Trauma

EOR | VOLUME 6 | SEPTEMBER 2021
DOI: 10.1302/2058-5241.6.210003
www.efortopenreviews.org

EFORT open reviews

Osteosynthesis or non-operative treatment of the fibula for distal lower-leg fractures with tibial nailing: a systematic review and meta-analysis

Andreas Frodl[1]
Benjamin Erdle[1]
Hagen Schmal[1,2]

- Fibular fixation to treat distal lower-leg fractures is a controversial intervention. To ensure better stability itself, better rotational stability, and to prevent secondary valgus dislocation – all these are justifications for addressing the fibula via osteosynthesis. High surgical costs followed by increased risks are compelling reasons against it. The purpose of this study was to systematically review the literature for rates of malunion and malrotation, as well as infections and nonunions.
- We conducted a systematic review searching the Cochrane, PubMed, and Ovid databases. Inclusion criteria were modified Coleman Methodology Score (mCMS) > 60, a distal lower-leg fracture treated by nailing, and adult patients. Biomechanical and cadaver studies were excluded. Relevant articles were reviewed independently by referring to title and abstract. In a meta-analysis, we compared five studies and 741 patients.
- A significantly lower rate of valgus/varus deviation is associated with fixation of the fibula (*OR* = 0.49; 95% CI: 0.29–0.82; p = .006). A higher risk for pseudarthrosis was revealed when the fibula underwent surgical therapy, but not significantly (*OR* = 1.46; 95% CI: 0.76–2.79; p = .26). Nevertheless, we noted an increased risk of postoperative wound infection following fibular plating (*OR* = 1.90; 95% CI: 1.21–2.99; p = .005). There was no statistically significant difference in the rate of nonunions between the two groups.
- Overall, the stabilization of the fibula may reduce secondary valgus/varus dislocation in distal lower-leg fractures but is associated with an increased risk of postoperative wound infections. The indication for fibula plating should be made individually.

Keywords: fibula; intramedullary nailing; lower-leg fracture

Cite this article: *EFORT Open Rev* 2021;6:816-822.
DOI: 10.1302/2058-5241.6.210003

Introduction

Distal lower-leg fractures often occur with a tibial fracture in conjunction with a fibular fracture. It is common practice not to fix the fibula in patients presenting tibial shaft fractures. In case of a fracture in the lower leg's distal third, osteosynthetic treatment of the fibula remains controversial. Reasons to recommend fibular fixation are greater stability itself, improved rotational stability, and to prevent secondary valgus dislocation. However, the intervention's complexity and associated risks are arguments against it. Osteosynthesis of the tibia is usually done by intramedullary nailing,[1] fibular osteosynthesis usually by plating.[2,3]

We carried out a meta-analysis to discover whether our hypothesis – namely that nailing the tibia alone is equally effective in treating distal lower-leg fractures as is combined fixation of the tibia and fibula – was valid.

Methods

This systematic review was conducted according to the guidelines of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses checklist (PRISMA).[4] The study protocol was registered in PROSPERO (ID: CRD42020172702), a database listing current meta-analyses, at the beginning of our literature search.

From March 2020 to August 2020, a database search was carried out independently by the authors . MEDLINE, PubMed and the Cochrane Library were searched for relevant studies reporting clinical outcome after intramedullary nail osteosynthesis with or without adjunctive fixation of the fibula for distal lower-leg fractures.

Search strategy

The following search strategy was applied: (((((fibular osteosynthesis) AND (tibial fractures) AND (distal)) OR

(fibula[MeSH Terms])) AND (tibial fracture[MeSH Terms] AND (fracture fixation, intramedullary[MeSH Terms] AND (distal)))) OR (tibial intramedullary nailing)) OR (fibular osteosynthesis) OR (fibula plate fixation) NOT (Femur) NOT (Knee) NOT (ankle) NOT (intraarticular).

Eligibility

We applied the following inclusion criteria: studies between 1990 and 2020 were included to exclude obsolete implants; a minimum patient age of 18 years was set to enable comparisons between fully grown adults only; only publications written in German or English were included. Our exclusion criteria were: an overall modified Coleman Methodology Score (mCMS) < 60, follow-up rate < 80%, pathological fractures, cadaver or biomechanical studies, and animal studies.

The same reviewers independently screened titles and abstracts for relevance according to the aforementioned inclusion and exclusion criteria. If no abstract was available, the full text was obtained to assess the study's relevance. To make sure we did not overlook any suitable studies, we cross-referenced the reference lists of included articles if they had been missed by our search algorithm. Appropriate publications were then independently analysed for the mCMS and level of evidence according to the Oxford Centre of Evidence-Based Medicine.[5]

Outcome criteria

Patient demographics, number of patients, malunion rate, malrotation, number of postoperative nonunions, follow-up period and surgical technique, as well as duration of surgery and number of infections were extracted by the authors (Table 1). According to the studies we included, malunion was defined as a tibial axis deviation > 5° in any plane or postoperative shortening > 20 mm of the surgically handled side.

Statistics

To analyse the collected data, RevMan 5® was used. Comparative analyses of malunion, rate of nonunions, and of postoperative infections were performed and the odds ratios (*OR*) calculated. Those results then were visualized in forest plots.

Results

Study selection

Our literature search and study selection procedure is depicted in Fig. 1, and a total of 1313 papers were identified by our search algorithm. Moreover, one paper was added from the reference list search. These papers were scanned, and any duplicates or topic-unrelated articles excluded. After analysing the eligibility criteria, five of the 18 studies could be included in our quantitative analysis.[6–10] There were one prospective and four retrospective case-control studies containing a total of 741 patients.

The number of patients included in the selected studies ranged from 60 to 329 with a mean age of 39.8 ± 4.3 years.

Operation and implants

Operating time was assessable in two of the studies: differences were marginal, with 115.5 ± 3.5 minutes without and 111.5 ± 21.5 minutes with fibula fixation. The implants used for fibula osteosyntheses were a 3.5 mm locking compression plate (LCP) and 1/3rd tubular plate, respectively. Postoperative follow-ups ranged from 6 to 21 months (Table 1).

Risk of bias assessment

All included studies possessed an evidence level III. There is a high risk of selection bias considering the retrospective design of four studies. Reporting and detection biases are considerable due to the lack of randomization and blinding. Surgical techniques were reported in detail in every study, minimizing the risk of operational bias even in cases in which several surgeons were operating. To calculate the risk of underlying bias, all included studies were analysed with the ROBINS-I tool. Our results for the risk of bias assessment are shown in Fig. 2.

Postoperative infection and rate of nonunions

Complications, in particular postoperative wound infections, were assessed in four studies containing a total of 570 patients. As we found low heterogeneity (I^2 = 0%; p = .42), a random-effects model was used for analysis, which revealed a significantly lower infection rate when fibular fixation had not been performed (*OR* = 1.90; 95% CI: 1.21–2.99; p = .005). A meta-analysis based on these data is shown in Fig. 3. We also conducted a meta-analysis to calculate potential differences in the rate of nonunions. Data on 498 patients revealed an overall number of 47 nonunions. We identified a difference in the rate of postoperative nonunions in conjunction with the type of surgical procedure (*OR* = 1.46; 95% CI: 0.76–2.79; p = .26) (Fig. 4). There was no statistical significance.

Malunion and malrotation

We recorded and screened postoperative valgus or varus deviations in 410 patients for effects according to operative intervention. As there was high heterogeneity (I^2 = 85%; p = .00002) a random-effects model was used. The fractured fibula was subjected to non-operative treatment in 309 patients, resulting in 113 postoperative varus/valgus deviations of the tibia. When the fibula had been fixed,

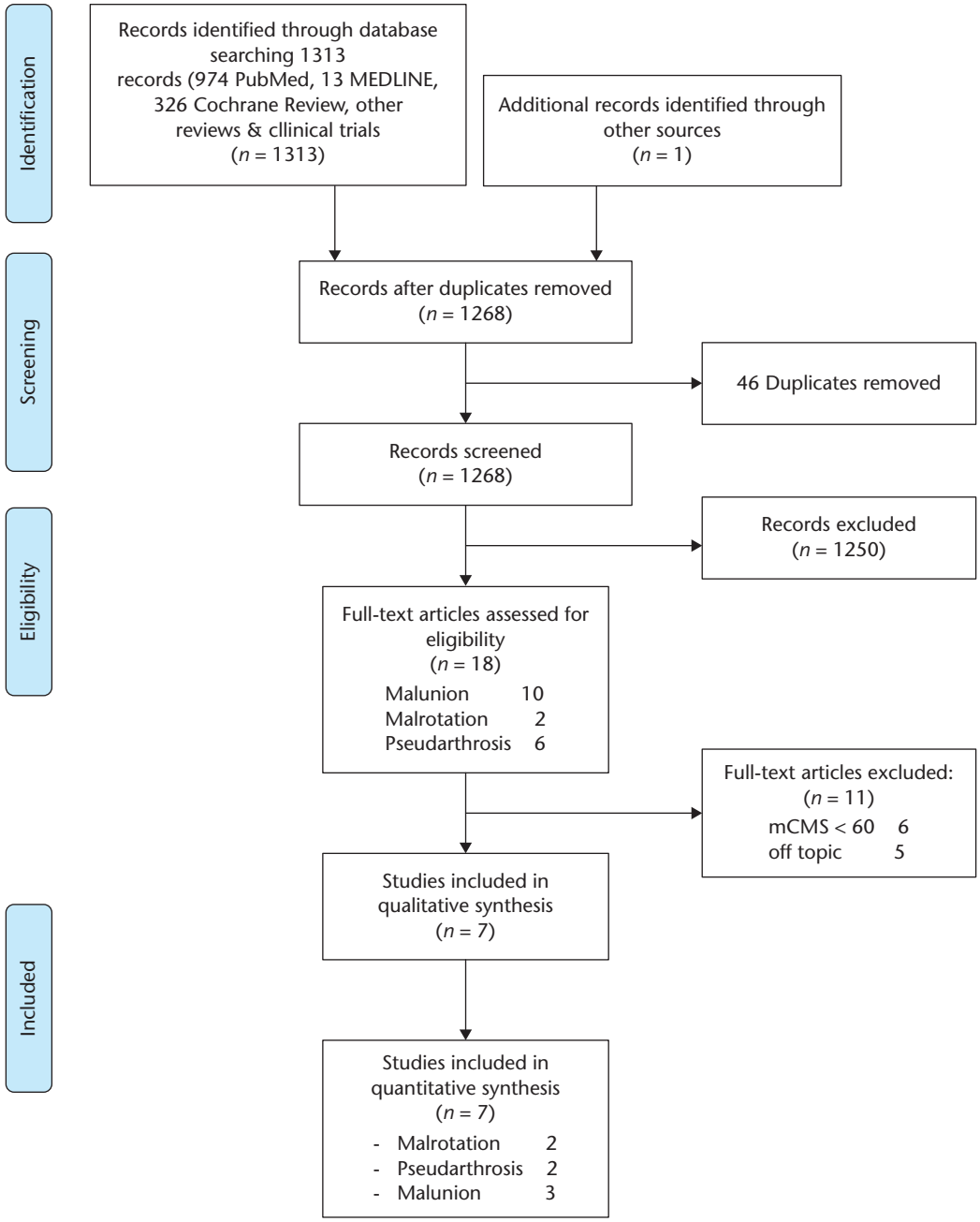

Fig. 1 PRISMA flow chart.

Note. mCMS, modified Coleman Methodology Score.

only 25 patients suffered from a postoperative varus/valgus deviation > 5°.

The risk of a postoperative valgus/varus deviation was statistically significantly higher in patients who had not undergone fibular osteosynthesis (*OR* = 0.49; 95% CI: 0.29–0.82; p = .006). Data and results are shown in Fig. 5.

Only one study provided information on postoperative malrotation.[6–10] Due to lack of comparative data, quantitative analysis of malrotation could not be performed.

Discussion

There is no consensus or evidence-based guideline to date concerning the treatment of distal lower-leg fractures. Summarizing the outcomes of this meta-analysis, our study's key finding is that malunion, as manifested by a postoperative valgus/varus deviation, is significantly less likely to occur when the patient in question has undergone fibular osteosynthesis. However, adjunctive

Table 1. Study demographics

Study	Study type	Level of evidence	Sample size *N*	Male:female ratio	age years ± *SD*	Surgical method	Operative time; mean in minutes		Follow-up in months
							Fibula fixed	fibula not fixed	
Egol et al, 2006[6]	R, multicentre	III	72 patients 47 NP 25 FP	50:22 31:16 19:6	42.6 ± 16.9 43.1 ± 18 41.6 ± 14.6	INTM 3.5 mm LC-DC plate or 1/3 tubular plate	90	119	8
Githens et al, 2017[7]	R	III	329 patients 167 NP 162 FP	241:89 131:36 113:49	Not stated 40 41	INTM Plate (not further specified)	NI	NI	21
Van Maele et al, 2018[8]	R	III	184 patients 152 NP 32 FP	114:70 Not stated Not stated	43.0 Not stated Not stated	INTM Plate and screw (not further specified)	NI	NI	6
Prasad et al, 2013[10]	P	III	60 patients 30 NP 30 FP	52:8 Not stated Not stated	31.3 Not stated Not stated	INTM 3.5 mm DCP	NI	NI	18
Taylor et al, 2015[9]	R	III	98 patients 83 NP 15 FP	61:37 49:34 12:3	 40.3 ± 16.5 42.8 ± 17.2	INTM 3.5 mm LCP	133	112	Not stated

Notes: R: retrospective, P: prospective, NP: no fibular plating, FP: fibular plating, INTM: intramedullary tibial nailing, LC-DC: limited contact dynamic compression plate, LCP: locking compression plate, NI: no information

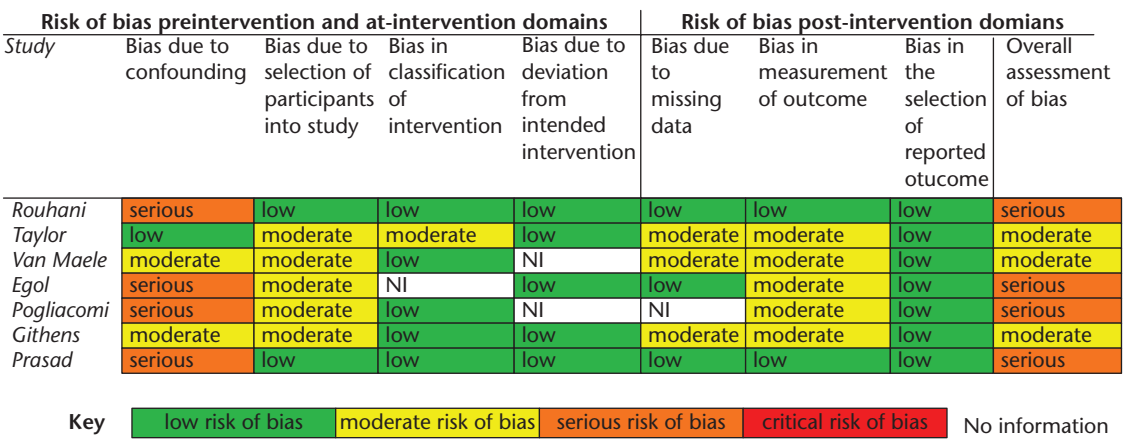

Tabelle 7: Bias-Assessment mit ROBINS-I tool

Fig. 2 Risk of bias assessment via ROBINS-I.

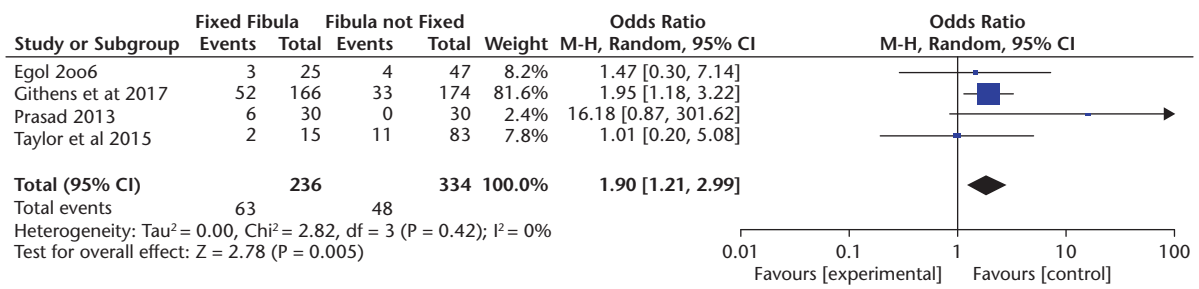

Fig. 3 Meta-analysis of postoperative infections.

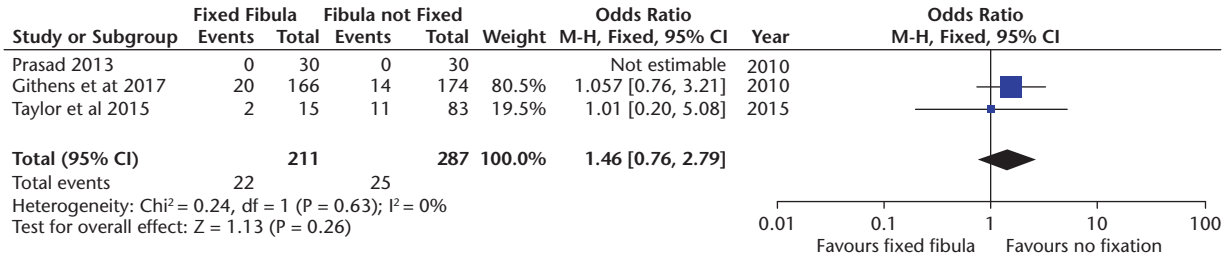

Fig. 4 Meta-analysis of nonunion rate.

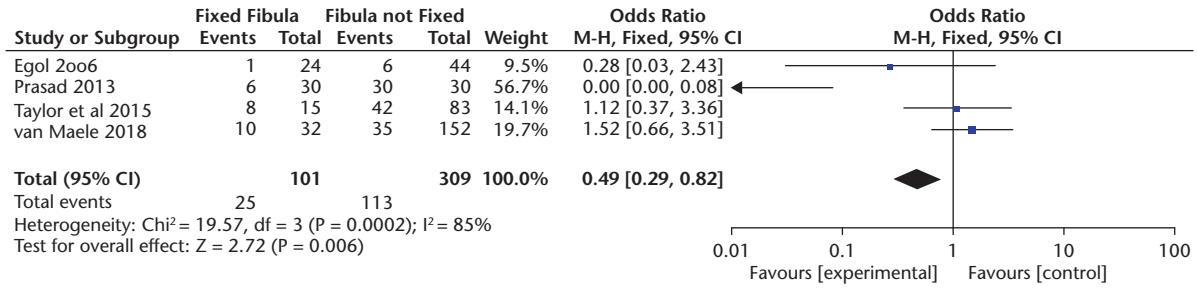

Fig. 5 Meta-analysis of postoperative malunion.

fibular fixation also raises the risk of wound infections significantly. This might be due to higher surgical costs and longer operation times, although the differences observed in this study are marginal. We detected no statistically significant difference in the rate of nonunions in conjunction with fixation of the fibula.

The fibula's influence on force applied axially is relatively low. Only 6–7% of the weight borne applies to the fibula.[11–13] The biomechanical importance of the fibula is that it strongly facilitates the ankle's in-gait stability – a fact that highlights the relevance of fibular osteosynthesis when the fracture is below the syndesmosis level.[14]

Morin et al and Kumar et al conducted biomechanical investigations on cadavers to assess the influence of fibular plating on rotational stability.[1,15] They demonstrated that axial rotation in metaphyseal lower-leg fractures treated with intramedullary tibial nailing (IMTN) can be lowered via adjunctive fibular plating. But the clinical relevance of their biomechanical investigation is questionable. There is a paucity of clinical evidence on postoperative malrotation. We identified just one applicable publication meeting our study's inclusion criteria.[10]

Egol et al investigated the postoperative alignment of distal lower-leg fractures with and without fibular fixation.[6] One of 25 patients who had undergone supplementary fibular stabilization later developed a valgus deformity, whereas six out of 47 who experienced conservative fibular management suffered a subsequent valgus/varus deformity. This factor was statistically significant, and mirrors our meta-analysis' results. However, Whittle et al failed to confirm such findings in their study.[16]

Concerns about fibular fixation include the risk of infection and irritating implants requiring removal. Our study reveals an increased risk of postoperative wound infections in conjunction with fibular osteosynthesis, as reported by Marsh et al and Williams et al.[17,18]

The rate of nonunions does not seem to be affected by whether the fibula was treated operatively or not, as we detected no statistically significant difference in this study.

Limitations

Bone healing is complex, and influenced by many factors other than the fixation method. Unfortunately, most of the studies we included in this analysis failed to report on co-morbidities and other influencing factors.[19] There are certain intrinsic risk factors that make some patients more prone to nonunions than others.[20,21] The use of tobacco slows healing, as nicotine impairs cell proliferation and causes vasoconstriction[22–24] – factors leading to both reduced osteoblasts and a less well-perfused fracture zone resulting in a statistically higher number of atrophic nonunions.[22] There are additional cofactors influencing bone healing (alcohol, osteoporosis, etc.) to consider when assessing a nonunion rate that is also free of confounders.

There are limitations to this study inherent in the type of publications we included and in our search algorithm. Our search strategy followed an English search algorithm. Potentially suitable publications in other languages were not considered. The risk of publication bias is imminent because only published articles were included. To minimize this kind of bias, the CochraneLibrary® was scanned for clinical trials, but we detected no relevant findings.

Most of the publications we included are retrospective case-control studies entailing a high risk for selection, detection, and reporting bias. To exclude methodologically inadequate studies, we focused on bias assessment as done by ROBINS-I and mCMS. There was no critical risk of bias in any included study.

The fact that we ruled out any publications appearing before 1990 enabled us to exclude obsolete implants. Nevertheless, modern implants like the angular stable locking system (ASLS) could not be taken into account because of the paucity of data available.

Conclusion

Fibular fixation in patients suffering a distal third lower-leg fracture improves the stability and quality of reposition, decreasing valgus/varus deviation. However, the additional operation is also associated with an increased risk of wound infection. Therefore, the indication for supportive fibular plating should be made individually.

AUTHOR INFORMATION

[1]Department of Orthopedics and Traumatology, Freiburg University Hospital, Freiburg, Germany.
[2]University Hospital Odense, Dep. Of Orthopedic Surgery, Sdr. Boulevard 29, 5000 Odense C, Denmark.

Correspondence should be sent to: Andreas Frodl, Hugstetter Str. 55, 79106 Freiburg, Germany.
Email: Andreas.Frodl@uniklinik-freiburg.de

ICMJE CONFLICT OF INTEREST STATEMENT

The author declares no conflict of interest relevant to this work.

FUNDING STATEMENT

No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.
The article processing charge was funded by the Baden-Wuerttemberg Ministry of Science, Research and Art and the University of Freiburg in the funding programme Open Access Publishing

REFERENCES

1. **Kumar A, Charlebois SJ, Cain EL, Smith RA, Daniels AU, Crates JM.** Effect of fibular plate fixation on rotational stability of simulated distal tibial fractures treated with intramedullary nailing. *J Bone Joint Surg [Am]* 2003;85-A:604–608.

2. **Wang J-Q, Chen Z-X, Guo W-J, Zhao Y-M, Peng Luo.** Comparison of plate and intramedullary nail fixation of extra-articular tibial fractures: a retrospective study exploring hidden blood loss. *Injury* 2019;50:546–550.

3. **Berlusconi M, Busnelli L, Chiodini F, Portinaro N.** To fix or not to fix? The role of fibular fixation in distal shaft fractures of the leg. *Injury* 2014;45:408–411.

4. **Moher D, Liberati A, Tetzlaff J, Altman DG, Group TP; PRISMA Group.** Preferred Reporting Items for Systematic Reviews and Meta-Analyses: the PRISMA statement. *PLoS Med* 2009;6:e1000097.

5. **OCEBM Levels of Evidence – Centre for Evidence-Based Medicine (CEBM), University of Oxford.** https://www.cebm.ox.ac.uk/resources/levels-of-evidence/ocebm-levels-of-evidence (date last accessed 1 November 2020).

6. **Egol KA, Weisz R, Hiebert R, Tejwani NC, Koval KJ, Sanders RW.** Does fibular plating improve alignment after intramedullary nailing of distal metaphyseal tibia fractures? *J Orthop Trauma* 2006;20:94–103.

7. **Githens M, Haller J, Agel J, Firoozabadi R.** Does concurrent tibial intramedullary nailing and fibular fixation increase rates of tibial nonunion? A matched cohort study. *J Orthop Trauma* 2017;31:316–320.

8. **Van Maele M, Molenaers B, Geusens E, Nijs S, Hoekstra H.** Intramedullary tibial nailing of distal tibiofibular fractures: additional fibular fixation or not? *Eur J Trauma Emerg Surg* 2018;44:433–441.

9. **Taylor BC, Hartley BR, Formaini N, Bramwell TJ.** Necessity for fibular fixation associated with distal tibia fractures. *Injury* 2015;46:2438–2442.

10. **Prasad M, Yadav S, Sud A, Arora NC, Kumar N, Singh S.** Assessment of the role of fibular fixation in distal-third tibia-fibula fractures and its significance in decreasing malrotation and malalignment. *Injury* 2013;44:1885–1891.

11. **Goh JC, Mech AM, Lee EH, Ang EJ, Bayon P, Pho RW.** Biomechanical study on the load-bearing characteristics of the fibula and the effects of fibular resection. *Clin Orthop Relat Res* 1992;279:223–228.

12. **Takebe K, Nakagawa A, Minami H, Kanazawa H, Hirohata K.** Role of the fibula in weight-bearing. *Clin Orthop Relat Res* 1984;184:289–292.

13. **Lambert KL.** The weight-bearing function of the fibula: a strain gauge study. *J Bone Joint Surg [Am]* 1971;53-A:507–513.

14. **Scranton PE Jr, McMaster JG, Kelly E.** Dynamic fibular function: a new concept. *Clin Orthop Relat Res* 1976;118:76–81.

15. **Morin PM, Reindl R, Harvey EJ, Beckman L, Steffen T.** Fibular fixation as an adjuvant to tibial intramedullary nailing in the treatment of combined distal third tibia and fibula fractures: a biomechanical investigation. *Can J Surg* 2008;51:45–50.

16. **Whittle AP, Wester W, Russell TA.** Fatigue failure in small diameter tibial nails. *Clin Orthop Relat Res* 1995;315:119–128.

17. **Marsh JL, Bonar S, Nepola JV, Decoster TA, Hurwitz SR.** Use of an articulated external fixator for fractures of the tibial plafond. *J Bone Joint Surg [Am]* 1995;77-A:1498–1509.

18. **Williams J, Gibbons M, Trundle H, Murray D, Worlock P.** Complications of nailing in closed tibial fractures. *J Orthop Trauma* 1995;9:476–481.

19. **Drosos GI, Bishay M, Karnezis IA, Alegakis AK.** Factors affecting fracture healing after intramedullary nailing of the tibial diaphysis for closed and grade I open fractures. *J Bone Joint Surg [Br]* 2006;88-B:227–231.

20. **Calori GM, Albisetti W, Agus A, Iori S, Tagliabue L.** Risk factors contributing to fracture non-unions. *Injury* 2007;38:S11–S18.

21. Kubosch EJ, Bernstein A, Wolf L, Fretwurst T, Nelson K, Schmal H. Clinical trial and in-vitro study comparing the efficacy of treating bony lesions with allografts versus synthetic or highly-processed xenogeneic bone grafts. *BMC Musculoskelet Disord* 2016;17:77.

22. Kwiatkowski TC, Hanley EN Jr, Ramp WK. Cigarette smoking and its orthopedic consequences. *Am J Orthop* 1996;25:590–597.

23. Hills JM, Khan I, Archer KR, et al. Metabolic and endocrine disorders in pseudarthrosis. *Clin Spine Surg* 2019;32:E252–E257.

24. Ziran B, Cheung S, Smith W, Westerheide K. Comparative efficacy of 2 different demineralized bone matrix allografts in treating long-bone nonunions in heavy tobacco smokers. *Am J Orthop* 2005;34:329–332.