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Plate vs. nail for extra-articular distal tibia fractures: How should we personalize surgical treatment? A meta-analysis of 1332 patients

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ABSTRACT

Background: Treatment for distal diaphyseal or metaphyseal tibia fractures is challenging and the optimal surgical strategy remains a matter of debate. The purpose of this study was to compare plate fixation with nailing in terms of operation time, non-union, time-to-union, mal-union, infection, subsequent re-interventions and functional outcomes (quality of life scores, knee- and ankle scores).

Methods: A search was performed in PubMed/Embase/CINAHL/CENTRAL for all study designs comparing plate fixation with intramedullary nailing (IMN). Data were pooled using RevMan and presented as odds ratios (OR), risk difference (RD), weighted mean difference (WMD) or weighted standardized mean difference (WSMD) with a 95% confidence interval (95%CI). All analyzes were stratified for study design.

Results: A total of 15 studies with 1332 patients were analyzed, including ten RCTs ($n = 873$) and five observational studies ($n = 459$). IMN leads to a shorter time-to-union (WMD: 0.4 months, 95%CI 0.1 – 0.7), shorter time-to-full-weightbearing (WMD: 0.6 months, 95%CI 0.4 – 0.8) and shorter operation duration (WMD: 15.5 min, 95%CI 9.3 – 21.7). Plating leads to a lower risk for mal-union (RD: -10%, OR: 0.4, 95%CI 0.3 – 0.6), but higher risk for infection (RD: 8%, OR: 2.4, 95%CI 1.5 – 3.8). No differences were detected with regard to non-union (RD: 1%, OR: 0.7, 95%CI 0.3 – 1.7), subsequent re-interventions (RD: 4%, OR: 1.3, 95%CI 0.8 – 1.9) and functional outcomes (WSMD: -0.4, 95%CI -0.9 – 0.1). The effect estimates of RCTs and observational studies were equal for all outcomes except for time to union and mal-union.

Conclusion: Satisfactory results can be obtained with both plate fixation and nailing for distal extra-articular tibia fractures. However, nailing is associated with higher rates of mal-union and anterior knee pain while plate fixation results in an increased risk of infection. This study provides a guideline towards a personalized approach and facilitates shared decision-making in surgical treatment of distal extra-articular tibia fractures. The definitive treatment should be case-based and aligned to patient-specific needs in order to minimize the risk of complications.

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Introduction

Surgical treatment of distal diaphyseal or metaphyseal tibia fractures is challenging and the optimal surgical strategy remains a matter of debate. Two core surgical modalities have been described including intramedullary nailing (IMN) and plate fixation.

In the search of defining which treatment is better, the main focus of past meta-analyses has been on pooling data from randomized controlled trials (RCTs). Recently, evidence is growing that the study population and effect estimates of observational studies tend to be quite similar to that of RCTs. Adding observational data in a meta-analysis increases sample size and might improve generalizability of results [1–6] as RCTs frequently have stringent inclusion criteria resulting in a selective study population [7–9].

The aim of this meta-analysis is to provide a complete and comprehensive overview on the optimal surgical treatment of distal tibia fractures by 1) analysing a broad pallet of outcome measures and 2) including both observational studies and RCTs comparing

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plate fixation to IMN. Outcomes of interest include operation time, non-union, time to union, mal-union, infection, subsequent re-interventions and functional outcomes (quality of life scores and knee- and ankle scores). Sub-group analysis is performed to compare outcomes derived from RCTs as well as observational studies.

Material and methods

This systematic review and meta-analysis is performed and reported according to the Meta-analysis of Observational Studies in Epidemiology (MOOSE) and the Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRISMA) checklist [10,11]. Ethical approval was not required for current study.

Search strategy and selection criteria

In order to answer the research question, a search in PubMed/Medline, Embase, CENTRAL and CINAHL was performed for studies comparing plate fixation (either open (ORIF) or minimal invasive plate osteosynthesis (MIPO)) and IMN for meta- or distal diaphyseal extra-articular fractures of the tibia (for search syntax see supplementary material Table 1). A junior doctor (NJB) and a consultant trauma surgeon as well as epidemiologist (BvdW) independently reviewed the title and abstract for suitability and both observational studies and RCTs were included. After screening for title and abstract, NJB and BvdW independently performed the full-text screening. Inclusion criteria of the study were meta- or distal diaphyseal extra-articular fractures of the tibia (type 42-A, 42-B, 42-C and 43-A), comparison of plate (either ORIF or MIPO) to IMN fixation, minimal follow-up of 6 months and reporting on relevant outcomes including operation time, non-union, time to union, mal-union, infection, subsequent re-interventions and functional outcomes (quality of life scores and knee- and ankle scores). Studies reporting on intra-articular fractures (43.B1– 43.C3), secondary or tertiary referrals for non-union or mal-union revision surgery, pathologic fractures or contra-indication for IMN (total knee arthroplasty) were excluded. Studies with languages other than English were also excluded. In case of disagreement on eligibility, a consensus meeting was organized with an independent third reviewer and senior consultant trauma surgeon (FJPB). References of all included studies were screened to identify studies not found in the original literature search.

Data extraction

Data extraction was performed by the two same independent reviewers (NJB, BvdW) with use of a predefined data extraction file. Conflicting data entries were resolved by discussion, and continued disagreement was resolved with the senior author. The following characteristics were extracted from the included studies: authors, year of study, year of publication, country, study design, study period, study subject and included patients. Furthermore, data on patient- and fracture characteristics such as gender, age, injured side, OTA/AO-classification [12], open/closed fractures according to the Gustilo classification [13] were collected.

Quality assessment

The methodological quality of each included study was independently assessed by NJB and BvdW according to the Methodological Index for Non-Randomized Studies (MINORS) [14]. The MINORS is considered to be a reliable and validated instrument for assessment of methodological quality of observational cohort studies [14]. RCTs were appraised using the same tool as well in order to measure quality on the same scale as observational studies (supplementary material Table 2) [1–6]. The MINORS contains 12

items, in which each item can be scored with “reported and adequate” = 2 points, “reported but inadequate” = 1 point and “not reported” = 0 points”. A total of 0 points indicated poor methodological quality and 24 indicated excellent methodological quality. Disagreements on this topic were resolved by organizing a consensus meeting.

Study outcomes

Outcome measures included: operation time, non-union, time to union, mal-union, infection, subsequent re-interventions and functional outcomes (quality of life scores, knee- and ankle scores). Non-union is defined as a lack of tricortical continuity after 6 months of fracture fixation. Mal-union was an angulation more than 5° in any plane or as a rotational deformity of >10° [15]. Infection included both superficial and deep surgical wound infections [16] and subsequent re-interventions included all re-operations during follow-up. General quality of life scores included the EuroQol-5D (EQ-5D), Disability Rating Index (DRI) and ShortForm-36 (SF-36). Functional ankle scores encompassed the Olerud Molander Ankle score (OMAS), Iowa Ankle score, American Orthopaedic Foot and Ankle Society score (AOFAS), Mazur Ankle score and Foot Ankle Index. Functional knee scores included Lysholm Knee Scoring Scale, Knee Injury and Osteoarthritis Outcome Score (KOOS), Oxford Knee Score (OKS), Kujala score, International Knee Documentation Committee (IKDC), Hospital for Special Knee Surgery score (HSS) and Irrgang Knee Outcome Survey Activities of Daily Living Scale. The quality of life scores and functional scores were pooled for each field (general quality of life, ankle function and knee function) separately. In case different scoring instruments were used within one field, then the scores were standardized for pooled analysis.

Statistical analysis

Statistics were performed using RevMan (version 5.3.5). Continuous variables are presented as means with standard deviation (SD) and dichotomous variables as counts and percentages. We used a method described in the Cochrane Handbook for Systematic Reviews of Interventions [17] to convert the reported range or interquartile range (IQR) to SD. The Mantel-Haenszel method was used to pool effects of plating or IMN on dichotomous outcomes and results were reported as weighted odds ratio (weighted OR), risk difference (weighted RD) with corresponding 95% confidence interval (95%CI). In case of zero-cell counts in one of the two treatment groups, 0.5 was added to all cells of contingency table of treatment and the outcome of those studies in which this occurred. The influence of plating or IMN on continuous outcomes were pooled using the inverse variance weighting method. These outcomes were presented as weighted mean difference (WMD) or weighted standardized mean difference (WSMD) with 95%CI. Heterogeneity between studies was assessed for all reported outcomes by the I^2 statistic for heterogeneity. All analyzes were stratified according to study design, i.e., RCTs and observational studies. Differences in effect estimates between RCTs and observational studies were assessed using the χ^2 -test as described in the Cochrane Handbook for Systematic Reviews of Interventions. A p-value below 0.05 was considered statistically significant. Publication bias was assessed by visual inspection of funnel plots. All funnel plots can be found in the supplementary material figures A–J.

Sensitivity analysis

A sensitivity analysis was performed to determine the influence of type of approach (MIPO or ORIF) and AO-classification (type 42 and type 43) on all outcomes of interests. Additionally, a sensitivity

Fig. 1. Search.

analysis on high quality studies was performed. High quality studies were defined as studies with a MINORS score of 16 or higher (range 0 – 24) [1,2].

Results

Search

The search and literature selection are presented in Fig. 1. A total of 34 articles were screened for full text. Finally, 15 studies were found to be eligible for inclusion (Fig. 1) [18–32]. The reported outcomes of Vallier et al. 2011 and Vallier et al. 2012 were based on the same cohort and therefore merged.

Baseline study characteristics

A total of 1332 patients were included in this meta-analysis: 634 patients (48%) were treated with plate fixation and 698 (52%) patients with an IMN. The mean follow up ranged from 11 to 33 months. The mean weighted age of the total study population was 39 years (range 31 – 52 years) with 866 (66%) being males. The

patient- and fracture characteristics per included study are presented in Tables 1 and 2.

Ten of the included studies were RCTs [19–26,29,31] including a total of 873 patients. The weighted mean age was 42 years (range 35 – 45 years) with 603 (69%) males. A total of 432 (49%) patients were treated with plate fixation with a weighted mean age of 42 years (range 33 – 46 years). IMN was performed in 441 (51%) patients. The weighted mean age in this group was 42 years (range 34 – 50 years). Nine studies reported on surgical approach for both treatment groups. Two studies used an open anteromedial approach for plate fixation [23,29] and seven studies used the medial minimal invasive approach [19–22,24,26,31]. For IMN, all studies used an infrapatellar approach [19–24,26,29,31].

Five retrospective observational studies were included with a total of 459 patients [18,27,28,30,32]. The overall weighted mean age was 41 years (range 31 – 52 years) with 263 (57%) being male. A total of 202 (44%) patients were treated with plate fixation and 257 (56%) patients with an IMN. In the plate group, patients had a weighted mean age of 40 (range 31 – 55). This was 42 years (range 31 – 48 years) in the IMN group. Bisaccia et al. used an open anteromedial approach for plate fixation and Vaienti et al. used a medial minimal invasive approach [18,28]. Three studies reported on

Table 1
Study characteristics of included studies.

Author	Year	Country	Design	Study period	Total N	Plate	IMN	Follow up(mean ± SD) months
Im-Gun et al.	2005	S-Korea	RCT	1998–2001	64	30	34	>6
Yang et al.	2006	Taiwan	Cohort	1999–2003	27	14	13	33 (11)
Vallier et al.	2008	USA	Cohort	1999–2003	113	37	76	>6
Guo et al.	2010	China	RCT	2005–2008	85	41	44	>6
Vallier et al.	2011	USA	RCT	2002–2008	104	48	56	>6
Mauffrey et al.	2012	USA	RCT	2008–2009	24	12	12	>6
Seyhan et al.	2013	Turkey	Cohort	2004–2009	61	36	25	21 (12)
Li et al.	2014	Japan	RCT	2002–2012	92	46	46	14.9 (1.1)
Polat et al.	2015	Turkey	RCT	2009–2012	25	15	10	23.1 (9.4)
Fang et al.	2016	China	RCT	2005–2013	56	28	28	28.9 (10)
Wani et al.	2017	India	RCT	2014–2016	60	30	30	11.5 (4.5)
Doalagupu et al.	2017	India	RCT	2014–2015	42	21	21	>6
Costa et al.	2017	UK	RCT	2013–2016	321	160	161	>6
Bisaccia et al.	2018	Italy	Cohort	2009–2015	75	34	41	>6
Vaienti et al.	2018	Italy	Cohort	2008–2017	183	81	102	>6
Total					1332	634	698	

Table 2
Patient and fracture characteristics of included studies.

Author	Design	Mean age		Open fractures		AO 42		AO 43		Fibula fractures	
		Plate	Nail	Plate	Nail	Plate	Nail	Plate	Nail	Plate	Nail
Im-Gun et al.	RCT	40(10.8)	42(11.5)	5	8	NR		A1–11 A2–10 A3–4 C1–5	A1–15 A2–9 A3–5 C1–5	15	22
Yang et al.	Cohort	54.6(18)	48.2(19)	NR		NR		A 13	A 14	NR	
Vallier et al.	Cohort	39.8(12.5)	38.4(15.3)	12	22	A 17 B 5 C 15	A 38 B 19 C 19	NR		100	
Guo et al.	RCT	44.4(11.5)	44.2(10.1)	NR				A1–13 A2–12 A3–16	A1–13 A2–16 A3–15	NR	
Vallier et al.	RCT	38.3(13)		19	21	A 31 B 10 C 7	A 32 B 17 C 7	NR		NR	
Mauffrey et al.	RCT	33(14.1)	50(15.6)	NR		NR		NR		NR	
Seyhan et al.	Cohort	39.7(12.7)	40.3(14.2)	5	7	A 28 B 4 C 4	A 19 B 3 C 3	NR		34	25
Li et al.	RCT	43(15)	44(15)	14	17	A 37 B 7 C 2	A 33 B 8 C 5	NR		NR	
Polat et al.	RCT	36.4(10.7)	34(9.7)	NR		A1–11 A2–1 A3–3	A1–6 A2–3 A3–1	NR		6	8
Fang et al.	RCT	38.6(7.5)	35(9.2)	6	4	A 15 B 10 C 3	A 16 B 8 C 4	NR		19	20
Wani et al.	RCT	38.4(8.7)	36.4(9.7)	NR		A1–20 A2–2 A3–8	A1–18 A2–9 A3–3	NR		8	6
Doalagupu et al.	RCT	39.1(10.1)	35.2(9.2)	NR		NR		A1–10 A2–9 A3–2	A1–11 A2–6 A3–4	NR	
Costa et al.	RCT	45.8(16.3)	44.3(16.3)	NR		NR		NR		NR	
Bisaccia et al.	Cohort	31(13.3)		NR		NR		A1–12 A2–16 A3–6	A1–14 A2–20 A3–7	NR	
Vaienti et al.	Cohort	42.6(13)	47.2(14.8)	19	34	NR		A 81	A 102	32	45

*NR= not reported.

surgical approach for IMN and all described an infrapatellar approach [18,28,32].

Quality assessment

The MINORS scores are shown in Table 3. The overall mean MINORS score for RCTs was 19 (range 15 to 22 points). The overall mean MINORS score for observational studies was 15 with a range from 13 to 16 points.

Outcome measure – operation time (minutes)

Eight studies reported on operation time (minutes), including two observational studies and six RCTs [18,20–24,26,28] with an overall weighted mean operation time of 97 min (range 51 – 114 min) in the plate group and 77 min (range 57 – 88 min) in the IMN group. The operation time was significantly longer for plate fixation in comparison to IMN (WMD 15.5 min, 95%CI 9.3 – 21.7, I^2 90%). There were no significant differences observed in effect estimates between observational studies (WMD 23.8 min, 95%CI 4.2 –

43.4, I^2 98%) and RCTs (WMD 11.8 min, 95%CI 6.3 – 17.4, I^2 57%) (test for subgroup difference $p = 0.3$) (Fig. 2).

Outcome measure – non-union

Seven studies reported on non-union, including two observational studies and five RCTs [21,23–25,27,29,30]. There was no difference in risk for non-union between the two treatment groups (weighted OR 0.7, 95%CI 0.3 – 1.7, I^2 0%) and the effect estimates of observational studies (weighted OR 0.7, 95%CI 0.1 – 3.5, I^2 0%) and RCTs (weighted OR 0.8, 95%CI 0.3 – 2.1, I^2 0%) were equal (test for subgroup difference $p = 0.9$) (Fig. 3). Non-union occurred in 4.3% of patients treated with plate fixation and 5.9% after IMN (weighted RD 1%, 95%CI –5% – 2%, I^2 0%).

Outcome measure – time to union

Eleven studies – four observational studies and seven RCTs – reported on time to union [18,20–24,26,28,30–32] with an overall weighted mean time to union of 4.5 months (range 3.5 –

Fig. 2. Forest plot for operation time in minutes.

Fig. 3. Forest plot for non-union after plate- or IMN fixation.

6.4 months) in the plate group and 4.2 months (range 3.6 – 5.2 months) in the IMN group. The time to union in the IMN group was significantly shorter compared to the plating group (WMD 0.4 months, 95%CI 0.1 – 0.7, I^2 88%). Furthermore, the effect estimates of observational studies (WMD 0.9 months, 95%CI 0.6 – 1.2, I^2 34%) and RCTs (WMD 0.2 months, 95%CI -0.1 – 0.5, I^2 59%) were significantly different (test of subgroup difference, $p < 0.005$) (Fig. 4).

Outcome measure – mal-union

Thirteen studies reported on mal-union (five observational studies and eight RCTs) [18,20,21,23–32]. There was a significant lower risk of mal-union for plate fixation (weighted OR 0.4, 95%CI 0.3 – 0.6, I^2 0%) with a significant difference in effect estimates of observational studies (weighted OR 0.2, 95%CI 0.1 – 0.4, I^2 0%) and RCTs (weighted OR 0.6, 95%CI 0.3 – 1.0, I^2 0%) (test for subgroup difference $p = 0.03$) (Fig. 5). Mal-union occurred in 7% of the patients

with plate fixation and 18% after IMN (weighted RD -11%, 95%CI -15% – -7%, I^2 0%).

Outcome measure – infection

Fourteen studies reported on infection, including four observational studies [18,27,28,30] and ten RCTs [19–26,29,31]. There was a significantly higher risk for infection among patients treated with plate fixation (weighted OR 2.4, 95%CI 1.5 – 3.8, I^2 3%). There was no difference in effect estimates of observational studies (weighted OR 3.3, 95%CI 0.7 – 16.4, I^2 26%) and RCTs (weighted OR 2.3, 95%CI 1.4 – 3.7, I^2 2%) (test for subgroup difference $p = 0.7$) (Fig. 6). Infection occurred in 14% of patients surgically treated with plate fixation and 5% after IMN (weighted RD 8%, 95%CI 4% – 12%, I^2 48%).

Seven studies divided infection into superficial and deep infection [19–21,23–25,27] and five studies reported on deep infections only [18,26,28–30]. The prevalence of deep infections was 3.7% af-

Table 3
MINORS-Criteria.

MINORS-criteria	Im-Gun et al.	Guo et al.	Vallier et al.	Mauffrey et al.	Li et al.	Polat et al.	Fang et al.	Wani et al.	Doalagupu et al.	Costa et al.	Observational studies	Yang et al.	Vallier et al.	Seyhan et al.	Bisaccia et al.	Vaienti et al.
Clearly stated aim	2	1	2	2	2	2	2	2	0	1		2	2	2	2	2
Inclusion of consecutive patients	2	2	2	2	2	2	2	2	2	2		0	2	2	1	2
Prospective data collection	2	2	2	2	2	2	2	2	2	2		0	0	0	0	0
Appropriate endpoints	1	2	2	2	2	2	2	2	2	2		2	2	2	0	2
Unbiased assessment	2	0	0	0	0	0	0	0	0	0		0	0	0	0	0
Appropriate follow-up (>1year)	2	2	2	1	2	2	2	1	1	2		2	2	2	2	1
Loss-to-follow up <5%	1	1	2	1	1	2	0	0	0	1		0	0	0	0	0
Prospective calculation study size	0	0	2	0	0	0	0	0	0	2		0	0	0	0	0
Adequate control group	2	2	2	2	2	2	2	2	2	2		2	2	2	2	2
Contemporary groups	2	2	2	2	2	2	2	2	2	2		2	2	2	2	2
Baseline equivalence of groups	2	2	2	2	2	2	2	2	2	2		2	2	2	2	2
Adequate statistical analysis	2	2	2	2	2	2	2	2	2	2		2	2	2	2	2
Total	20	18	22	18	19	20	18	17	15	20		14	16	16	13	15

ter plate fixation and 1.3% after IMN. The prevalence of superficial infections was 10.2% after plate fixation and 4.1% after IMN.

Outcome measure – subsequent re-interventions

Subsequent re-interventions were reported in fourteen studies, including five observational studies and nine RCTs [18,19,21–32]. There was no difference in risk of subsequent re-interventions between plate fixation and IMN (weighted OR 1.3, 95%CI 0.8 – 1.9, I^2 45%). The effect estimates of observational studies (weighted OR 1.4, 95%CI 0.4 – 4.3, I^2 73%) were equal to the effect estimates of the RCTs (weighted OR 1.3, 95%CI 0.9 – 1.9, I^2 5%) (test for subgroup difference $p = 1.0$) (Fig. 7). A subsequent re-intervention was required in 38% of the plate fixation group and 33% in the IMN fixation group (weighted RD 4%, 95%CI –3% – 11%, I^2 59%). The majority of subsequent re-interventions included implant removal (72% versus 75%) and revisions (6% versus 12%). The indications for re-intervention are listed in Table 4 and supplementary material Table 3.

Outcome measure – time to weightbearing (months)

Six studies evaluated time to weightbearing, including three observational studies and three RCTs [18,20,26–28,31]. The weighted mean time to full weightbearing for patients treated with plate fixation was 2.9 months (range 1.4 – 3.5 months) and 2.3 months (range 1.2 – 3.0 months) for patients treated with an IMN. Time to weightbearing was significantly shorter for patients treated with an IMN (WMD 0.6 months, 95%CI 0.4 – 0.8, I^2 72%) with no difference between observational studies (WMD 0.7 months, 95%CI 0.5 – 0.9, I^2 45%) and RCTs (WMD 0.4 months, 95%CI 0.0 – 0.9, I^2 84%) (test for subgroup difference $p = 0.3$) (Fig. 8).

Outcome measure – anterior knee pain

Seven studies reported on anterior knee pain – three observational studies and four RCTs [18,20,21,24,26,28,32]. Anterior knee pain was reported in 20% of the patients treated with IMN (weighted RD –25%, 95%CI –41% – –9%, I^2 89%) and 0% after plate fixation.

Outcome measure – general quality of life scores (6 to 12 months postoperatively)

Only three studies – one observational study and two RCTs – reported on general quality of life and all used the Disability Rating Index [19,25,28]. The overall weighted mean score for plate fixation was 30 points (range 21.5 – 39.8) and also 30 points (range 29.8 – 31.2) for IMN (0 points indicating no disability and 100 points indicating complete disability). This outcome did not differ significantly between both treatment groups (WMD –1.9, 95%CI –13.3 – 9.6, I^2 84%) (Fig. 9). Subgroup analysis stratified for study design was not possible as only one observational study was available for comparison to RCTs.

Outcome measure – functional ankle scores (6 to 12 months postoperatively)

Eight studies reported on functional ankle scores – two observational studies and six RCTs – using the OMAS, AOFAS score and Foot Ankle Index [19,21,22,25,26,28,31,32]. There was no significant difference in functional ankle scores between both treatment groups (WSMD –0.4, 95%CI –0.9 – 0.1, I^2 88%) and there was no difference observed between observational studies (WSMD –1, 95%CI –2.2 – 0.1, I^2 87%) and RCTs (WSMD –0.2, 95%CI –0.3 – 0.0, I^2 0%) (test for subgroup difference: $p = 0.1$) (Fig. 10).

Fig. 4. Forest plot for time to union (months) for plate fixation versus IMN.

Fig. 5. Forest plot for risk for mal-union after plate- or nail fixation.

Outcome measure – functional knee scores (6 to 12 months postoperatively)

None of the included studies reported on functional knee scores.

Sensitivity analysis

The weighted effects of both treatment groups on different outcomes stratified by quality of studies, AO-classification and surgical approach for plate fixation (ORIF and MIPO) did not signifi-

Fig. 6. Forest plot for risk of infection.

Fig. 7. Forest plot for subsequent re-interventions.

Fig. 8. Forest plot for time to full weightbearing in months.

Fig. 9. Quality of Life Scores.

Fig. 10. Functional Ankle Scores.

Table 4
Specification of subsequent re-interventions after plate- or IMN fixation.

Study	Revision		Infection		Implant removal		Not specified	
	Plate	Nail	Plate	Nail	Plate	Nail	Plate	Nail
Observational Studies								
Yang et al.	NR		NR		11	12	NR	
Vallier et al.	2	13	1	4	3	6	NR	
Seyhan et al.	3	1	4	0	13	2	NR	
Bisaccia et al.	NR		2	0	NR		NR	
Vaienti et al.	NR		NR		57	72	NR	
Total	5 (5%)	14 (12%)	7(7%)	4(4%)	84(88%)	92(84%)	NR	
(plate, n = 96)								
(nail, n = 110)								
RCTs								
Im-Gun et al.	1	3	1	0	NR		NR	
Guo et al.	NR		NR		24	23	NR	
Vallier et al.	3	5	4	2	4	6	4	1
Mauffrey et al.	NR		1	0	4	1	NR	
Li et al.	NR	1	NR	1	22	25	NR	
Polat et al.	NR		1	0	NR		NR	
Fang et al.	NR	1	1	NR	13	9	NR	
Wani et al.	NR		NR		NR		3	4
Costa et al.	5	2	5	1	14	11	22	17
Total	9(7%)	12(11%)	13(10%)	4(4%)	81(61%)	75(66%)	29(22%)	22(19%)
(plate, n = 132)								
(nail, n = 113)								
Total Observational & RCTs	14(6%)	26(12%)	20(9%)	8(3%)	165(72%)	167(75%)	29(13%)	22(10%)
(plate, n = 228)								
(nail, n = 223)								

Table 5
Sensitivity analysis for quality of studies, AO-classification and surgical approach for plate fixation.

	Non-union	Time to union (months)	Mal-union	Infection	Subsequent re-interventions	Functional ankle scores
All studies	OR 0.7 [0.3 – 1.7]	MD 0.4 [0.1 – 0.7]	OR 0.4 [0.3 – 0.6]	OR 2.4 [1.5 – 3.8]	OR 1.3 [0.8 – 1.9]	SMD –0.4 [–0.9 – 0.1]
High quality studies	OR 0.7 [0.3 – 1.7]	MD 0.1 [0.0 – 0.2]	OR 0.5 [0.3 – 0.8]	OR 2.3 [1.3 – 4.1]	OR 1.3 [0.8 – 2.2]	SMD –0.2 [–0.3 – 0.1]
Low quality studies	*	MD 1.0 [0.8 – 1.1]	OR 0.3 [0.1 – 0.7]	OR 6.1 [1.3 – 29.1]	OR 1.0 [0.4 – 2.5]	SMD –1.0 [–2.2 – 0.1]
AO type 42	OR 0.7 [0.3 – 2.0]	MD 0.1 [0.0 – 0.3]	OR 0.5 [0.3 – 0.8]	OR 3.1 [1.3 – 7.0]	OR 1.2 [0.6 – 2.6]	SMD –0.0 [–0.4 – 0.3]
AO type 43	OR 0.7 [0.1 – 4.7]	MD 0.7 [0.3 – 1.0]	OR 0.3 [0.1 – 0.6]	OR 4.4 [1.5 – 12.6]	OR 1.1 [0.7 – 1.7]	SMD –0.7 [–1.7 – 0.3]
MIPO	OR 1.1 [0.2 – 5.3]	MD 0.3 [–0.1 – 0.7]	OR 0.5 [0.3 – 0.9]	OR 2.3 [1.4 – 3.6]	OR 1.4 [0.8 – 2.2]	SMD –0.4 [–1.1 – 0.3]
ORIF plate	OR 0.6 [0.2 – 1.7]	MD 0.7 [0.3 – 1.1]	OR 0.3 [0.1 – 0.7]	OR 1.8 [0.5 – 6.8]	OR 1.0 [0.5 – 2.5]	SMD –0.5 [–1.1 – 0.1]

OR – odds ratio, MD – mean difference, SMD – standardised mean difference, [...] – 95% confidence interval.

* Less than 2 studies available for pooled analysis.

cantly differ between the main analysis and the stratified analyzes (Table 5).

Discussion

The aim of this meta-analysis was to determine the optimal surgical strategy for distal tibia fractures by comparing plate fixation to IMN using both observational studies and RCTs and analysing a broad pallet of outcome measures. Time to union, time to full weightbearing and operation duration was significantly shorter and the infection rate lower among patients treated with IMN. On the contrary, there was a lower risk for mal-union and anterior knee pain for patients treated with plate fixation compared to IMN. No significant differences were detected with regard to non-union, of patient reported quality of life scores, ankle scores and subsequent re-interventions. Subsequent re-interventions were mostly performed for implant removal in both groups. Although the effect estimates of observational studies and RCTs pointed in the same direction for all outcomes, the magnitude was different for the outcomes time to union and mal-union. Sensitivity analysis for

high/low quality studies, AO-classification and surgical approach for plate fixation (MIPO or ORIF) showed no relevant differences in all outcomes.

Comparison to previous literature

The present meta-analysis differs from previous meta-analyses in several ways. Firstly, we included observational studies in the pooled analysis and stratified for design. Adding observational studies increases sample size and the ability to detect small differences not previously detectable in previous meta-analyses (e.g. time to union and operation duration)(1–4). Stratification creates the possibility to study differences in effect estimates between observational studies and RCTs which, as shown in the present and previous meta-analyses comparing surgical treatments (1–4), tend to be quite similar. Secondly, the purpose of this study was to provide a comprehensive overview and comparison on plate fixation versus IMN of distal tibia fractures by analysing a broad pallet of outcomes measures ranging from operation time to complications and functional outcomes. Thirdly, there are several question-

naires for measuring, for example, ankle function. As such, different questionnaires measure functionality on a different scale. For pooled analysis, one can either pool the scores of the same questionnaire together or standardize the scores of questionnaires in the same field (for example general quality of life or ankle function). The previous meta-analyses used the first method and the present study the latter. Both have their advantages and disadvantages with regard to statistical power and precision. As both methods have led to the same conclusion, it is fairly certain that there truly is no difference in functional outcomes between the two treatments.

This meta-analysis found a significant higher rate of mal-union and anterior knee pain after IMN and a significant higher rate of infection after plate fixation for distal tibia fractures. Furthermore, significant differences were found in terms of time to union, time to full weightbearing and operation duration in favour of IMN. Previous studies found almost equal outcomes with regard to IMN leading to a higher rate of mal-union and anterior knee pain and that plate fixation is leading to a significant higher rate of wound complications [9,33–36]. Two studies came to different conclusions about the mal-union rate, which was not significantly different in both groups [7,37]. It is noteworthy, however, that Wang et al. merged the rates of mal-union and non-union and that Goh et al. included a selected group consisting of closed or Gustilo I open extra-articular (43-A) fractures. As this meta-analysis included the entire spectrum of distal tibia fractures and pooled data on mal-union and non-union separately, a reliable comparison with these studies was not possible.

Interpretation of results

There were several pronounced differences between plate fixation and IMN.

There was a fairly large difference in risk of infection between the two treatment groups: in the plate fixation group, 14% developed an infection versus 5% after IMN. It should however be acknowledged that this encompasses both superficial and deep infections combined. From a clinical point of view, deep infections are the most relevant of the two as they frequently lead to re-intervention and/or prolonged durations of antibiotic treatment. Deep infections were rare and occurred in 3.7% of patients treated with plate fixation versus 1.3% for nailing.

Minimally invasive techniques tend to have less risk for infection. Interestingly, this concept did not apply in the sensitivity analysis on type of approach. The risk for infection was equally high in the comparison of MIPO to IMN and ORIF to IMN. This may be subscribed to the slender soft tissue envelope on the medial aspect of the tibia. Introducing the plate in a MIPO fashion on the medial side of the tibia as well as its prominence might compromise the insertion wounds. Therefore, the outcomes might be not as promising as compared to MIPO techniques of the femur as there is sufficient more soft tissue coverage. However, the current study was designed to compare plate fixation (ORIF and MIPO) versus IMN. Direct comparison of MIPO to ORIF is outside of the scope of this study. This study also sought to establish the relation between open fracture type and infection through a sensitivity analysis. However, as the included studies had a mix of both open and closed fractures, this sensitivity analysis was not possible.

Mal-union occurred in 18% of the patients after IMN and 7% after plate fixation. The difference could be subscribed to the difficulty in establishing correct alignment during IMN due to soft tissue injury, swelling, often closed reduction without direct vision of the fracture, displacement of multiple fracture fragments and difficulties in interpretation of fluoroscopy images as opposed to direct reduction techniques when applying a plate.

IMN shortens the time to union and full weightbearing with approximately two weeks. It should be acknowledged that assessment of time to union and time to full weightbearing depends on a few factors. Firstly, measuring radiographic union on plain radiographs is challenging and susceptible to high degrees of inter-observer variability [38]. Secondly, full weightbearing is a subjective outcome which ideally should be measured on day to day basis. The ability to fully weight bear was determined at fixed intervals due to the nature of the studies included in this meta-analysis. Therefore, it is difficult to ascertain how this two-week difference translates into a clinical setting and how patients experience this contrast.

It is widely considered that IMN leads to high rates of anterior knee pain. Anterior knee pain was found up to 20% of cases and is the leading cause for implant removal. If anterior knee pain would have been a temporary issue, treatable with nail removal, then this high percentage need not be a decisive factor in the choice between plate fixation or IMN. However, previous studies have shown that patients still suffer from ongoing knee pain even after nail removal up to 58% [39–41]. As the incidence of anterior knee pain is equally high for both an infra-patellar and supra-patellar approach, this problem applies to both nailing techniques [42–46].

The operation duration was significantly shorter for IMN in comparison to plating (77 min versus 97 min). However, the absolute difference is small and the analysis showed high degrees of heterogeneity. The source of the heterogeneity is most likely caused by the fact that operation duration is very dependent on the surgeon's experience and hospital logistics.

All in all, the choice of implant based on the results found in this meta-analysis, is not straight forward and should be made on a case-by-case basis. Patients who have a high risk for infection (due to high age, co-morbidities, smoking, severe soft tissue injury) should preferably be treated with a nail. Young, active and healthy patients who are less prone for infection, might benefit more from plate fixation as it minimizes risk of knee pain and mal-union.

Finally, the effect estimates of observational studies and RCTs did not differ for the majority of outcomes. However, for time to union and the occurrence of mal-union, observational studies tend to overestimate the difference.

Implications for further research

In current literature there is sufficient evidence that both plate fixation and IMN are suitable for treatment of distal tibia fractures. Future studies should focus more on aligning the optimal treatment with the potential for infection, mal-union and anterior knee pain as important parameters. Data on treatment through a case-by-case basis is limited and subsequent research should therefore center surgical decision making on individual factors such as co-morbidities, physical state and social factors. Good quality prospective data for such risk stratification to personalize trauma care is currently scarce, but in other fields of medicine Machine Learning algorithms have shown promising results to facilitate shared decision making by data driven risk stratification.

Limitations

This study has several limitations that should be addressed. The first restriction is the limited value of the pooled analysis of time to union ($I^2=88\%$), operation duration ($I^2=90\%$), anterior knee pain ($I^2=89\%$), general quality of life scores ($I^2=84\%$) and functional ankle scores ($I^2=88\%$) caused by heterogeneity. These results should be interpreted with caution. Secondly, baseline characteristics seemed similar across treatment groups. This however does not fully rule out selection bias. There might still be unmeasured

characteristics which might be different across treatment groups causing residual selection bias among the observational studies. Thirdly, the majority of the included studies used the terms “superficial and deep” to indicate infection rates, which is clearly subjective to heterogeneity. Since the establishment of the consensus definition of fracture-related infection, introduced by Metsemakers et al. in 2018, more uniformity might be expected in future studies with regard to this diagnosis [47].

Conclusion

Plate fixation and IMN are both viable options with implant specific merits and demerits. IMN leads to a higher rate of malunion and anterior knee pain and plate fixation is associated with an increased risk of infection. This study provides a guideline towards personalized treatment and facilitates shared decision-making in future treatment of distal tibia fractures. The surgical treatment should be based on a case-by-case basis and dictated by whether surgeons want to prevent malunion and anterior knee pain versus the potential of infection. Logically, the definitive interpretation and how to integrate this evidence into clinical practice is up to the treating surgeon/reader.

Declaration of Competing Interest

Each author certifies that he has no commercial associations (e.g., consultancies, stock ownership, equity interest, patent/licensing arrangements, etc.) or financial remunerations that might pose a conflict of interest in connection with the submitted article.

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