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TRAUMA

Non-unions and wound infections do not differ following intramedullary nailing and plate osteosynthesis for distal third femur fractures: a meta-analysis

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- *Purpose:* The fixation method of distal, extra-articular femur fractures is a controversially discussed. To ensure better stability itself, earlier mobilization and to prevent blood loss – all these are justifications for addressing the femur via reamed intramedullary nailing (RIMN). Anatomical reposition of multifragmentary fractures followed by increased risks of non-union are compelling reasons against it. The purpose of this study was to systematically review the literature for rates of non-union and wound infection, as well as blood loss and time of surgery.
- *Methods:* According to the PRISMA guidelines we conducted this systematic review by searching the Cochrane, PubMed, Ovid, MedLine, and Embase databases. Inclusion criteria were the modified Coleman methodology score (mCMS) >60, age >18 years, and extra-articular fractures of the distal femur. Biomechanical and animal studies were excluded. By referring to title and abstract relevant articles were reviewed independently. In the consecutive meta-analysis, we compared 9 studies and 639 patients.
- *Results:* There is no statistically significant difference comparing superficial wound infections when RIMN was performed (OR = 0.50; 95% CI: 0.18 – 1.42; $P = 0.19$) as well as in deep wound infections (OR = 0.74; 95% CI: 0.19–2.81; $P = 0.62$). However, these results were not significant. We also calculated for potential differences in the rate of non-unions depending on the surgical treatment applied. Data of 556 patients revealed an overall number of 43 non-unions. There was no significant difference in rate of non-unions between both groups (OR = 0.97; 95% CI: 0.51–1.85; $P = 0.92$).
- *Conclusion:* No statistical difference was found in our study among RIMN and plate fixation in the treatment of distal femoral fractures with regard to the incidence of non-union and wound infections. Therefore, the indication for RIMN or plating should be made individually and based on the surgeon's experience.

Keywords: femoral fracture; intramedullary nailing; plate osteosynthesis

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Introduction

The distal femur fracture accounts for 3–6% of all femur fractures (1). This kind of fracture shows a bimodal distribution with a larger variation in young, male adults and older women (2). The latter mostly due to osteoporosis.

Especially in elderly patients early rehabilitation and mobilization is important (3). To allow early mobilization, sufficient intrinsic stability has to be achieved. In matter of surgical treatment, there are numerous options for fixation of distal femoral fractures, such as an angled blade plate, a locking plate and retrograde intramedullary nailing. Reamed Intramedullary nailing (RIMN) minimizes tissue damage and damage to blood circulation, but is limited in anatomical reposition. With open reduction and plate fixation due to direct visualization, nearly anatomical reposition of the fracture can be achieved. Biomechanical investigations have shown sufficient torsional stability and fixation with each device (4, 5).

But in terms of non-union, delayed union and wound infections there is no consensus concerning the treatment of distal femoral fractures.

We carried out a meta-analysis to validate our hypothesis, that RIMN is superior to plate fixation for lowering the risk of wound infections and time of hospitalization.

Methods

We conducted a systematic review according to the guidelines of the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) checklist (6, 7).

The databases were screened independently from August 2021 to October 2022 by the authors (AF and JH). MEDLINE, PubMed, Embase, and the Cochrane Library were searched for relevant studies reporting clinical outcome after intramedullary nail fixation or plate fixation of the distal femur fractures.

Search strategy

The following search strategy was applied:

(femoral fracture* or femur fracture*) and ((plate* or LISS) and (nail* or intramedullar*)) and distal

Eligibility

Following inclusion criteria were applied: studies between 2000 and 2021 were included to exclude obsolete implants. To enable comparisons between fully grown adults, a minimum patient age of 18 years was set. Only publications written in German or English were included. Studies were excluded if there was/were: an overall modified Coleman Methodology Score (mCMS) <60, follow-up rate <80%, pathological fractures, intra-articular fractures, cadaver or biomechanical studies, and animal studies (8).

All titles and abstracts were screen by the same reviewers independently for relevance according to the aforementioned inclusion and exclusion criteria. In cases were no abstract was available, the full text was obtained to assess the study's relevance. To ensure we did not overlook any relevant studies, the references within the included articles were screened and compared against our search results. These articles were also screened per protocol. Suitable publications (full-text) underwent analyzation with mCMS and Level of evidence according to the Oxford Centre of Evidence-Based Medicine (9, 10).

Outcome criteria

Patient demographics, number of patients, number of postoperative non-unions, delayed unions, follow-up period and surgical technique, time of hospitalization, blood loss, as well as duration of surgery and number of infections, divided in deep and superficial infections, were extracted by the authors.

Statistical analysis

RevMan 5® was used to analyze the collected data. Comparative analyses of rate of non-unions and of postoperative infections were performed and the odds ratios calculated. Those results then were visualized in forest plots.

Results

Study selection

The results of our literature search and study selection procedure is depicted in Fig. 1. A total of 660 papers were identified by our search algorithm. All papers were scanned, and duplicates ($n = 228$) or topic-unrelated articles excluded. After screening for the eligibility criteria, nine of the 19 studies could be included in our quantitative analysis.

Containing a total of 639 patients, there were five randomized controlled trials (RCT), one prospective case–control and three retrospective case–control studies (11, 12, 13, 14, 15, 16, 17, 18, 19).

The number of patients included in the selected studies ranged from 23 to 115 with a mean age of 50.4 ± 11.8 years.

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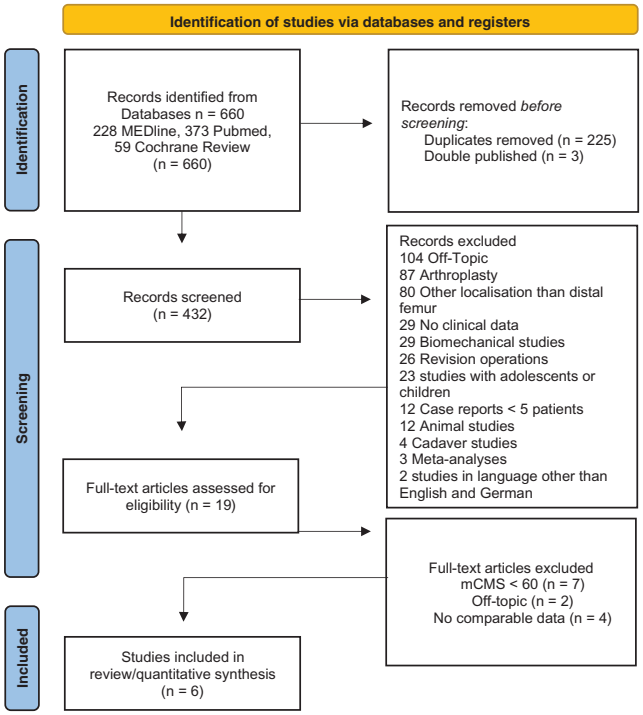

Figure 1

Overview of the PRISMA study selection process.

Operation and implants

Operating time was assessed in five studies. The mean surgery time in intramedullary nailing (IN) was 99.2 ± 30.6 min and 104.0 ± 32.6 min with plate fixation.

Used implants were retrograde intramedullary nails and 4.5 mm LCPs or femur LISS plates. A detailed overview of implants and postoperative follow-ups is seen in table 1.

Risk of bias assessment

All included studies possessed an evidence level I–III.

Surgical techniques were reported in every study, minimizing the risk of operational bias even in cases in which several surgeons were operating. For calculating the risk of underlying bias, all non RCTs were analyzed with the ROBINS-I tool and RCTs with the ROBINS-II tool (20, 21).

Our results for the risk of bias assessment are shown in Figs. 2 and 3.

Postoperative infection and rate of non-unions

Complications were divided in superficial and deep wound infections.

Superficial wound infections were assessed in seven studies containing a total of 517 patients. Data for deep wound infections were assessed in six studies with a total of 417 patient. As we found low heterogeneity (I^2 = 0%), a fixed-effects model was used for analysis. There were 5 (2.1%) cases of deep wound infections with RIMN (n = 241) and 11 (4.0%) with plate osteosynthesis (n = 276). A nearly same distribution was seen in superficial wound infections. Three (1.6%) patients out of 191, who underwent RIMN presented with superficial wound infections compared to 6 (2.7%) out of 226 patients, which were treated by open reduction and plate osteosynthesis

A tendency of lower superficial wound infections was seen when RIMN was performed (OR = 0.50; 95% CI: 0.18–1.42; P = 0.19) as well as with deep wound infections (OR = 0.74; 95% CI: 0.19–2.81; P = 0.62). However, these results were not significant.

A meta-analysis based on these data is shown in Fig. 4.

We also calculated for potential differences in the rate of non-unions depending on the surgical treatment applied. Data of 556 patients revealed an overall number of 43 non-unions. 18 (6.9%) non-unions were observed with RIMN (n = 260) and 25 (8.4%) with plate osteosynthesis (n = 296). There was no significant difference in rate of non-unions between both groups (OR = 0.97; 95% CI: 0.51–1.85; P = 0.92) (Fig. 5).

Blood loss and time of surgery

Analysis of blood loss and time of surgery was hampered by patchy data. Some studies presented results mean with standard deviation (S.D.) and others with range. By using the 'range rule of thumb' approximate measures can be made calculating the standard deviation from the given range data (22, 23). Thus, approximate standard deviations could be generated from given ranges.

Blood loss was analyzed with data of 182 patients. Because of a high heterogeneity (I^2 = 99%), a random effect-model was used and the Standard Mean difference was calculated. There was no significant difference in blood loss between both groups (SMD = 2.21; 95% CI: −1.61 to 6.04; P = 0.26).

Additionally, we calculated differences for time of surgery. A tending lower amount of time was needed with IN than with plating. However, the analysis of 172 patient data revealed no significant differences (SMD = 2.22; 95% CI: −0.68 to 5.12; P = 0.13). The results are depicted in Fig. 6.

Discussion

There is no consensus or evidence-based guideline to date concerning the treatment of distal, extraarticular femur fractures. Summarizing the outcomes of this meta-analysis, our study's key finding is that there is no significant difference in rate of non-unions, deep and

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Table 1 Demographic overview.

Study/ implant	mCMS† Total	mCMS† Part A	mCMS† Part B	Study type	LOE	Patients, *n*	Age, years	M:F	Mean surgery time, min (range)	Follow-up, months
Markmiller *et al.* (18)	61	33	28	PS	II	32	NI	20:12		12
RIN						19	43.7	14:2	155	
LCP (LISS)						20	57.2	6:10	142	
Hierholzer *et al.* (19)	64	40	24	RS	III	115	54	74:41		14 (6–36)
RIN						59	NI	NI	NI	13
LCP (LISS)						56	NI	NI	NI	15
Gill *et al.* (14)	75	49	26	RCT	I	42	NI	29:13		
RIN						20	36.0 ± 14.1	13:7	102	28
LCP (LISS)						22	38.7 ± 15.6	16:6	88	29
Ocalan *et al.* (11)	68	40	28	RS	III	97	NI	49:48		
AIN						69	48.0 ± 21.7	19:9	NI	50 (12–130)
LCP						28	35.3 ± 17.8	30:39	NI	45 (10–130)
Mahar *et al.* (13)	73	42	31	RCT	I	100	NI	65:35		6
RIN						50		30:20	NI	
LCP (LISS)						50		35:15	NI	
Meccariello *et al.* (12)	68	37	31	RS	III	60	NI	63:27		
RIN						30	42.7 ± 18.3	8:22	52 (29–76)	17 (12–24)
LCP						30	42.8	10:20	63 (38-89)	16 (12–24)

†Overall mean mCMS was 68.2 ± 4.8.
AIN: antegrade intramedullary nail; F, female; LCP, locking compression plate; LOE, level of evidence; M, male, mCMC, modified Coleman methodology score; NI, no information; PS, non-randomized prospective study; RCT, randomized controlled trail; RIN, retrograde intramedullary nail; RS: retrospective study.

	Risk of bias preintervention and at-intervention domains				Risk of bias post-intervention domains			
	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
Markmiller *et al*. (18)	low	low	serious	low	low	moderate	low	serious
Hierholzer *et al*. (19)	serious	moderate	low	low	low	moderate	low	serious
Ocalan *et al*. (11)	moderate	moderate	low	low	moderate	moderate	moderate	moderate
Meccariello *et al*. (12)	moderate	moderate	low	low	low	moderate	low	moderate

Figure 2

Bias assessment with ROBINS-I tool.

Study	Selection bias	Allocation concealment	Blinding of patients/ personnel	blinding of outcome assessment	Incomplete outcome data	Selective reporting
Gill *et al*. (14)	+	–	–	–	–	+
Mahar *et al*. (13)	NI	–	–	–	–	+

+: no risk of bias, –: risk of bias, NI: no Information

Figure 3

Risk of bias assessment with ROBINS-2 tool for RCTs.

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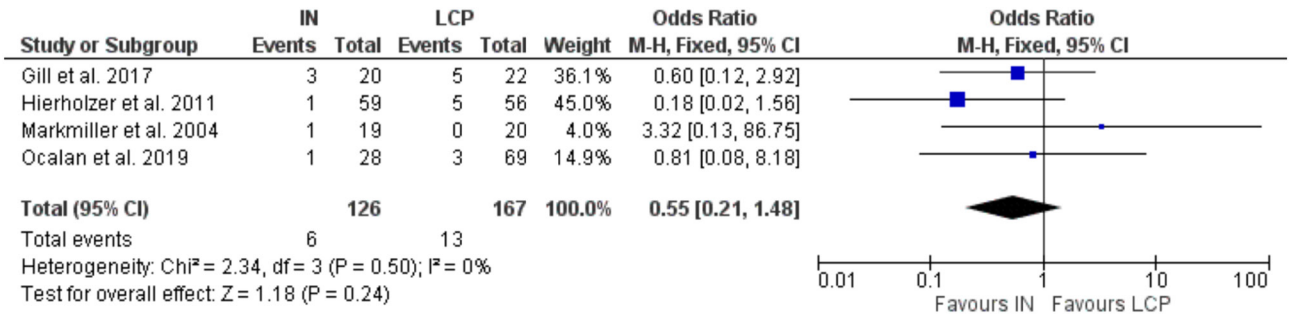

Figure 4

Forest plot: wound infection.

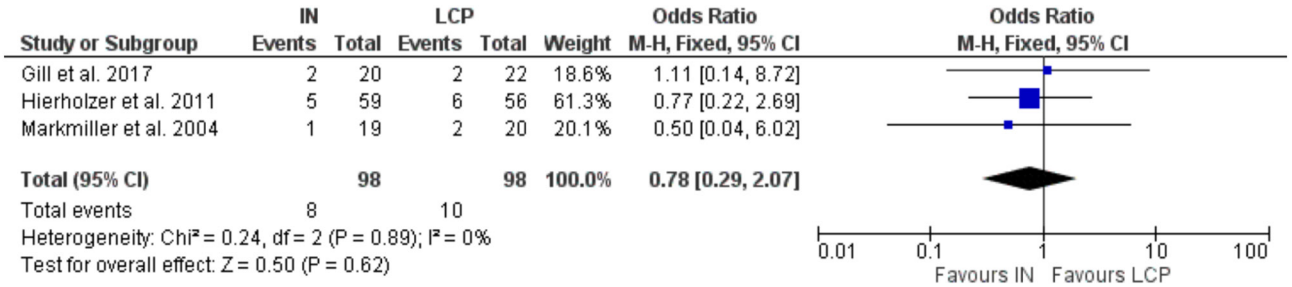

Figure 5

Forest plot: non-union.

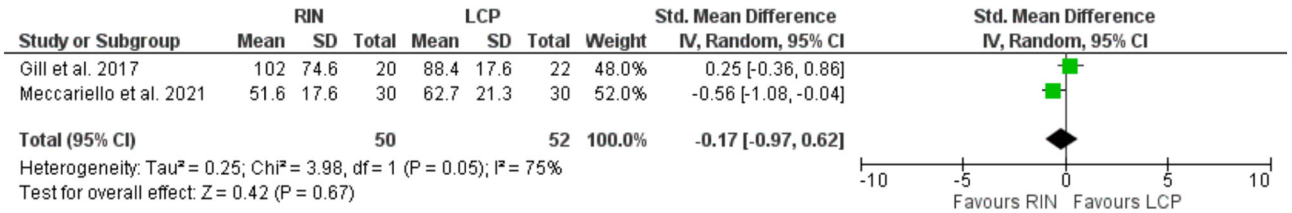

Figure 6

Forest plot: time of surgery.

superficial wound infections as well as time of surgery and blood loss depending on IN or plate fixation.

Concerns about plate fixation are the risk of infection and implant failure requiring revision surgery (24). Our study reveals no significantly increased risk for postoperative wound infections in conjunction with plate osteosynthesis, as reported by Hierholzer *et al.* and Markmiller *et al.* (18, 19).

Zlowodzki *et al.* conducted biomechanical investigations to assess the influence of plating and IN on torsional stability with osteoporotic bone. They demonstrated that both implants showed sufficient anchoring of screws, which makes IN and plate fixation applicable for elderly patients (5, 25, 26).

Early mobilization is of high importance especially in elderly patients to lower postsurgical mortality (27). IN allows early weight bearing and mobilization, but is deemed to be connected with higher blood loss and surgery time, because of intramedullary reaming (28). These findings are mirrored by Gao *et al.* and Gill *et al.* (14, 29, 30). However, our study's findings showed a slightly shorter time of surgery for intramedullary nailing.

Jankowski *et al.* and Neradi *et al.* demonstrated that the rate of non-unions does not seem to be affected by whether the femur was treated with IN or plating (1, 28).

Furthermore, bone healing is influenced by many factors other than the fixation method. Unfortunately, most of

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the studies we included in this analysis failed to report on co-morbidities and other influencing factors (11, 14, 15, 16). There are certain intrinsic risk factors that make one patient more prone to non-unions than another (31). The use of tobacco slows healing, as nicotine impairs cell proliferation and causes vasoconstriction – factors leading to both reduced osteoblasts and a less well-perfused fracture zone resulting in a statistically higher number of atrophic non-unions (32, 33).

Limitations

Our search strategy followed an English search algorithm. Thus, potentially suitable publications in other languages were not considered. The risk of publication bias is imminent because only published articles were included. The Cochrane Library® was scanned for clinical trials to minimize this kind of bias, but we detected no relevant findings.

With mostly RCTs as well as prospective case–control studies and just one retrospective case–control study, the entailing risk for selection, detection, and reporting bias was low. To exclude methodologically inadequate studies, we focused on bias assessment as done by ROBINS-I/ROBINS-II and mCMS. There was no critical risk of bias in any included study.

The fact that we ruled out any publications appearing before 2000 enabled us to exclude obsolete implants. However, especially with multifragmentary fractures, plate osteosynthesis and open reduction is more likely, which is not displayed by the data included. Moreover, classification of fracture type was not taken into account by some authors and can be seen as a potential cofounder.

Conclusion

No statistical difference was found in our study among IN and plate fixation in the treatment of distal femoral fractures with regard to non-union and wound infections.

A tending lower blood loss as well as time of surgery was noted in cases where IN was used; however, these results remained non-significant too.

Based on the relatively scarce and inconclusive available data in literature a definitive recommendation concerning the choice of implant cannot be given. The indication for IN or plating should thus be made individually and based on the surgeons experience.

ICMJE Conflict of Interest Statement
The authors confirm that there is no conflict of interest that could be perceived as prejudicing the impartiality of the study reported.

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