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Review Articles

A Systematic Review Investigating the Effectiveness of Surgical Versus Conservative Management of Unstable Ankle Fractures in Adults

Lugman Elgayar, MBChB, MRCS, MSc[1], Frances Arnall, MPhil, MCSP, HPC, PGCAP[2], Jim Barrie, FRCS Ed[3]

[1] *Clinical Research Fellow, Trauma and Orthopaedic Department, University Hospital of Wales, Cardiff, United Kingdom*
[2] *Consultant Physiotherapist, School of Health and Society, University of Salford, Manchester, United Kingdom*
[3] *Honorary Professor of Orthopaedics Education, School of Health and Society, University of Salford, Manchester, United Kingdom*

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ABSTRACT

Nine percent of all fractures affect the ankle, with an annual incidence of 122/100,000 in Edinburgh, UK. While unstable fractures are usually treated surgically, there has been no recent systematic review of the evidence supporting this decision. In this systematic review, relevant electronic databases (such as MEDLINE and CINHAL) were searched from inception to February 2017. Five randomized controlled trials that examined surgical versus conservative interventions in 951 adults with closed ankle fractures, with follow-up for at least 6 months, were selected for further synthesis of evidence. The risk of selection bias in all selected trials was relatively low. However, most of the trials had a high risk of performance and detection bias. Three of the 5 selected trials used the validated functional Olerud Molander Ankle Score. One trial (n = 43), reported a statistically better score for the surgical group at 27-month follow-up, whereas a second (n = 81) and a third (n = 620) trial found no significant difference at 12 and 6 months, respectively. No significant differences between surgical and conservative treatments were reported in 2 trials (n = 111) and (n = 96) in nonvalidated functional outcome measures. Other outcomes were malunion (9/334 [2.6%] versus 48/301 [15.9%], $p < .0001$) and nonunion (3/408 [0.7%] versus 28/383 [7.3%], $p < .0001$) and were considerably higher in the conservatively treated group. Early treatment failure was significantly lower with surgery (7/435 [1.6%] versus 70/419 [16.7%], $p < .0001$). The risk of malunion, nonunion, and loss of reduction were greater in nonoperative care. However, the 2 treatment approaches provided equivalent functional outcomes.

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Ankle fractures are articular fractures that occur when the distal tibia or fibula that forms the ankle joint is broken, and this is often associated with ligament and soft tissue injuries (1). Nine percent of all fractures affect the ankle joint (2), with an incidence of 122 fractures per 100,000 people per year in Edinburgh, UK (3). Ankle fracture incidence has been increasing in the population aged >50 years, and both females and males are affected (3). There are 3 commonly used classification systems for ankle fractures [Lauge-Hansen (4), Weber (5), and Müller AO (6)], and they are based on different theories such as the morphology and the mechanism of injury. However, none of them provides sufficient consideration to the stability, which is the most important determinant in clinical decision-making (7).

Stable fractures can be treated conservatively, and surgical intervention is reserved for unstable fractures with a high risk of secondary displacement (7). Although there is a general perception that open reduction and internal fixation (ORIF) of unstable fractures would yield better radiographic and clinical outcomes, previous systematic reviews have not reported this clinical advantage consistently, and no recent systematic review of the evidence supports this decision. Therefore, with no consensus among the researchers, there is a need to investigate the clinical and radiological outcomes as well as the adverse events of the 2 therapeutic options for unstable ankle fractures.

Materials and Methods

Randomized controlled trials (RCTs) that compared surgical and conservative treatments of unstable ankle fractures (dislocation, bimalleolar, and trimalleolar fracture and lateral malleolar fracture with the radiological signs of talar shift) in adults were included in this systematic review. Surgical interventions included ORIF by any means of fixation. Conservative modalities included all types of noninvasive interventions to stabilize ankle fractures. The language and publication date were not restricted in the present systematic review. Adult patients >18 years old were only included as fractures in children have different management approaches (8). Six-month follow-up was the minimum period, which is the time needed to consider the diagnosis of nonunion in ankle fractures (9). Open and extensive fractures of the distal third of the tibia were excluded, as conservative management is not feasible. Preferences were given to validated functional outcome measures such as Olerud Molander ankle score (OMA) (10), validated generic Short-Form 36-Item health survey (SF-36) (11), and the Short Form 12-Item health survey (SF-12

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Address correspondence to: Lugman Elgayar, MBChB, MRCS, MSc, University Hospital of Wales, Heath Park Way, Cardiff, CF14 4XW, UK.
E-mail address: lugmanelgayar85@gmail.com (L. Elgayar).

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version) (12), but other different clinical measures and questionnaires were also considered. The outcomes of radiological evaluation of nonunion and malunion as measured by a variety of anatomical measurements such as the criteria of Magnusson (13) and Cedell (14), the widening of medial clear space (MCS >5 mm), and talar subluxation or shift (>2 mm) were included. Three adverse events were considered: early treatment failure, infection, and ankle osteoarthritis.

The PubMed search engine was used to search the MEDLINE database using the following MeSH terms: "ankle fractures" [MeSH] AND "surgical procedures, operative" [MeSH]. A combination of keywords such as "ankle fractures AND surgery* AND "conservative management" AND "functional outcomes" were used in the search engines of Web of Science and Science Direct. CINHAL database was also searched. In addition, reference lists of relevant studies were checked, and authors of included trials as well as some foot and ankle consultants in the United Kingdom were contacted to get additional information on any ongoing or unpublished studies.

The first reviewer (L.E.) evaluated relevant trials against the prespecified inclusion criteria, and the second reviewer (F.A.) was consulted when there was doubt. The process of data extraction was performed by 2 reviewers (L.E. and F.A.) using a standardized form. Potential biases in the included studies' practices were assessed by 2 independent reviewers (L.E. and F.A.) using the Cochrane Collaboration tool for assessing risk of bias in RCTs (15), and any disagreement was resolved by discussion. Where judged appropriate, we used the probability values (p value), risk ratio (RR), and 95% percent confidence intervals (CIs). Also, whenever possible, we pooled and represented data using the fixed-effect model based on the assumption that the estimated effects from the selected studies come from a single homogeneous population (i.e., adult participants with similar condition exposed to the same treatment) (16). Meta-analysis was performed using RevMan 5.3 review manager (17). I^2 and χ^2 statistical tests were used to assess the statistical heterogeneity of the included studies. For the differences in the effect size, the standard p value should be $\leq$.05 for the comparison to be significant.

Results

Seven hundred fifty-four articles were returned by using the search strategy, of which 5 (0.66%) RTCs with 951 participants met our inclusion criteria (Fig. 1). Two of 5 studies were published in 1985 (18,19), and both had relatively long follow-up at 7 years (18) and 3.5 years (19). In 2 studies published in 2001 (12) and 2016 (21), the authors limited their studies to elderly patients, and the follow-up was at 27 months and 6 months, respectively. The follow-up in the 2012 study (22) was at 6, 12, 24, and 52 weeks. However, only data at 12 months were included in this analysis.

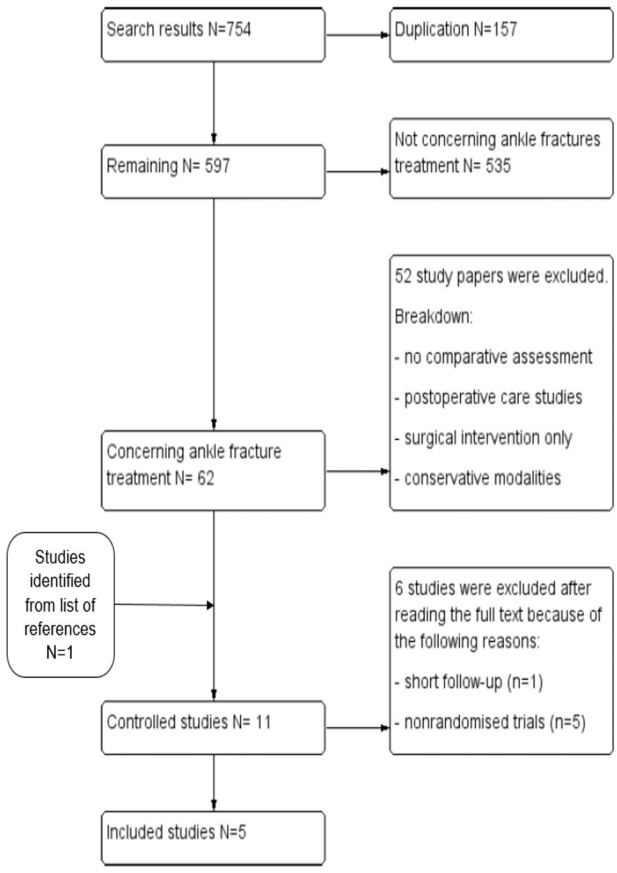

Fig. 1. Flow diagram of the systematic review.

The included studies provided a direct comparison between the surgically treated group (n = 446) versus the conservatively treated group (n = 455). Mean age of participants in the trials varies from a mean age of 41.6 years (19) to 71 years (21). The range of age was also variable among the trials with (range 15 to 78 years) in 1 trial (19) to 55 to 88 years in another trial (20). Two thirds of all participants were female. Different classification systems of ankle fractures were used: Weber in 2 articles (18, 22), the Lauge-Hansen in 1 article (19), and neither in 2 articles (20, 21) (Table. 1), but only displaced or unstable fractures that would usually be offered surgery were included.

Risk of bias in included studies is illustrated in Fig. 2. Overall, the risk of selection bias in all trials was relatively low, and only the Bauer et al study in 1985 (18) was judged to have high risk in allocation concealment. Due to the nature of the interventions, it was not possible to mask the surgeons or participants in all studies. However, in the Willett et al study in 2016 (21), the risk of bias in the assessment of clinical outcome was minimized by applying opaque ankle bandages to obscure the ankle. The risk of attrition bias was low in Willett et al in 2016 (21) as 93% of the participants completed the study. Makwana et al in 2001 (20) and Phillips et al in 1985 (19) were judged at high risk of attrition bias as the dropout rate was 28% and 49%, respectively. One study (21) was judged at low risk of reporting bias as all prespecified outcomes were reported as per study protocol.

Function and Clinical Outcomes

No significant differences in clinical outcomes between surgical and conservative treatments were reported by the oldest 2 trials, Bauer et al (18) and Phillips et al (19) in nonvalidated functional outcome measures (Table 2). Although swelling rate in Bauer et al (18) was higher in the surgical group (15 of 43 [34%] versus 8 of 49 [16%], p = .04), the clinical outcomes at 7 years were similar. However, in Phillips et al (19), the total combined score was significantly better in the surgical group (127 of 150 versus 116.7 of 150, p = .05), but there was no significant difference between the 2 groups in clinical outcomes with (88.8 of 100 versus 84.3 of 100, p = .2) (Table. 2).

Three (of 5) trials used the validated OMA score (10) (Table 3). The first trial, Makwana et al (20), reported a better score (mean difference = 17.00, p = .03) for the surgical group at 27 months, whereas Sanders et al (22) and Willett et al (21) found no significant difference at 12 and 6 months, respectively (Table 3). Similar to the OMA score, the SF-36 in Sanders et al (22) failed to demonstrate a significant difference between the 2 groups with results of 79.5 of 100 for the surgical approach and 77.5 of 100 for the conservative approach (p = .07). The SF-12 in Willett et al (21) demonstrated similar results with 45.6 of 100 for surgery and 44.0 of 100 for conservative management.

Radiological Evaluation

The rates of nonunion and malunion observed after the surgical and nonsurgical treatments are illustrated in Table 4. The total nonunion (3 of 408 [0.7%] versus 28 of 383 [7.3%], $p < .0001$) and malunion (9 of 334 [2.6%] versus 48 of 301 [15.9%], $p < .0001$) rates were considerably higher in the conservatively treated group (Figs. 3 and 4).

Complication Rate

Table 4 illustrates the rates of 3 adverse events (early treatment failure, infection, and osteoarthritis) observed after the 2 treatment

Table 1
Population characteristics

Study Authors (Year)	Participants			Mean Age (y)	Sex Ratio (M: F)	Classification	Comorbidities	Design
	Total	S	C					
Bauer et al (18)	111 (baseline data = 108)	51	57	44	44/64	Weber B and Weber A (n = 8)	NM	RCT
Makwana et al (20)	43	22	21	66	12/31	Displaced ankle fracture	HT = 14 CS = 5 Smoker = 6	RCT
Phillips et al (19)	96 (followed 49 only)	23	26	41.6	42/54	SER-4 or PER-4 Lauge-Hansen system	NM	RCT
Sanders et al (22)	81	41	40	41	41/40	Weber B	DM = 3 Smoker = 19	RCT
Willett et al (21)	620	309 (309 − 7 = 302)	311(311 − 34 = 277)	71	160/460	Unstable ankle fracture	HT = 266 OA = 184 Smoker = 57	RCT
Total	951	446	455		299/649			

Abbreviations: C, conservative; CS, corticosteroid; DM, diabetes mellitus; F, females; HT, hypertension; M, males; NM, not mentioned; OA, osteoarthritis; PER, pronation external rotation; S, surgery; SER, supination external rotation; RCT, randomized controlled trial.

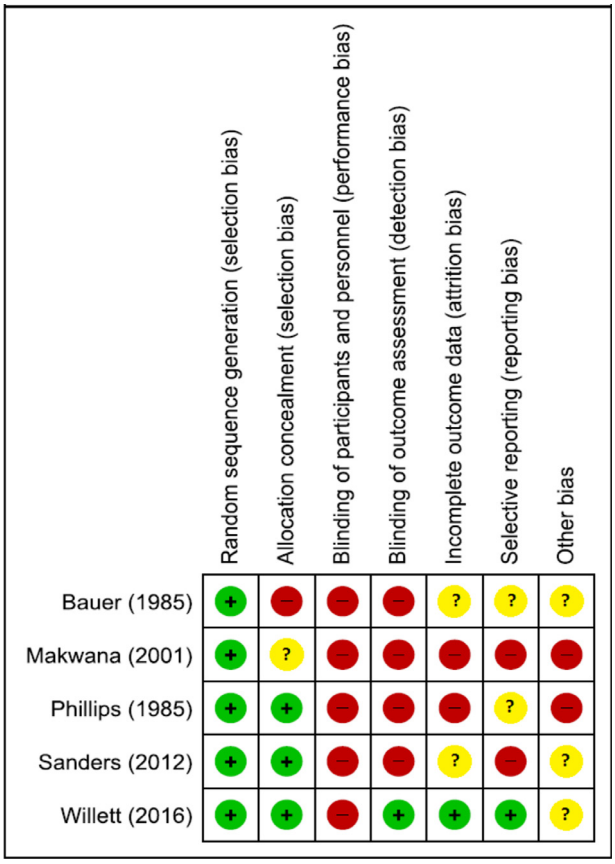

Fig. 2. Risk of bias summary.

approaches. Early treatment failure was significantly lower with surgery (7 of 435 [1.6%] versus 70 of 419 [16.7%]; RR 0.11, 95% CI 0.06 to 0.23; $p < .0001$) (Fig. 5). The total infection rate reported was greater after ORIF, but this difference was not statistically significant with the numbers available (16 of 424 [3.7 %] versus 6 of 402 [1.4 %]; RR 2.21, 95% CI 0.95 to 5.13; $p = .07$). Finally, the number of patients with radiological signs of osteoarthritis reported by 2 of 5 trials [Bauer et al (18) and Phillips et al (19)] was slightly higher in the conservative group (46 of 66 [69.6%] versus 50 of 75 [66.6%]; RR 1.05, 95% CI 0.83 to 1.31; $p = .70$).

Discussion

Application of the preidentified criteria of eligibility leads to the inclusion of 5 RCTs, which is a relatively small number. However, the comprehensive electronic search strategy allowed confidence to conclude that almost all the important trials related to the review question were successfully included. Hence, the conclusion arising from this review was based on the synthesis of evidence from all the key research available in the literature.

Overall, there were noticeable differences between the 5 included studies, particularly in the study dates, classification system, demographic data, interventions and postintervention instructions, outcome measures, and duration of follow-up. These studies were conducted in the past 5 decades in different time periods. While 3 of the 5 recent trials (20–22) are expected to provide up-to-date information about the comparative effectiveness of the previously mentioned treatment approaches, the other 2 are relatively old trials (18,19) and could provide information that might not be valid in the current practice. Another variation among the included studies that might lead to miscategorization of the participants is the lack of a unified classification system that clearly defines the criteria of an unstable fracture.

Table 2
Summary of the questionnaire values used by Bauer et al (1985) and the combined score used by Phillips et al (1985) to assess function

Study/Subgroup		Follow-Up (y)	Surgical		Conservative		
			n/N	Mean (SD)	n/N	Mean (SD)	*p*
Bauer et al (18)	1: Complaints of significant symptoms (pain, restricted range of motion, and walking difficulties)	7	11/43 (25.5%)	NM	14/49 (28.5%)	NM	NM
	2: Swelling		15/43 (34.8%)	NM	8/49 (16.3%)	NM	<.05
Phillips et al (19)	1: Combined score (clinical plus anatomical pus arthritis: 0 to 150 best)	3.5	23/23	127 (13.9)	26/26	116.7 (19.4)	<.05
	2: Clinical score		23/23	88.8	26/26	84.3	.2

Abbreviations: NM, not mentioned; SD, standard deviation.

Table 3
Olerud Molander Ankle score reported by Makwana et al, 2001, Sanders et al, 2012, and Willett et al, 2016

Study Authors (Year)	Follow-Up (mo)	Surgical		Conservative		P Value
		n	Mean (SD)	n	Mean (SD)	
Makwana et al (20)	27	19	77 (25)	12	60 (21)	.03
Sanders et al (22)	12	41	85.6 (19.1)	40	82.4 (25.2)	.42
Willett et al (21)	6	291	66.0	267	64.5	NM

Abbreviations: NM, not mentioned; SD, standard deviation.

studies (21,22), there were no differences between the groups regarding medical history or substance use, and this could limit the possible confounding elements. However, in Makwana et al (20), 6 smokers were detected in the conservative group, whereas the surgical group was free from smokers. With the already known effect of smoking in delaying, the tissue healing (23), this demographic element can be considered as a confounder, particularly in this study, where the conclusion favored the surgical intervention.

There were some differences between the included studies in the surgical technique used, the postsurgical protocol, and the type and duration of cast immobilization. For example, and unlike the other tri-

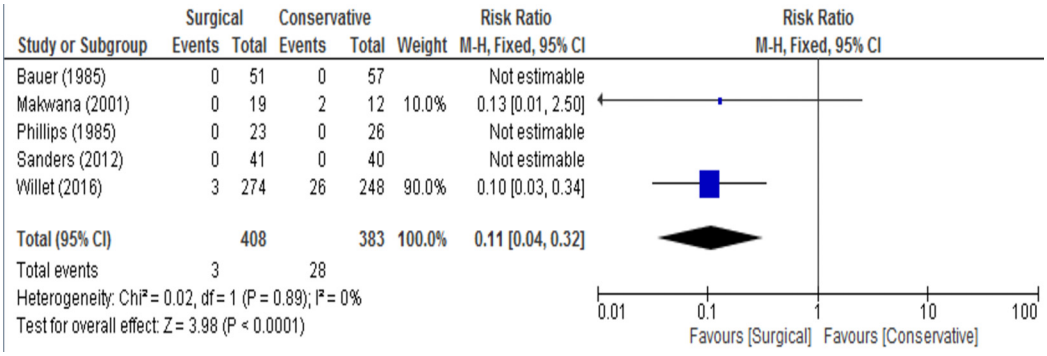

Fig. 3. Forest plot analysis showing nonunion rate.

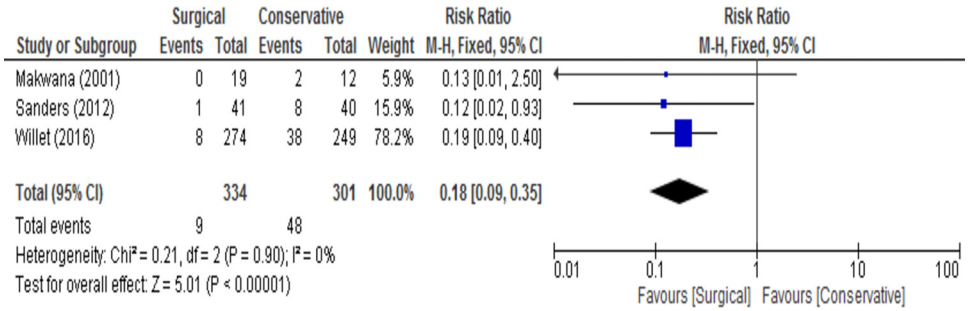

Fig. 4. Forest plot analysis showing malunion rate.

The mean age of participants varies from 41.6 years (19) to 71 years (21), which is representative of the population who are commonly presented with ankle fractures. However, when elderly only were recruited by 2 of 5 studies (20,21) the mean age was >60 years, and there was a significant difference in sex ratio toward females (Table. 1). Other demographic details such as regular substance use (tobacco, alcohol, etc.) and the medical history of participants were reported only by Makwana et al (20), Sanders et al (22), and Willet et al (21). In the latest

als, Bauer et al (18) surgically repaired the ligamentous injuries associated with ankle fractures. This surgical repair could have different clinical effects and different possible findings. In addition, the type and duration of cast immobilization and the time of weightbearing and active movement in the conservatively treated group were not similar, which, again, could lead to different clinical findings and different complication rates (24). In 3 of 5 studies (20–22), early protected weightbearing was allowed for some patients in the conservative group.

Table 4
Nonunion, malunion, and adverse events rates (early treatment failure, infection, and osteoarthritis)

Study Authors (Year)	Early Treatment Failure		Infection		Osteoarthritis		Nonunion		Malunion	
	S	C	S	C	S	C	S	C	S	C
Buer et al (18)	2/51	8/57	0/43	4/49	31/43	32/49	0/51	0/57	NM	NM
Makwana et al (20)	0/22	8/21	1/19	0/12	NM	NM	0/19	2/12	0/19	2/12
Phillips et al (19)	0/23	1/26	1/23	0/26	15/23	18/26	0/23	0/26	NM	NM
Sanders et al (22)	0/41	1/40	6/41	0/40	NM	NM	0/41	0/40	1/41	8/40
Willett et al (21)	5/298	52/275	8/298	2/275	NM	NM	3/274	26/248	8/274	38/249
Total	7/435 (1.6%)	70/419 (16.7%)	16/424 (3.7%)	6/402 (1.4%)	46/66 (69.6%)	50/75 (66.6%)	3/408 (0.7%)	28/383 (7.3%)	9/334 (2.6%)	48/301 (15.9%)

Values given as n/N.
Abbreviations: C, conservative; NM, not mentioned; S, surgery.

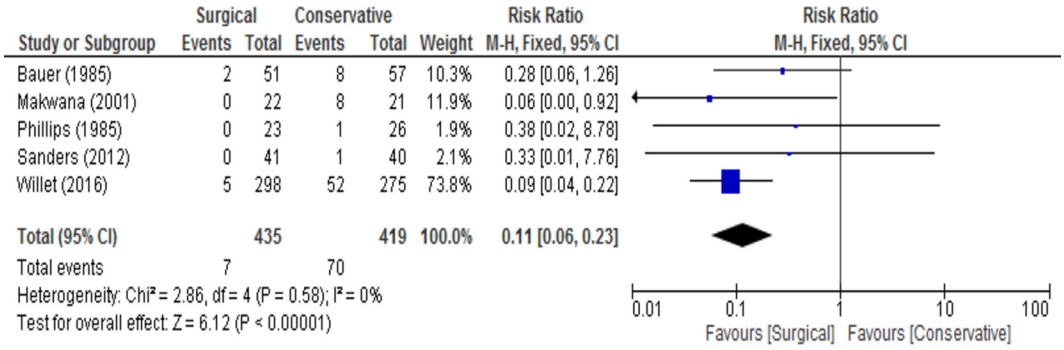

Fig. 5. Forest plot analysis showing early treatment failure.

Although this was protected weightbearing, no information was provided about the compliance of those patients, and this could be a possible explanation for the high rates of malunion reported in these 3 studies.

It was difficult to pool an overall functional result from these studies as the clinical outcome measures were heterogeneous and measured at different follow-up intervals. In 2 of 5 studies (21,22), where validated functional outcome measures were used, the conclusions demonstrate no significant differences between the 2 treatment approaches. Similarly, the studies used the nonvalidated functional outcome measures (18,19) had the same conclusion. Makwana et al (20) was the only study that reported a significant difference in favor of the surgical treatment, but it should be remembered that there are different factors that could have biased this result. These factors include high dropout rate, smoking as a confounder in the conservative group, and the older population recruited by the authors.

Overall, in this review, there was a general trend that both surgical and conservative approaches provide equivalent functional outcomes and the anatomical reduction and rigid surgical fixation could provide better protection against malunion, nonunion, and loss of reduction. This conclusion was in line with the systematic review conducted by Michelson et al (7), which recommended surgical fixation of unstable ankle fractures for radiological outcomes but not for functional outcomes, on the basis of fewer included trials. However, in another 2 systematic reviews, Donken et al (1) and Petrion et al (25), there was insufficient evidence to conclude whether surgical or conservative treatment produces superior outcomes for ankle fractures in adults.

Although this systematic review strictly adhered to preidentified unchanged protocol and the risk of publication bias was minimized by performing a thorough search strategy, it still has some recognizable limitations. First, the small sample size of most of the trials, the relatively small number of reviewed trials, and the potential biases observed have negatively affected the power of this research work. Second, the incompatibility of the functional outcome measures and the follow-up intervals have limited the possibility to draw a summative conclusion about functional outcomes as meta-analysis for this domain was impossible. Finally, although we tried to gather further data from the study authors, we were unsuccessful and, thus, the lack of detailed information is still one of the limitations of this review.

Implications for Future Research

Adequately powered clinical studies with good methodology are essential in future prospective randomized trials to draw an accurate conclusion about the comparative treatment effectiveness. The use of validated and reliable tools to assess the functional and the radiological outcomes at unified follow-up intervals is also important to provide more robust data. In addition, to be more clinically useful and pragmatic, a simplified classification of ankle fracture based only on stability should be considered in the future.

References

1. Donken CC, Al-Khateeb H, Verhofstad MH, van Laarhoven CJ. Surgical versus conservative interventions for treating ankle fractures in adults. Cochrane Database Syst Rev 2012;8 CD008470.
2. Court-Brown CM, Caesar B. Epidemiology of adult fractures: a review. Injury 2006;37:691–697.
3. Court-Brown CM, McBirnie J, Wilson G. Adult ankle fractures—an increasing problem? Acta Orthop Scand 1998;69:43–47.
4. Lauge-Hansen N. Fractures of the ankle: II. Combined experimental-surgical and experimental-roentgenologic investigations. Arch Surg 1950;60:957–985.
5. Weber BG. Die Verletzungen des Oberen Sprunggelenkes. 2nd ed. Huber, Bern, Switzerland, 1972.
6. Müller ME, Nazarian S, Koch P, Schatzker J. *The Comprehensive Classification of Fractures of Long Bones*. Springer Verlag, Berlin, 1990.
7. Michelson JD, Magid D, McHale K. Clinical utility of a stability-based ankle fracture classification system. J Orthop Trauma 2007;21:307–315.
8. Yeung DE, Jia X, Miller CA, Barker SL. Interventions for treating ankle fractures in children. Cochrane Database Syst Rev 2016;4:CD010836.
9. Bhadra AK, Roberts CS, Giannoudis PV. Nonunion of fibula: a systematic review. Int Orthop 2012;36:1757–1765.
10. Olerud C, Molander H. A scoring scale for symptom evaluation after ankle fracture. Arch Orthop Traum Surg 1984;103:190–194.
11. Ware JE, Snow KK, Kosinski M, Gandek B. *SF-36 Health Survey Manual and Interpretation Guide*. New England Medical Center, The Health Institute, Boston, MA, 1993 7.
12. Gandek B, Ware JE, Aaronson NK, Apolone G, Bjorner JB, Brazier JE, Sullivan M. Cross-validation of item selection and scoring for the SF-12 Health Survey in nine countries: results from the IQOLA Project. J Clin Epidemiol 1998;51:1171–1178.
13. Magnusson R. On the late results in non-operated cases of malleolar fractures: fractures by external rotation. Acta Chir Scand 1944;90(suppl 84):1–36.
14. Cedell CA. Supination-outward rotation injuries of the ankle: a clinical and roentgenological study with special reference to the operative treatment. Acta Orthop Scand 1967;38(suppl 110):1–148.
15. Higgins JPT, Altman DG, Gøtzsche PC, Jüni P, Moher D, Oxman AD, Sterne JAC. The Cochrane Collaboration's tool for assessing risk of bias in randomised trials. BMJ 2011;343.
16. Demets DL. Methods for combining randomized clinical trials: strengths and limitations. Stat Med 1987;6:341–350.
17. Review Manager (RevMan) [computer program]. *Version 5*. The Nordic Cochrane Centre, The Cochrane Collaboration, Copenhagen 2014. p.3.
18. Bauer M, Bergstrom B, Hemborg A, Sandegard J. Malleolar fractures: nonoperative versus operative treatment a controlled study. Clin Orthop Relat Res 1985;199:17–27.
19. Phillips WA, Schwartz HS, Keller CS, Woodward HR, Rudd WS, Spiegel PG, Laros GS. A prospective, randomized study of the management of severe ankle fractures. J Bone Joint Surg Am 1985;67:67–78.
20. Makwana NK, Bhowal B, Harper WM, Hui AW. Conservative versus operative treatment for displaced ankle fractures in patients over 55 years of age. A prospective, randomised study. Bone Joint J 2001;83:525–529.
21. Willett K, Keene DJ, Mistry D, Nam J, Tutton E, Handley R, Chesser TJ. Close contact casting vs surgery for initial treatment of unstable ankle fractures in older adults: a randomized clinical trial. JAMA 2016;316:1455–1463.
22. Sanders DW, Tieszer C, Corbett B. Operative versus nonoperative treatment of unstable lateral malleolar fractures: a randomized multicenter trial. J Orthop Trauma 2012;26:129–134.
23. Guo S, DiPietro LA. Factors affecting wound healing. J Dent Res 2010;89:219.
24. Thomas G, Whalley H, Modi C. Early mobilization of operatively fixed ankle fractures: a systematic review. Foot Ankle Int 2009;30:666.
25. Petrisor BA, Poolman R, Koval K, Tornetta P 3rd, Bhandari M. Management of displaced ankle fractures. J Orthop Trauma 2006;20:515–518.