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

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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

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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,

(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

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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.

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only 25 patients suffered from a postoperative varus/varus 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 | Male:female ratio | age years ± SD | Surgical method | Operative time; mean in minutes | Follow-up in months |
|-------------------|------------|-------------------|-------------|-------------------|----------------|----------------|--------------------------------|---------------------|
| Egol et al, 2006  | R, multicentre | III               | 72 patients | 50:22             | 42.6 ± 16.9 | INTM           | 90                             | 8                   |
|                   |            |                   | 47 NP       | 31:16             | 43.1 ± 18     | 3.5 mm LC-DC plate or 1/3 tubular plate | 119                |                     |
|                   |            |                   | 25 FP       | 19:6              | 41.6 ± 14.6   |                 |                                |                     |
| Githens et al, 2017 | R              | III               | 329 patients | 241:89            | Not stated    | INTM           | NI                             | 21                  |
|                   |            |                   | 167 NP      | 131:36            | 40            | Plate (not further specified) | NI                |                     |
|                   |            |                   | 162 FP      | 113:49            | 41            |                 |                                |                     |
| Van Maele et al, 2018 | R              | III               | 184 patients | 114:70            | 43.0          | INTM           | NI                             | 6                   |
|                   |            |                   | 152 NP      | Not stated        | Not stated    | Plate and screw (not further specified) | NI                |                     |
|                   |            |                   | 32 FP       | Not stated        | Not stated    |                 |                                |                     |
| Prasad et al, 2013 | P              | III               | 60 patients  | 52.8              | Not stated    | INTM           | NI                             | 18                  |
|                   |            |                   | 30 NP       | Not stated        | Not stated    | 3.5 mm DCP | NI                |                     |
|                   |            |                   | 30 FP       | Not stated        | Not stated    |                 |                                |                     |
| Taylor et al, 2015 | R              | III               | 98 patients  | 61:37             | Not stated    | INTM           | 133                            | Not stated          |
|                   |            |                   | 83 NP       | 49:34             | 40.3 ± 16.5  | 3.5 mm LCP | 112               |                     |
|                   |            |                   | 15 FP       | 12:3              | 42.8 ± 17.2  |                 |                                |                     |

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

Risk of bias preintervention and at-intervention domains

| Study          | Bias due to confounding | Bias due to selection of participants into study | Bias in classification of intervention | Bias due to deviation from intended intervention | Bias due to missing data | Bias in measurement of outcome | Bias in the selection of reported outcome | Overall assessment of bias |
|----------------|-------------------------|-----------------------------------------------|----------------------------------------|-----------------------------------------------|-------------------------|---------------------------------|------------------------------------------|---------------------------|
| Rouhani        | serious                 | low                                           | low                                    | low                                           | low                     | low                             | low                                      | serious                    |
| Taylor         | low                     | moderate                                      | low                                    | high                                          | low                     | low                             | high                                     | low                       |
| Van Maele      | moderate                | moderate                                      | low                                    | low                                           | moderate                | moderate                        | moderate                                 | low                       |
| Egol           | serious                 | low                                           | low                                    | low                                           | low                     | low                             | low                                      | serious                    |
| Pogliacomi     | moderate                | low                                           | low                                    | low                                           | low                     | low                             | low                                      | moderate                   |
| Githens        | serious                 | low                                           | low                                    | low                                           | low                     | low                             | low                                      | serious                    |
| Prasad         | serious                 | low                                           | low                                    | low                                           | low                     | low                             | low                                      | serious                    |

Key

- low risk of bias
- moderate risk of bias
- serious risk of bias
- critical risk of bias
- No information

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

Fig. 3 Meta-analysis of postoperative infections.
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 vasoconstriction22–24 – 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 entails 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.

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ICMJE CONFLICT OF INTEREST STATEMENT

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