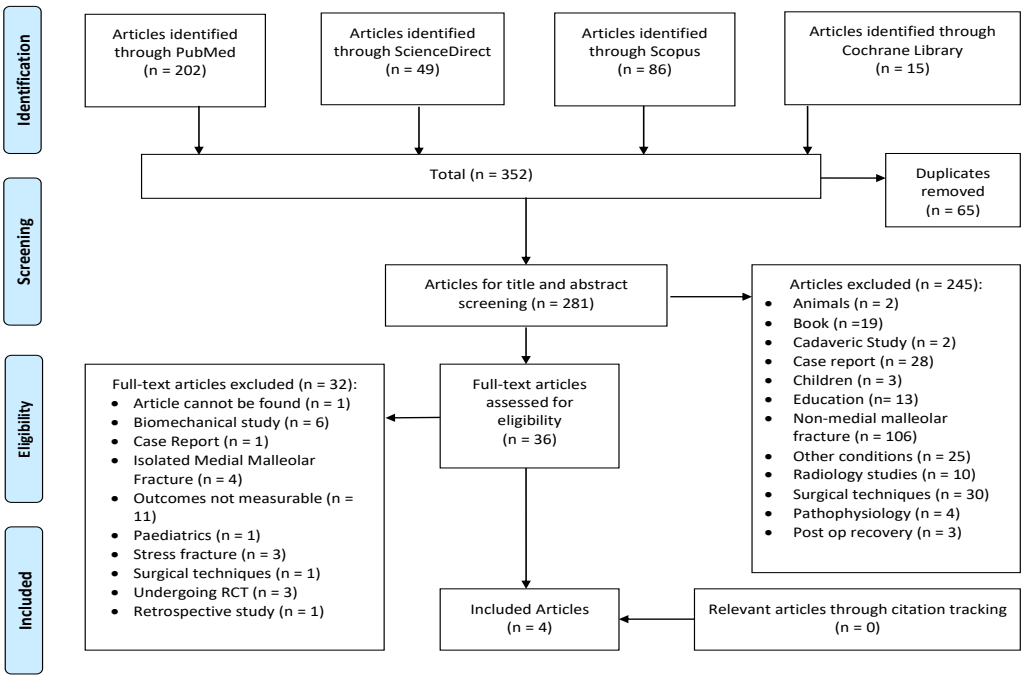

Figure 1: PRISMA flow diagram for the selection of studies.

The flow diagram for our literature search is depicted in Figure 1. Four articles [10, 11, 16, 17] were selected for this systematic review, after screening according to our inclusion and exclusion criteria. There were no additional articles found through reference checking of these articles.

Quality of studies

The MINORS score was used to assess the quality of the included studies as shown in Table 1. The mean score was 11.5 (range 10-13). All studies scored low on the "assessment of endpoints" component as blinding was not possible due to the nature of the intervention. Furthermore, two studies [16, 17] did not exhibit power analysis on their sample size, attributing to their lower scores in the criteria for quality of study size.

Table 1: Quality assessment of the four articles for this systematic review using MINORS assessment tool.

Author	Aim	Inclusion of patients	Data collection	Endpoints	Assessment of endpoints	Follow-up period	Loss to follow up	Study size	Total
Carter *et al.*(11)	2	2	2	2	0	2	1	1	**12**
Hoelsbrekken *et al.*(10)	2	2	2	2	0	2	1	2	**13**
Braunstein *et al.*(16)	2	2	2	2	0	2	1	0	**11**
Tekin *et al.*(17)	2	1	1	2	0	2	2	0	**10**

Baseline characteristics of studies

Table 2 contains the baseline characteristics of the four studies [10, 11, 16, 17]. Of these, one is a randomised controlled trial [10] and three prospective cohort studies [11, 16, 17]. Two studies (40%) compared operative and non-operative treatment [10, 11] and two (60%) analysed operative treatment alone [16, 17]. Overall, there were 373 patients, with a mean age of 60.9 (range 20 – 96) and mean follow up time of 44.4 months (range 8-120 months). Various fixation methods were used, including screws, tension band wires, and arthroscopic treatment. For the two comparative studies, 230 patients were treated operatively while 99 patients were treated non-operatively. The two comparative studies included patients with BTMF exclusively. In the other two studies, the patients were split into those with isolated medial malleolar, bimalleolar or trimalleolar fractures. As per our inclusion criteria, only the patients with BTMF were included for the purpose of our systematic review. Table 3 shows the number of patients classified according to the AO Foundation/Orthopaedic Trauma Association (AO/OTA) or Hersovici classification and fracture type.

Table 2: Table containing baseline characteristics of the four studies included for this systematic review. NR: not recorded; PS: prospective study; RCT: randomised controlled trial

Author	Year	Study design	Intervention	Treatment method (n)	Number of patients/feet	Age of patients (years)	Mean follow-up (months)	Level of evidence
Carter *et al.* [11]	2019	PS	Surgical	Cancellous screws (165) tension band wire (28)	193/193	65 (range 25-96)	57.6 (range 8-120)	III
			Conservative	-	54/54	72 (range 31-96)	57.6 (range 8-120)	
Hoelsbrekken *et al.* [10]	2013	RCT	Surgical	Two lag screws (35) two k-wires (1) single k-wire and one lag screw (1)	37/37	49 ± 17	44 (range 24-72)	II
			Conservative	-	45/45	56 ± 14	41 (range 24-67)	
Braunstein *et al.* [16]	2020	PS	Surgical	Arthroscopically assisted ankle fracture treatment (32)	32/32	46 (27)	12	IV
Tekin *et al.* [17]	2016	PS	Surgical	Anterograde headless cannulated screws (12)	12/12	39.3± 9.1 (range 27-55)	17.2 ± 5.3 (range 12-23)	III

Table 3: Table containing the number of patients according to the AO/OTA or Hersovici classification and type of fracture. NR – not reported.

Author	Intervention	AO/OTA classification	Hersovici Classification	Type of fracture	Number of patients
Carter *et al.* [11]	Surgical	44-B2/B3	NR	NR	158
		44-C1			9
		44-C2			26
	Conservative	44-B2/B3	NR	NR	46
		44-C1			0
		44-C2			8
Hoelsbrekken *et al.* [10]	Surgical	44-B2	NR	NR	16
		44-B3			14
	Conservative	44-B2	NR	NR	20
		44-B3			17

Braunstein *et al.* [16]	Surgical	44-A (3) 44-B (24) 44-C (7)	NR	Bimalleolar	7
				Trimalleolar	20
Tekin *et al.* [17]	Surgical	44-B2	B	Bimalleolar	5
				Trimalleolar	0

Outcomes

Various metrics of functional outcomes and complication rates were reported in the studies. These are shown in Table 4 and 5 respectively.

Table 4: Table showing the outcomes of the two studies comparing surgical to conservative treatment. OMAS - Olerud-Molander Ankle Score; MOXFQ - Manchester-Oxford Foot Questionnaire; VAS – visual analogue scale; AOFAS - American Orthopaedic Foot & Ankle Society. NR – not reported.

Author	Intervention	EQ-5D	OMAS	MOXFQ	VAS - pain	VAS - health	AOFAS	Return to work (weeks)	Return to sport (weeks)
Carter *et al.*(11)	Surgical	0.81	80	9.4	9*	8.0*	NR	8	12
	Conservative	0.8	85	17.2	9.2*	8.1*	NR	6	12
		p-value 0.846	p-value 0.885	p-value 0.380	p-value 0.626	p-value 0.306		p-value 0.476	p-value 0.771
Hoelsbrekken *et al.*(10)	Surgical	NR	80	NR	7.6*	NR	88	NR	NR
	Conservative	NR	81	NR	7.7*	NR	87	NR	NR
			p-value 0.91		p-value 0.87		p-value 0.85		
Braunstein *et al.*(16)	Surgical	NR	87.6**	NR	NR	NR	91.8**	NR	NR
Tekin *et al.*(17)	Surgical	NR	NR	NR	NR	NR	89.4 (range 87 - 97)	NR	NR

*VAS scale used here 0-10 with 10 being least pain **calculated by author by averaging outcomes of both bimalleolar and trimalleolar fractures

Table 5: Table showing the complications reported in each of the four studies. DVT - Deep Vein Thrombosis

Author	Intervention	Revision surgery (%)	Malunion/ nonunion (%)	Soft tissue infection (%)	Metalwork removal (%)	Malposition (%)	Posttraumatic osteoarthritis (%)	DVT (%)	Superficial skin necrosis (%)
Carter *et al.*(11)	Surgical	11 (6)	22 (11)	18 (9)	14 (7)	NR	NR	NR	NR
	Conservative	4 (7)	16 (30)	NR	-	NR	NR	NR	NR
		p-value 0.634	p-value 0.002						
Hoelsbrekken *et al.*(10)	Surgical	0 (0)	0 (0)	2 (5)	NR	4 (11)	3 (8)	1 (3)	NR
	Conservative	0 (0)	4 (9)	4 (9)	NR	3 (7)	1(2)	0 (0)	NR
			p-value 0.063	p-value 0.55		p-value 0.15	p-value 0.22	p-value 0.45	
Braunstein *et al.*(16)	Surgical	NR	1 (3)	0 (0)	0 (0)	NR	NR	NR	2 (6)
Tekin *et al.*(17)	Surgical	NR	0 (0)	0 (0)	NR	NR	0 (0)	NR	NR

Functional outcomes

Overall, all surgical patients displayed good function following intervention, according to the various functional scoring systems. Between the operative and non-operative groups there were no significant differences in functional outcome in either of the two comparative studies [10, 11], nor were there significant differences between time taken for return to work (8 weeks vs 6 weeks, p = 0.476) or sports (12 weeks vs 12 weeks, p = 0.771) [11].

AOFAS

The American Orthopaedic Foot & Ankle Society (AOFAS) system describes pain, function and alignment. In Hoelsbrekken *et al.*'s study [10], there were no significant differences between the operative and non-operative groups (p = 0.85), giving a mean 88 and 87 AOFAS score respectively. All the studies looking at surgical interventions had AOFAS scores of 89 and above [16, 17].

EQ-5D

EQ-5D is a standardised scoring system used for measuring health-related quality of life across five domains: mobility, self-care, usual activities, pain and anxiety/ depression. EQ-5D was measured in Carter *et al.*'s study [11], which showed no significant difference between the

groups. The operative group showed a mean of 0.81, compared to the non-operative group with a mean of 0.8 (p = 0.846).

OMAS

The Olerud-Molander Ankle Score (OMAS) score, considered to be a reliable and validated measure of functional outcome following ankle fracture, is based on nine items: pain, stiffness, swelling, stair climbing, running, jumping, supports and work/activities of daily life. OMAS scores in the two comparative studies showed no significant differences [10,11]. OMAS scores were a median of 80 in operative versus 85 in the non-operative group in Carter *et al.*'s study (p = 0.885, 247 patients) [11], and a median of 80 in the operative versus 81 in the non-operative group in Hoelsbrekken *et al.*'s study (p = 0.91, 82 patients) [10]. OMAS scores were also measured in Braunstein *et al.*'s study [16], showing a mean of 95 in patients with bimalleolar fractures and 85 in patients with trimalleolar fractures.

MOXFQ

The Manchester-Oxford Foot Questionnaire (MOXFQ) is a validated measure assessing health-related quality of life following foot and/or ankle corrective surgery, with 16 items assessing outcome. Carter *et al.* [11] is the only study which used the MOXFQ outcome measure, showing that operative management displayed a lower mean of 9.4, compared to non-operative treatment with a mean of 17.2. A lower mean demonstrates a more positive outcome. However, this did not reach statistical significance (p = 0.380).

VAS

The visual analogue scale (VAS) score similarly showed low pain rates amongst the studies after intervention. Carter er al [11] demonstrated a median of 9 and 9.2 to indicate pain, and 8 and 8.1 to indicate health, in operative and non-operative groups respectively. Hoelsbrekken *et al.* [10] demonstrated a mean VAS pain score of 7.6 and 7.7 in operative and non-operative groups. In both studies the VAS outcomes were shown to not have significant differences between the two groups.

Complication rates

Non-union, Mal-union

In Carter *et al.*'s study [11], radiographic evidence of medial malleolar fracture consolidation was reviewed between six and eight weeks post-operatively, with 16 (30%) patients of the non-operative group failing to show radiological union compared to 22 (11%) patients of the operative group, displaying a significant difference (p = 0.002). In Hoelsbrekken *et al.*'s study, there was no significant difference of non-union between operative and non-operative groups (p = 0.063), although the non-operative group had a higher incidence of non-union (4 patients, 9%) compared with none (0%) of the operative group.

One patient (3%) of Braunstein *et al.*'s study [16] required revision surgery following non-union of fracture; whereby cannulated screws were replaced by a locking hook plate. Tekin *et al.*'s study [17] had no malunion/nonunion complication in their patients.

In one study [10], there was no significant difference (p value = 0.15) of healing in malposition (malunion is the usual terminology), with four patients (11%) of the operative group experiencing this compared to three (7%) in the non-operative group. In the operative group, one patient required further surgery due to malposition of screws. [11, 12, 16, 17].

Metalwork Removal

In Carter *et al.*'s study [11], 14 of 158 (7%) patients who underwent surgical fixation, with either a partially threaded cancellous screw or a tension band wire construct, required metalwork removal due to painful medial prominence. Metalwork removal was not required in one study [17], and was not evaluated in the other two studies [10,16].

Soft tissue infection and other complications

In Hoelsbrekken *et al.*'s study [10], rates of complications had no significant difference between the two groups. Soft tissue infections occurred in 2 (5%) of the operative group and 4 (9%) of the non-operative group (p = 0.55). Post-traumatic osteoarthritis occurred in 3 (8%) of the operative group compared to 1 (2%) of the non-operative group (p = 0.22). A single patient (3%) of the operative group experienced a DVT, compared to none being reported in the non-operative group (p = 0.45).

Meanwhile, Carter *et al.* [11] reported 18 patients (9%) of the operative group developed soft tissue infection. Two patients (6%) in Braunstein *et al.*'s study [16] displayed superficial skin necrosis at the site of skin incision and required management with antibiotics and superficial surgical debridement. No complications were reported in Tekin *et al.*'s study [17].

DISCUSSION

Our study shows that there is no significant difference in functional outcome following operative or non-operative treatment of the medial malleolus for BTMF [10, 11]. However, the non-union rate was significantly higher in the non-operative group [11], with the other study approaching statistical significance with a p-value of 0.063 [10]. It is interesting that despite higher non-union rate in the conservative group, there is no significant difference in functional outcomes between the two groups. This could be explained by our current understanding that displacement of the medial malleolus play less of a biomechanical significance as long as the lateral component is anatomically reduced [10].

As mentioned previously, a systematic review has shown IMMF of <2mm displacement has similar outcomes with operative vs non-operative management [13]. Nonetheless, the fact that IMMF can be managed nonoperatively, should not be taken as an indication that the medial component of BTMF should be managed nonoperatively. This is because such an approach does not take into consideration the criterion of fracture stability as indication for surgical management. Stability is the key issue in ankle fractures, thus, one can argue that many of those IMMF managed nonoperatively (in some studies) were stable, and therefore the outcome was good. BTMF are by definition unstable, therefore would require fixation. If we wanted to prove the MM fixation is not necessary for BTMF, an RCT would be needed, including fractures of one type (eg supination external rotation), following exactly the same rehabilitation protocol postoperatively. This means allowing removal of cast and weight bear at the same time for both groups. Leaving the MM containing the deep deltoid ligament attachment "unfixed", is beyond the rationale of fracture stability, and would require more protective rehabilitation. Such a study should be carefully designed and adequately powered to show whether the potential benefits (from not fixing one side), outweigh the risk (nonunion, malunion, ankle instability).

Additionally, this study found complications of soft tissue infection to be generally higher in the surgical group[7–9]. However we are unable to draw conclusions about this from ours results as Carter *et al.*. [11] did not report soft tissue infection rates in the conservative group, while Hoelsbrekken *et al.*'s study showed a higher rate of 4 infections in the conservative compared to 2 in the surgical group[10]. Hoelsbrekken did

not specify the site of infection, meaning that it is likely due to lateral site fixation. Furthermore, the small sample size could have confounded this result.

Metalwork removal is another well-recognised surgical complication, secondary to pain and prominence of metalwork over the medial malleolus. This finding is particularly relevant to the management of elderly female patients in whom these fractures occur frequently [1, 5] and who are at increased risk of post-op complications due to poorer skin quality over the medial malleolus [9]. Interestingly, our study found that new surgical methods had higher average AOFAS scores [16], reduced need for metalwork removal [16] and no soft tissue infections [16,17]. Such novel methods have been developed to reduce discomfort and pain associated with prominent metalwork over the medial malleolus, which is a common complaint in patients [18], with one study showing the need of further surgeries for removal of metalwork in up to 17% of the patients [19]. This is hugely beneficial to both the patients and healthcare providers as repeated surgeries would require prolonging the non-weight bearing period along with increased healthcare costs [20]. However, it is to be noted that the age groups of patients in these studies were relatively younger than Carter's and Hoelsbrekken's patient group, which may account for the better functional outcome scores. Furthermore, as these studies only had small study sizes, the authors would cautiously withhold recommendations on these surgical techniques until further studies have been carried out to validate their benefit.

Limitations

A scoping review was performed to establish the current existing evidence in this topic. The authors noted that there are limited studies comparing operative vs non-operative management of BTMF. Therefore, the authors decided to include studies looking at solely operative or non-operative management of BTMF as well in this systematic review, which allows for greater comparison in the context of limited data [21].

This systematic review included only one RCT, demonstrating a lack of availability of high-quality studies investigating this specific topic. Studies were excluded when outcomes could not be analysed, as all different types of medial malleolar fractures were grouped together. Nonetheless, the comparative studies reviewed in our study were of level of evidence II and III respectively. The baseline characteristics between the two groups in Carter *et al.*'s study were not controlled for which could have affected comparison of the outcomes; in particular, the 54 non-operative ankles were minimally displaced, and did not have high energy injury or open fracture, compared to the operative group. A meta-analysis also could not be performed due to limited data.

It must also be noted that the RCT only included patients with medial malleolar fractures with displacement of <2mm. Therefore, findings of insignificant differences between operative and non-operative groups may be limited to patients with minimally displaced fractures. The 2mm "displacement" rule is dogmatic, has never been proven and should not guide management until proven. However, the other prospective study with a larger study size included all medial malleolar in BTMF, and similarly found insignificant differences in functional outcomes between the two groups. A trial, called the MOON study – Medial Malleolus: Operative or Non-operative is currently underway to investigate the utility of conservative treatment for minimally displaced multimalleolar medial malleolar fracture, and it is hoped that their findings will add further evidence towards treatment of this condition.

CONCLUSION

Overall, there is currently limited evidence to guide decision making in the management of BTMF. The choice of operative vs non-operative treatment of medial malleolus in BTMF should be guided by patient characteristics and current practices. Although there is existing belief that surgical approach to BTMF would lead to better outcomes, there is currently no existing evidence that shows surgical fixation is superior to conservative management. We have found limited evidence that functional outcomes are similar between operative and non-operative management for undisplaced/minimally displaced medial malleolus in BTMF, provided the fibula is appropriately stabilised. Although, the non-union rate in the non-operative group has been found to be significantly higher in one of the studies, further studies need to be performed in this field before a definitive conclusion can be made.

Appendix

Appendix 1: (medial[All Fields] AND malleolus[All Fields]) AND (("fracture fixation, internal"[MeSH Terms] OR ("fracture"[All Fields] AND "fixation"[All Fields] AND "internal"[All Fields]) OR "internal fracture fixation"[All Fields] OR ("internal"[All Fields] AND "fixation"[All Fields]) OR "internal fixation"[All Fields]) OR conservative[All Fields])

Appendix 2:

Methodological items	2	1	0
Aim	Aim or hypothesis including clear outcomes has been reported	Aim or hypothesis has been reported without a clear outcome	Not reported
Inclusion of patients	Explicit inclusion or exclusion criteria have been reported	Unclear or poor description of inclusion and exclusion criteria have been reported	Not reported
Data collection	Prospective	Retrospective	Not reported
Endpoints	Outcomes are appropriate to the aim of the study	Outcomes are not appropriate to the aim of the study	Not reported
Assessment of endpoints	Blind evaluations of objective outcomes and double-blind	Blinding of one or more outcomes has been reported	Blinding not performed or not reported
Follow-up period	≥1 year	<1 year	Not reported
Loss to follow up	≤5%	>5% and ≤20%	Not reported or >20%
Study size	Power analysis has been performed	Explanation of study size has been reported	Power analysis and explanation of study size not reported

Conflict of Interest

The authors declare that they have no conflict of interest.

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Ethical approval

This article does not contain any studies with human participants or animals performed by any of the authors.

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