Supplementary Information

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Search and screening

Supplementary Information 1 (SI1)

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Inclusion/Exclusion criteria

(SI1.1)

SI1.1

PICOS framework	Include	Exclude
Population	Skeletally mature patients (age ≥16) treated surgically for an acute distal tibia fracture.	Paediatric patients (age <16).
Intervention/Comparators	All studies comparing at least two of the following interventions: • Intramedullary nailing • Circular frame • Plate fixation	Non-comparative studies.
Outcomes	Studies investigating at least one of the following outcomes: • Time to union (weeks) • Time to weight-bearing • Infections • Overall complications • Ultimate clinical/radiological outcomes	Studies not investigating any of the outcomes.
Study design	• Randomised Control Trials (RCTs) • Cohort/case-control studies	• Case reports/series • Other reviews • Editorials

Search terms

(SI1.2)

SI1.2.1

PubMed (Advanced search) *= 487 search results*

((("External Fixators"[MeSH] OR "Ilizarov Technique"[MeSH] OR "circular fram*"[tiab] OR "external fixat*"[tiab] OR "Ilizarov*"[tiab] OR "fram*"[tiab]) AND ("Fracture Fixation, Internal"[MeSH] OR "Bone Plates"[MeSH] OR "plate fixat*"[tiab] OR "internal fixat*"[tiab] OR "plate*"[tiab] OR "osteosynthesis"[tiab])) OR (("Fracture Fixation, Internal"[MeSH] OR "Bone Plates"[MeSH] OR "plate fixat*"[tiab] OR "internal fixat*"[tiab] OR "plate*"[tiab] OR "osteosynthesis"[tiab]) AND ("Fracture Fixation, Intramedullary"[MeSH] OR "intramedullary nail*"[tiab] OR "intramedullary fixat*"[tiab] OR "IM nail*"[tiab] OR "nail fixat*"[tiab])) OR (("External Fixators"[MeSH] OR "Ilizarov Technique"[MeSH] OR "circular fram*"[tiab] OR "external fixat*"[tiab] OR "Ilizarov*"[tiab] OR "fram*"[tiab]) AND ("Fracture Fixation, Intramedullary"[MeSH] OR "intramedullary nail*"[tiab] OR "intramedullary fixat*"[tiab] OR "IM nail*"[tiab] OR "nail fixat*"[tiab]))) AND ("Tibia"[MeSH] OR "distal tibia*"[tiab] OR "lower tibia*"[tiab] OR "distal third tibi*"[tiab] OR "lower third tibi*"[tiab]) AND ("Fractures, Bone"[MeSH] OR fracture*[tiab]) AND (randomi*[tiab] OR trial[tiab] OR cohort[tiab] OR "case control"[tiab] OR "case-control"[tiab] OR observational*[tiab] OR prospective[tiab] OR retrospective[tiab] OR "follow-up"[tiab] OR "follow up"[tiab]) NOT ("case report"[ti] OR "case series"[ti] OR "systematic review"[ti] OR "scoping review"[ti] OR "narrative review"[ti] OR "umbrella review"[ti] OR "meta analysis"[ti] OR editorial[pt]) AND english[lang]

SI1.2.2

Web of Science *= 151 search results*

((TS=(("external fixation" OR "circular frame" OR ilizarov) AND ("plate fixation" OR "internal fixation" OR osteosynthesis))) OR (TS=(("plate fixation" OR "internal fixation" OR osteosynthesis) AND ("intramedullary nailing" OR "intramedullary fixation" OR "IM nail" OR "nail fixation"))) OR (TS=(("external fixation" OR "circular frame" OR ilizarov) AND ("intramedullary nailing" OR "intramedullary fixation" OR "IM nail" OR "nail fixation")))) AND TS=("distal tibia" OR "lower tibia" OR "distal third tibia" OR "lower third tibia") AND TS=(fracture) AND TS=(randomi* OR trial OR cohort OR "case-control" OR observational OR prospective OR retrospective OR "follow-up") NOT TI=("case report" OR "case series" OR "systematic review" OR "scoping review" OR "narrative review" OR "umbrella review" OR "meta analysis" OR editorial)

Apply English language only in the filters

SI1.2.3

<u>CINAHL(EBSCO)</u> *= 73 search results*

(((TI "external fixat*" OR AB "external fixat*" OR TI "circular fram*" OR AB "circular fram*" OR TI ilizarov* OR AB ilizarov* OR TI fram* OR AB fram*) AND (TI "plate fixat*" OR AB "plate fixat*" OR TI "internal fixat*" OR AB "internal fixat*" OR TI plate* OR AB plate* OR TI osteosynthesis OR AB osteosynthesis)) OR ((TI "plate fixat*" OR AB "plate fixat*" OR TI "internal fixat*" OR AB "internal fixat*" OR TI plate* OR AB plate* OR TI osteosynthesis OR AB osteosynthesis) AND (TI "intramedullary nail*" OR AB "intramedullary nail*" OR TI "intramedullary fixat*" OR AB "intramedullary fixat*" OR TI "im nail*" OR AB "im nail*" OR TI "nail fixat*" OR AB "nail fixat*")) OR ((TI "external fixat*" OR AB "external fixat*" OR TI "circular fram*" OR AB "circular fram*" OR TI ilizarov* OR AB ilizarov* OR TI fram* OR AB fram*) AND (TI "intramedullary nail*" OR AB "intramedullary nail*" OR TI "intramedullary fixat*" OR AB "intramedullary fixat*" OR TI "im nail*" OR AB "im nail*" OR TI "nail fixat*" OR AB "nail fixat*"))) AND (TI "distal tibia*" OR AB "distal tibia*" OR TI "lower tibia*" OR AB "lower tibia*" OR TI "distal third tibi*" OR AB "distal third tibi*" OR TI "lower third tibi*" OR AB "lower third tibi*") AND (TI fracture* OR AB fracture*) AND (TI (randomi* OR trial OR cohort OR "case-control" OR observational* OR prospective OR retrospective OR "follow-up") OR AB (randomi* OR trial OR cohort OR "case-control" OR observational* OR prospective OR retrospective OR "follow-up")) NOT TI ("case report" OR "case series" OR "systematic review" OR "scoping review" OR "narrative review" OR "umbrella review" OR "meta analysis" OR editorial)

Apply English language only in the filters

SI1.2.4

<u>Clinicaltrials.gov (grey literature)</u> *= 13 search results*

(distal tibia OR lower tibia OR distal third tibia) AND (fracture OR fractures) AND (((external fixator OR Ilizarov OR circular frame) AND (internal fixation OR bone plates OR osteosynthesis)) OR ((internal fixation OR bone plates OR osteosynthesis) AND (intramedullary nail OR IM nail OR nail fixation OR intramedullary fixation)) OR ((external fixator OR Ilizarov OR circular frame) AND (intramedullary nail OR IM nail OR nail fixation OR intramedullary fixation))) AND (randomized OR trial OR cohort OR observational OR prospective OR retrospective OR follow-up)

SI1.2.5

Scopus = *378 search results*

((TITLE-ABS-KEY("external fixat*" OR "circular fram*" OR ilizarov* OR fram*) AND TITLE-ABS-KEY("plate fixat*" OR "internal fixat*" OR plate* OR osteosynthesis)) OR (TITLE-ABS-KEY("plate fixat*" OR "internal fixat*" OR plate* OR osteosynthesis) AND TITLE-ABS-KEY("intramedullary nail*" OR "intramedullary fixat*" OR "im nail*" OR "nail fixat*")) OR (TITLE-ABS-KEY("external fixat*" OR "circular fram*" OR ilizarov* OR fram*) AND TITLE-ABS-KEY("intramedullary nail*" OR "intramedullary fixat*" OR "im nail*" OR "nail fixat*"))) AND TITLE-ABS-KEY("distal tibia*" OR "lower tibia*" OR "distal third tibi*" OR "lower third tibi*") AND TITLE-ABS-KEY(fracture*) AND TITLE-ABS-KEY(randomi* OR trial OR cohort OR "case-control" OR observational* OR prospective OR retrospective OR "follow-up") AND NOT TITLE("case report" OR "case series" OR "systematic review" OR "scoping review" OR "narrative review" OR "umbrella review" OR "meta analysis" OR editorial) AND (LIMIT-TO(LANGUAGE, "English"))

SI1.2.6

#	**Search (Ovid: MEDLINE, CENTRAL, AMED)** = *181 search results*
1	“Circular fram*”/ OR "External Fixat*"/ OR “Ilizarov*”/ OR “fram*”/
2	(“Circular fram*” OR "External Fixat*" OR “Ilizarov*” OR “fram*”).ti,ab
3	1 OR 2
4	“Plate fixat*”/ OR "Internal Fixat*”/ OR "plate*"/ OR “osteosynthesis”/
5	(“Plate fixat*” OR "Internal Fixat*” OR "plate*" OR “osteosynthesis”).ti,ab
6	4 OR 5
7	“intramedullary nail*”/ OR "Intramedullary fixat*”/ OR "IM nail*"/ OR "nail fixat*"/
8	(“intramedullary nail*” OR "Intramedullary fixat*” OR "IM nail*" OR "nail fixat*").ti,ab
9	7 OR 8
10	(3 AND 6) OR (3 AND 9) OR (6 AND 9) OR (3 AND 6 AND 9)
11	“distal tibia*”/ OR “lower tibia*”/ OR “distal third tibi*”/ OR “lower third tibi*”/
12	(“distal tibia*” OR “lower tibia*” OR “distal third tibi*” OR “lower third tibi*”).ti,ab
13	11 OR 12
14	“fracture*”/
15	“fracture*”.ti
16	14 OR 15
17	13 AND 16
18	10 AND 17
19	(“case report” OR “case series” OR “systematic review” OR “Scoping review” OR “narrative review” OR “umbrella review” OR “meta analysis” OR “editorial”).ti
20	18 NOT 19
21	(randomi* OR “trial” OR “cohort” OR "case control" OR "case-control" OR "observational*" OR “prospective” OR “retrospective” OR “follow-up” OR "follow up").ti,ab
22	20 AND 21
23	Limit 22 to English Language

SI1.2.7

#	**Search (Ovid: Embase)** *= 180 search results*
1	“Circular fram*”/ OR "External Fixat*"/ OR “Ilizarov*”/ OR “fram*”/
2	(“Circular fram*” OR "External Fixat*" OR “Ilizarov*” OR “fram*”).ti,ab,kw
3	1 OR 2
4	“Plate fixat*”/ OR "Internal Fixat*”/ OR "plate*"/ OR “osteosynthesis”/
5	(“Plate fixat*” OR "Internal Fixat*” OR "plate*" OR “osteosynthesis”).ti,ab,kw
6	4 OR 5
7	“intramedullary nail*”/ OR "Intramedullary fixat*”/ OR "IM nail*"/ OR "nail fixat*"/
8	(“intramedullary nail*” OR "Intramedullary fixat*” OR "IM nail*" OR "nail fixat*").ti,ab,kw
9	7 OR 8
10	(3 AND 6) OR (3 AND 9) OR (6 AND 9) OR (3 AND 6 AND 9)
11	“distal tibia*”/ OR “lower tibia*”/ OR “distal third tibi*”/ OR “lower third tibi*”/
12	(“distal tibia*” OR “lower tibia*” OR “distal third tibi*” OR “lower third tibi*”).ti,ab,kw
13	11 OR 12
14	“fracture*”/
15	“fracture*”.ti,kw
16	14 OR 15
17	13 AND 16
18	10 AND 17
19	(“case report” OR “case series” OR “systematic review” OR “Scoping review” OR “narrative review” OR “umbrella review” OR “meta analysis” OR “editorial”).ti,kw
20	18 NOT 19
21	(randomi* OR “trial” OR “cohort” OR "case control" OR "case-control" OR "observational*" OR “prospective” OR “retrospective” OR “follow-up” OR "follow up").ti,ab,kw
22	20 AND 21
23	Limit 22 to English Language

Data-extraction tables

Supplementary Information 2 (SI2)

Contents:

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* denotes statistically significant result ($p < 0.05$)

Abbreviations:

AOFAS = American foot and ankle score
OMAS = Olerud-Molander ankle score
DRI = Disability Rating Index
FFI = Foot function Index
IMN = Intramedullary nail
MIPO = Minimally invasive plate osteosynthesis
ORIF = Open reduction + internal fixation
CF = Circular frame
MTC = Major Trauma Centre
POI = Points of Interest column
FUP = Follow-up

Randomised Control Trials

(SI2.1)

SI2.1.1 – Baseline characteristics for the randomised control trials

Study	Country	Setting	Intra- or Extra-Articular	Intervention	Comparator(s)	Sample size				
						Total	IMN	Plate	Circular frame	Missing
Im et al., 2005	South Korea	University-affiliated tertiary care hospital	Both	Nail	Plate (ORIF)	78	34	30		12 patients lost to FUP
Guo et al., 2010	China	University-affiliated tertiary care hospital	Extra (AO43A only)	Nail	Plate (MIPO)	85	44	41		0
Vallier et al., 2011	USA	Level 1 Trauma centre ≈ MTC	Extra (OTA 42-A, B, C)	Plate (ORIF)	Nail	104	56	48		0
Li et al., 2014	China	Tertiary centre	Extra (OTA 42-A, B, C)	Plate (MIPO)	Nail ; [monolateral external fixator]	121	40	42		15 lost to FUP/death/other
Polat et al., 2015	Turkey	Level 1 Trauma centre ≈ MTC	Extra (AO42A1, 43A1)	Nail	Plate (MIPO)	25	10	15		0
Imran et al., 2016	Pakistan	Tertiary centre	Extra	Plate (MIPO)	Nail	86	43	43		0
Wani et al., 2017	India	Tertiary centre	Extra (AO42A1-3)	Nail	Plate (MIPO)	60	30	30		0
Costa et al., 2018	UK	28 acute trauma centres.	Extra	Nail	Plate (MIPO)	321	161	160		10 withdrawals post-randomisation
Ahmed et al., 2018	Egypt	University-affiliated tertiary care hospital	Intra	Plate (ORIF)	Circular frame	45		22	20	3 missing: 2 lost to FUP (1 from each group) and 1 refused treatment
Sharma et al., 2018	Nepal	Tertiary centre	Extra & Intra	Plate (MIPO)	Circular frame (hybrid Ilizarov)	80		40	40	0
KC et al., 2021	Nepal	Tertiary centre	Extra	Nail	Plate (MIPO)	100	50	50		0
Kumar et al., 2022	India	University-affiliated tertiary care hospital	Extra (AO43A only)	Nail	Plate (MIPO)	52	26	26		0
Ahmed et al., 2023	Iraq	University-affiliated tertiary care hospital	Extra	Plate (MIPO)	Nail	20	10	10		0
Hamdy et al., 2024	Egypt	2 tertiary centres	Extra (AO43A1 only)	Nail (Poller screws)	Plate (ORIF)	65	31	34		3 lost to FUP in IMN group: 34-3=31
Prabhat et al., 2025	India	Single tertiary centre	Extra (AO43A only)	Nail (ETN)	Plate (ORIF)	60	30	30		0

SI2.1.2 – Radiographically assessed data from the randomised control trials

Study	Main Outcomes	Outcome Timepoints	Time to union (weeks)			Time to partial weight bearing (weeks)			Time to full weight bearing (weeks)			Teeny and Wiss			Points of interest
			IMN	Plate	Circular frame	IMN	Plate	Circular frame	IMN	Plate	Circular frame	IMN	Plate	Circular frame	
Im et al., 2005	Time to union; Infection (superficial & deep); OMAS	Time to Union = weeks; OMAS = 2 years; Infection = cumulative (final review at 2 years)	18 (range = 12– 64)	20 (range = 12– 72)											Significantly higher angulation in IMN compared to MIPO. However, IMN had significantly better ankle range of motion.
Guo et al., 2010	Time to union; AOFAS; Pain; Function; Wound problems (delayed wound healing & superficial infection)	AOFAS, Pain, Function = 12 months (cumulative 3, 6, 12 month reviews); Time to union = weeks; Wound problems = 5 days, 14/15 days	17.66 (95% CI = 16.7-18.6)	17.59 (95% CI = 16.9- 18.3)											Alignment was equal between groups. IMN had increased pain but better function.
Vallier et al., 2011	Malunion; Nonunion; Infection; Secondary operations	Infection and secondary complications = not specified (likely reviewed cumulatively at routine follow up appointments - see Points of Interest ["POI"])													Significantly greater malalignment in IMN group.
Li et al., 2014	Time to union (radiographic); Ankle function (Mazur ankle score)	Time to union = weeks; Ankle function (Mazur ankle score) = 12 months; infection = not specified (likely reviewed cumulatively at routine follow up appointments - see "POI")	15.6 ± 3.2	15 ± 3.4											No significant difference in malunion but IMN had greater knee pain reported (transtendinous approach).

SI2.1.2 – Radiographically assessed data from the randomised control trials (continued)

Polat et al., 2015	Time to union; Time for full weight-bearing; Foot function Index score; Superficial Infection	Time to union = mean days; Time for full weight-bearing = mean days; Foot Function Index score (FFI) = final FUP (mean ; Superficial Infection = cumulative until final FUP	18.4 ± 1.97	19.13 ± 2.17					5.64 ±2.54	6.51 ±3.17					Malunion was similar but there was significantly greater malalignment due to rotation in the IMN group.
Imran et al., 2016	Union rates	Measured 3 months after surgery	Union rates at: 3 months = 79.07%	Union rates at: 3 months = 97.67%											
Wani et al., 2017	FFI; Complications (inc. malunion, infection, implant removal, time to union and secondary operations); Time to union; Time to full weight-bearing	FFI = 12 months; Time to union, time to full weight-bearing = days; Complications = not specified (likely reviewed cumulatively at routine follow up appointments - see "POI")	18.44 ± 1.93	19.14 ± 0.73					5.36 ±2.26	6.23±2.99					Malunion was similar but there was significantly greater malalignment due to rotation in the IMN group.
Costa et al., 2018	DRI; OMAS, EQ-5D, Complications (inc. malunion, nonunion, infection, wound problems, neurovascular and tendon injury, VTE, ankle osteoarthritis, malalignment and shortening)	DRI, OMAS, EQ-5D and radiographs (nonunion, arthritis, malalignment, shortening, malunion) = baseline, 6weeks and 12 months; DRI, OMAS, EQ-5D, complications = 6 weeks, 3 months, 6 months and 12 months													Significantly more patients weight-bearing at the 6-week timepoint.

SI2.1.2 – Radiographically assessed data from the randomised control trials (continued)

Ahmed et al., 2018	Time to Union; AOFAS	Time to Union = mean days; AOFAS = final FUP 2 years post-op		16.13	14										Malunion rate is equal in both groups. Significantly better AOFAS score in frame group.
Sharma et al., 2018	Infection; Time to full weight-bearing; Clinical and radiological union rates	Infection = 2nd postop day, 2 weeks, 6 weeks, 12 weeks. time to full weight bearing = not specified (cumulative to final FUP). Clinical and radiological union = 2, 6 and 12 weeks.		Union rates at: 12 weeks = 90%	Union rates at: 12 weeks =82.5%										Malunion, malalignment and ROM was similar between groups. However, rotational malalignment was not measured.
KC et al., 2021	Time to Union; Time to partial weight-bearing; AOFAS; Superficial infection; Deep infection	Time to Union = mean weeks; Time to partial weight-bearing = mean weeks; AOFAS = final FUP 1 year after fracture; [Superficial infection; Deep infection] = cumulative FUPs every 6 weeks for 6 months and every 3 months after that until final FUP (1 year)	25.90 ± 5.19	26.06 ± 5.35		7.02 ± 1.55	7.32 ± 1.49								Knee pain / malunion significantly higher in IMN compared to plate. But MIPO had significantly more superficial infection.
Kumar et al., 2022	Time to union; Time to full weight-bearing; Teeny and Wiss; Deep & superficial infections; Overall complications rate (inc. superficial &	Time to union = mean weeks; Time to full weight-bearing = mean weeks; Teeny and Wiss = measured at final FUP (24 weeks); Complications	23 ± 5.35	23.69 ± 7.20					11.48	12.96		84.84 ± 9.66	84.26 ± 11.79		

	deep infection, malunion, delayed union and implant failure)	= measured cumulatively until 24-week final FUP													
Ahmed et al., 2023	Time to union; Knee Society Score; Superficial infection	Time to weight bearing = mean weeks; Knee Society Score = "0-100" after final FUP at 24 weeks; Superficial infection = cumulative until final 24-week FUP	9.3 ± 1.77	10.2 ± 1.48											No malunions reported + no significant difference in complications between groups. Knee pain reported in 20% of IMN patients compared to none in the plating group. (infra/suprapatellar approach not specified)
Hamdy et al., 2024	OMAS; Deep infection; Overall complications rate (inc. deep infection, nonunion. DVT, delayed union, malunion coronal deformity, malunion rotation); Time to union	OMAS = 3&6 months; Complications = cumulative (final FUP = 6 months); Time to union = mean weeks	21.16±0.58 SD converted (assumed to be SEM mislabelled) 0.58 --> 3.23	22.17±0.53 SD converted (assumed to be SEM mislabelled) 0.53 --> 3.09											
Prabhat et al., 2025	AOFAS; Infection; Time to union; Weight-bearing; radiological outcomes	AOFAS = 6 months final FUP; Infection = cumulative at 6-month final FUP; Time to union = mean months; WB = not specified; Rad. = not specified	21.811±4.7584	23.833±6.9918											

SI2.1.3 – Patient-assessed data from the randomised control trials

Study	Main Outcomes	Outcome Timepoints	AOFAS (mean)			OMAS			Other			Points of interest
			IMN	Plate	Circular frame	IMN	Plate	Circular frame	IMN	Plate	Circular frame	
Im et al., 2005	Time to union; Infection (superficial & deep); OMAS	Time to Union = weeks; OMAS = 2 years; Infection = cumulative (final review at 2 years)				24 months = 88.5	24 months = 88.2					Significantly higher angulation in IMN compared to MIPO. However, IMN had significantly better ankle range of motion.
Guo et al., 2010	Time to union; AOFAS; Pain; Function; Wound problems (delayed wound healing & superficial infection)	AOFAS, Pain, Function = 12 months (cumulative 3, 6, 12 month reviews); Time to union = weeks; Wound problems = 5 days, 14/15 days	12 months = 86.1 (95% CI = 83.7 to 88.6)	12 months = 83.9 (95% CI = 81.7 to 86.1)								Alignment was equal between groups. IMN had increased pain but better function.
Vallier et al., 2011	Malunion; Nonunion; Infection; Secondary operations	Infection and secondary complications = not specified (likely reviewed cumulatively at routine follow up appointments - see Points of Interest ["POI"])										Significantly greater malalignment in IMN group.
Li et al., 2014	Time to union (radiographic); Ankle function (Mazur ankle score)	Time to union = weeks; Ankle function (Mazur ankle score) = 12 months; infection = not specified (likely reviewed cumulatively at routine follow up appointments - see "POI")							Proportion with "excellent/good" Mazur score 12 months = 87%	Proportion with "excellent/good" Mazur score 12 months = 90%		No significant difference in malunion but IMN had greater knee pain reported (transtendinous approach).

SI2.1.3 – Patient-assessed data from the randomised control trials (continued)

Polat et al., 2015	Time to union; Time for full weight-bearing; Foot function Index score; Superficial Infection	Time to union = mean days; Time for full weight-bearing = mean days; Foot Function Index score (FFI) = final FUP (mean ; Superficial Infection = cumulative until final FUP							Foot function index 12 months = 25.7 ± 11.1	Foot function index 12 months = 25.3 ± 16.4		Malunion was similar but there was significantly greater malalignment due to rotation in the IMN group.
Imran et al., 2016	Union rates	Measured 3 months after surgery										
Wani et al., 2017	FFI; Complications (inc. malunion, infection, implant removal, time to union and secondary operations); Time to union; Time to full weight-bearing	FFI = 12 months; Time to union, time to full weight-bearing = days; Complications = not specified (likely reviewed cumulatively at routine follow up appointments - see "POI")							Foot function index 12 months = 23.7±7.0	Foot function index 12 months = 25.4±16.3		Malunion was similar but there was significantly greater malalignment due to rotation in the IMN group.
Costa et al., 2018	DRI; OMAS, EQ-5D, Complications (inc. malunion, nonunion, infection, wound problems, neurovascular and tendon injury, VTE, ankle osteoarthritis, malalignment and shortening)	DRI, OMAS, EQ-5D and radiographs (nonunion, arthritis, malalignment, shortening, malunion) = baseline, 6weeks and 12 months; DRI, OMAS, EQ-5D, complications = 6 weeks, 3 months, 6 months and 12 months				3 months = 42.3 ±22.1 6 months = 62.4 ±23.1 12 months = 73.8 ±22.5	3 months = 36.0 ±21.3 6 months = 57.6 ±24.9 12 months = 70.8 ±24.2		DRI (primary outcome) 3 months = 44.2 ±19.9 6 months = 29.8 ±23.1 12 months = 23.1 ±23.3	DRI (primary outcome) 3 months = 52.6 ±19.9 6 months = 33.8 ±24.7 12 months = 24.0 ±24.6		Significantly more patients weight-bearing at the 6-week timepoint.
Ahmed et al., 2018	Time to Union; AOFAS	Time to Union = mean days; AOFAS = final FUP 2 years post-op		24 months = 82.3	24 months = 86.7							Malunion rate is equal in both groups. Significantly better AOFAS score in frame group.

SI2.1.3 – Patient-assessed data from the randomised control trials (continued)

Sharma et al., 2018	Infection; Time to full weight-bearing; Clinical and radiological union	Infection = 2nd postop day, 2 weeks, 6 weeks, 12 weeks. time to full weight bearing = not specified (cumulative to final FUP). Clinical and radiological union = 2, 6 and 12 weeks.								Lower Extremity Functional Score (% of maximum function) = 83.93±3.26	Lower Extremity Functional Score (% of maximum function) = 83.18±3.83	Malunion, malalignment and ROM was similar between groups. However, rotational malalignment was not measured.
KC et al., 2021	Time to Union; Time to partial weight-bearing; AOFAS; Superficial infection; Deep infection	Time to Union = mean weeks; Time to partial weight-bearing = mean weeks; AOFAS = final FUP 1 year after fracture; [Superficial infection; Deep infection] = cumulative FUPs every 6 weeks for 6 months and every 3 months after that until final FUP (1 year)	12 months = 83.84 ± 8.87	12 months = 84.16 ± 8.80								Knee pain / malunion significantly higher in IMN compared to plate. But MIPO had significantly more superficial infection.
Kumar et al., 2022	Time to union; Time to full weight-bearing; Teeny and Wiss; Deep & superficial infections; Overall complications rate (inc. superficial & deep infection, malunion, delayed union and implant failure)	Time to union = mean weeks; Time to full weight-bearing = mean weeks; Teeny and Wiss = measured at final FUP (24 weeks); Complications = measured cumulatively until 24-week final FUP										

Ahmed et al., 2023	Time to union; Knee Society Score; Superficial infection	Time to weight bearing = mean weeks; Knee Society Score = "0-100" after final FUP at 24 weeks; Superficial infection = cumulative until final 24-week FUP							KSS at 24 weeks = 79 ± 7.0	KSS at 24 weeks = 76 ± 6.14		No malunions reported + no significant difference in complications between groups. Knee pain reported in 20% of IMN patients compared to none in the plating group. (infra/suprapatellar approach not specified)
Hamdy et al., 2024	OMAS; Deep infection; Overall complications rate (inc. deep infection, nonunion. DVT, delayed union, malunion coronal deformity, malunion rotation); Time to union	OMAS = 3&6 months; Complications = cumulative (final FUP = 6 months); Time to union = mean weeks				3 months = 48.23±1.05 6 months = 64.83±1.32 SDs converted (assumed to be SEMs mislabelled) 1.05 --> 5.85 1.32 --> 7.35	3 months = 36.02±1.07 6 months = 57.94±1.14 SDs converted (assumed to be SEMs mislabelled) 1.07 --> 6.24 1.14 --> 6.65					
Prabhat et al., 2025	AOFAS; Infection; Time to union; Weight-bearing; radiological outcomes	AOFAS = 6 months final FUP; Infection = cumulative at 6 month final FUP; Time to union = mean months; WB = not specified; Rad. = not specified	6 months = 90.8333 ±6.8145	6 months = 90.5000 ±5.9234								

SI2.1.4 – Clinician-assessed data from the randomised control trials

Study	Main Outcomes	Outcome Timepoints	Superficial Infections (%)			Deep infections (%)			Infection rate (%)			Overall complication rate (%)			Points of interest
			IMN	Plate	Circular frame	IMN	Plate	Circular frame	IMN	Plate	Circular frame	IMN	Plate	Circular frame	
Im et al., 2005	Time to union; Infection (superficial & deep); OMAS	Time to Union = weeks; OMAS = 2 years; Infection = cumulative (final review at 2 years)	2.94%	20.00%		0%	3.33%								Significantly higher angulation in IMN compared to MIPO. However, IMN had significantly better ankle range of motion.
Guo et al., 2010	Time to union; AOFAS; Pain; Function; Wound problems (delayed wound healing & superficial infection)	AOFAS, Pain, Function = 12 months (cumulative 3, 6, 12 month reviews); Time to union = weeks; Wound problems = 5 days, 14/15 days													Alignment was equal between groups. IMN had increased pain but better function.
Vallier et al., 2011	Malunion; Nonunion; Infection; Secondary operations	Infection and secondary complications = not specified (likely reviewed cumulatively at routine follow up appointments - see Points of Interest ["POI"])				5.36%	6.25%								Significantly greater malalignment in IMN group.
Li et al., 2014	Time to union (radiographic); Ankle function (Mazur ankle score)	Time to union = weeks; Ankle function (Mazur ankle score) = 12 months; infection = not specified (likely reviewed cumulatively at routine follow up appointments - see "POI")	2.50%	16.67%		5.00%	2.38%								No significant difference in malunion but IMN had greater knee pain reported (transtendinous approach).
Polat et al., 2015	Time to union; Time for full weight-bearing; Foot function Index score; Superficial Infection	Time to union = mean days; Time for full weight-bearing = mean days; Foot Function Index score (FFI) = final FUP (mean ; Superficial Infection = cumulative until final FUP	0.00%	6.67%											Malunion was similar but there was significantly greater malalignment due to rotation in the IMN group.

SI2.1.4 – Clinician-assessed data from the randomised control trials (continued)

Imran et al., 2016	Union rates	Measured 3 months after surgery													
Wani et al., 2017	FFI; Complications (inc. malunion, infection, implant removal, time to union and secondary operations); Time to union; Time to full weight-bearing	FFI = 12 months; Time to union, time to full weight-bearing = days; Complications = not specified (likely reviewed cumulatively at routine follow up appointments - see "POI")	0.00%	10.00%											Malunion was similar but there was significantly greater malalignment due to rotation in the IMN group.
Costa et al., 2018	DRI; OMAS, EQ-5D, Complications (inc. malunion, nonunion, infection, wound problems, neurovascular and tendon injury, VTE, ankle osteoarthritis, malalignment and shortening)	DRI, OMAS, EQ-5D and radiographs (nonunion, arthritis, malalignment, shortening, malunion) = baseline, 6weeks and 12 months; DRI, OMAS, EQ-5D, complications = 6 weeks, 3 months, 6 months and 12 months				0.62%	3.13%								Significantly more patients weight-bearing at the 6-week timepoint.
Ahmed et al., 2018	Time to Union; AOFAS	Time to Union = mean days; AOFAS = final FUP 2 years post-op													Malunion rate is equal in both groups. Significantly better AOFAS score in frame group.
Sharma et al., 2018	Infection; Time to full weight-bearing; Clinical and radiological union	Infection = 2nd postop day, 2 weeks, 6 weeks, 12 weeks. time to full weight bearing = not specified (cumulative to final FUP). Clinical and radiological union = 2, 6 and 12 weeks.		5% (2nd day post-op)	5% (2nd day post-op)		7.5% (at 12 weeks post -op requiring debridement)	0%							Malunion, malalignment and ROM was similar between groups. However, rotational malalignment was not measured.
KC et al., 2021	Time to Union; Time to partial weight-bearing; AOFAS; Superficial infection; Deep infection	Time to Union = mean weeks; Time to partial weight-bearing = mean weeks; AOFAS = final FUP 1 year after fracture; [Superficial infection; Deep infection] = cumulative FUPs	4.00%	8.00%		2%	2.00%								Knee pain / malunion significantly higher in IMN compared to plate. But MIPO had significantly more superficial infection.

SI2.1.4 – Clinician-assessed data from the randomised control trials (continued)

		every 6 weeks for 6 months and every 3 months after that until final FUP (1 year)													
Kumar et al., 2022	Time to union; Time to full weight-bearing; Teeny and Wiss; Deep & superficial infections; Overall complications rate (inc. superficial & deep infection, malunion, delayed union and implant failure)	Time to union = mean weeks; Time to full weight-bearing = mean weeks; Teeny and Wiss = measured at final FUP (24 weeks); Complications = measured cumulatively until 24 week final FUP	11.53%	0.00%		3.85%	15.38%					23.08%	26.92%		
Ahmed et al., 2023	Time to union; Knee Society Score; Superficial infection	Time to weight bearing = mean weeks; Knee Society Score = "0-100" after final FUP at 24 weeks; Superficial infection = cumulative until final 24-week FUP	0.00%	10.00%											No malunions reported + no significant difference in complications between groups. Knee pain reported in 20% of IMN patients compared to none in the plating group. (infra/suprapatellar approach not specified)
Hamdy et al., 2024	OMAS; Deep infection; Overall complications rate (inc. deep infection, nonunion. DVT, delayed union, malunion coronal deformity, malunion rotation); Time to union	OMAS = 3&6 months; Complications = cumulative (final FUP = 6 months); Time to union = mean weeks				0.00%	10%					3.20%	17.7%		
Prabhat et al., 2025	AOFAS; Infection; Time to union; Weight-bearing; radiological outcomes	AOFAS = 6 months final FUP; Infection = cumulative at 6 month final FUP; Time to union = mean months; WB = not specified; Rad. = not specified	10.00%	33.33%		0.00%	6.70%		10.00%	40.00%					

Non-randomised studies

(SI2.2)

SI2.2.1 – Baseline characteristics for the non-randomised studies

Study	Study Design	Country	Setting	Intra- or Extra-Articular	Intervention	Comparator(s)	Sample size				
							Total	IMN	Plate	Circular frame	Missing
Harris et al., 2006	Retrospective	US	Level 1 Trauma Centre	Intra (OTA43-B1, B2, B3 OR OTA43-C1, C2, C3)	Plate (ORIF)	Circular frame	79 (based on number of fractures, not patients of which there were 76)		63	16	Only 33 of the 76 patients completed outcomes questionnaires.
Yang et al., 2006	Retrospective	Taiwan	University-affiliated tertiary care hospital	Extra (AO43A)	Nail	Plate (ORIF)	27	13	14		
Janssen et al., 2007	Retrospective	Netherlands	University-affiliated tertiary care hospital	Extra (AO42A1-3, B2)	Nail	Plate (ORIF)	112	92	20		
Koulouvaris et al., 2007	Retrospective	Greece	Tertiary Centre	Intra (Type C1, C2, C3, B2 & B3)	Plate (MIPO)	Circular frame	55		13	22	20 patients treated with a half-pin external fixator (not ring) making up the total participants to 55
Vallier et al., 2008	Retrospective	USA	Two level 1 trauma centres ≈MTCs	Extra (AO42A, B, C)	Nail	Plate (both MIPO and ORIF)	113	76	37		
Li et al., 2012	Retrospective	China	Tertiary Centre	Extra	Nail	Plate (MIPO)	46	23	23		
Seyhan et al., 2013	Retrospective	Turkey	Tertiary Centre	Extra	Nail	Plate (MIPO)	61	25	36		
Fadel et al., 2014	Prospective	Egypt	Tertiary Centre	Extra	Nail	Plate (ORIF)	40		20	20	
Ali et al., 2015	Retrospective	Egypt/Saudi Arabia	2 tertiary centres	Both	Nail	Plate (MIPO)	60	30	30		
Jöstl et al., 2015	Retrospective	Austria	Level 1 Trauma Centre	Extra (AO42-A, B, C or 43-A, B1)	Nail	Circular frame; Plate	93	66	15	12	
Ali et al., 2016	Prospective	India	University-affiliated tertiary care hospital	Extra (AO43A only)	Nail	Plate (MIPO)	60	30	30		
Barcak et al., 2016	Prospective	USA	Level II regional trauma center.	Both (OTA 43-A1-3, 43-C1-2)	Nail	Plate (MIPO)	86	27	37		22 did not meet inclusion criteria.
Shen et al., 2016	Retrospective	China	Tertiary Centre	Extra (AO43A only)	Nail	Plate (MIPO)	125	61	64		134 met inclusion criteria. 9 excluded due to lack of follow up data
Beytemur et al., 2017	Retrospective	Turkey	Tertiary Centre	Intra (AO43C1-2)	Nail	Plate (MIPO)	73	37	36		
Imren et al., 2017	Retrospective	Turkey	University-affiliated tertiary care hospital	Intra (Ruedi and Allgower Type B and C)	Plate (MIPO)	Circular frame (Tasarimmed)	41		21	20	
Chandrakant et al., 2018	Retrospective	India	Tertiary Centre	Extra (AO43A only)	Nail	Plate (MIPO)	63	31	32		
Mahendra et al., 2018	Prospective	India	University-affiliated tertiary care hospital	Extra (AO43A only)	Nail	Plate (MIPO)	55	25	20		
Vaienti et al., 2019	Prospective	Italy	First level Trauma centre ≈ MTC	Extra & Intra (close or G&A Type I)	Nail	Plate (MIPO)	183	102	81		

SI2.2.1 – Baseline characteristics for the non-randomised studies (continued)

Say et al., 2020	Retrospective	Turkey	University-affiliated tertiary care hospital	Extra (AO43A1, 43A2, 43A3)	Nail	Plate (MIPO)	35	18	17		
El Zohairy et al., 2021	Prospective	Egypt	University-affiliated tertiary care hospital	Extra (AO43A1, 43A2 & 43A3 only)	Nail	Plate (MIPO)	96	48	48		
Keerio et al., 2021	Prospective	Pakistan	University-affiliated tertiary care hospital	Extra	Nail	Plate (ORIF)	60	30	30		
Kumar et al., 2021	Prospective	India	Tertiary Centre	Extra	Nail	Plate (MIPO)	40	20	20		
Almishri et al., 2022	Prospective	Egypt	University-affiliated tertiary care hospital	Extra	Nail	Plate (MIPO)	18	9	9		
Bleeker et al., 2022	Retrospective	Switzerland	Level 1 Trauma centre ≈ MTC	Extra (AO 42-A, 42-B, 42-C, 43-A)	Nail	Plate (MIPO)	135	63	72		
Sharma et al., 2022	Prospective	India	Tertiary Centre	Extra	Nail	Plate (MIPO)	30	15	15		
Bastías et al., 2023	Retrospective	Chile	MTC	Intra (AO43C only)	Plate (ORIF)	Circular frame (hexapod)	53		30	23	
Kaya et al., 2023	Retrospective	Turkey	University-affiliated tertiary care hospital	Extra (AO42A1-3, 42B1-3, 42C1-3)	Nail	Plate (MIPO)	69	35	34		
Kumar et al., 2023	Prospective	India	Tertiary Centre	Extra	Nail	Plate (ORIF)	20	10	10		
Nath et al., 2023	Prospective	India	University-affiliated tertiary care hospital	Extra (AO43 only)	Nail	Plate (MIPO)	40	20	20		20 patients were analysed. 5 IMN patients and 3 plate patients did not meet the inclusion criteria and excluded prior.
M. Singh et al., 2023	Prospective	India	Tertiary Centre	Extra	Nail	Plate (ORIF)	30	15	15		
S. Singh et al., 2023	Prospective	India	Tertiary Centre	Extra	Nail	Plate (ORIF)	30	15	15		
Taori et al., 2023	Prospective	India	Tertiary Centre	Both	Nail	Plate (MIPO); [monolateral external fixator]	60	18	30	0	
Tukade, 2023	Prospective	India	Tertiary Centre	Both	Nail	Plate (ORIF), Circular frame (Ilizarov)	30	11	15	4	
Wang et al., 2023	Retrospective	China	University-affiliated tertiary care hospital	Extra (AO 43-A or AO42)	Nail	Plate (MIPO)	266	156	110		
Jang et al., 2024	Retrospective	USA	Level-I academic trauma centre.	Intra (AO43C1-2)	Nail	Plate	110	33	77		
Liu et al., 2024	Retrospective	China	Level 1 Trauma centre ≈ MTC	Extra (AO43A1-3)	Nail (retrograde)	Plate (MIPO)	48	21	27		
Rafiq et al., 2024	Retrospective	Pakistan	Tertiary Centre	Extra / Partial Intra (AO43-A&B)	Nail	Plate (MIPO)	35	17	18		
Shaikh et al., 2024	Retrospective	Pakistan	Level 1 Trauma centre ≈ MTC	Intra (AOC1, C2, C3)	Plate (ORIF)	Circular frame	41		15	26	
Singh et al., 2025	Prospective	India	Tertiary Centre	Extra	Nail	Plate (MIPO); Circular frame	35	12	11	12	

SI2.2.2 – Radiographically assessed data from the non-randomised studies

Study	Main relevant Outcomes	Outcome Timepoints	Time to union (weeks)			Time to partial weight bearing (weeks)			Time to full weight bearing (weeks)			Teeny and Wiss			Points of interest
			IMN	Plate	Circular frame	IMN	Plate	Circular frame	IMN	Plate	Circular frame	IMN	Plate	Circular frame	
Harris et al., 2006	Deep & superficial infection rate; Overall complications rate (inc. deep & superficial infections, nonunion, malunion, wound complications)	Complications = cumulative to final FUP													ORIF associated with fewer complications and less post-traumatic arthritis
Yang et al., 2006	OMAS; Time to union; Overall infection rate	Time to union = weeks; OMAS, Malalignment, Malunion, Anterior knee pain = not specified (final FUP ≈ 33months)	22.6 ± 4.3 (range 18-30)	27.8 ± 7.6 (range 18-36)											No significant difference in Iowa ankle score nor malunion/misalignment (rotational was not measured). Anterior knee pain reported in some IMN patients compared to none in the plate group.
			p = 0.037* (independent t-test)												
Janssen et al., 2007	Time to union; Infection; Time to weight-bearing	Time to union, time to weight-bearing = mean weeks; Infection (likely cumulative at final FUP - see points of interest ["POI"])	21 (range 13-28)	19 (range 14-32)					14.34	16.51					Main reason for plate removal was because patients "felt it there". Main reason for IMN removal was knee pain. Insignificant differences in malalignment/malunion (including rotational), despite their hypotheses. IMN had low-grade infection around locking screw. Could not distinguish between superficial or deep so overall infection rate extracted.
			p = 0.44 (paired t-test)						p = 0.14 (paired t-test)						
Koulouvaris et al., 2007	Time to union; Infection	Time to union = months; Infection = 1 week, 1 month, monthly for 12 months & annual follow-up (cumulative)		22.16 ± 2.17 (range 17.38-26.07)	24.33 ± 4.78 (range 17.38-39.11)										Significant relationship with the type of fracture and infection. No malunions or nonunions.
			p = 0.688 (one-way ANOVA)												

SI2.2.2 – Radiographically assessed data from the non-randomised studies (continued)

Vallier et al., 2008	Complications (inc. infection)	Infection = cumulative at final FUP													Significantly greater malunion following IMN malalignment. IMN also had significantly greater procedures other than hardware removal (reasons including malalignment).
Li et al., 2012	Time to Union; Time to full weight-bearing; OMAS; Deep infection; Superficial infection	Time to union = mean weeks; Time to full weight-bearing = mean weeks; OMAS = measured at final FUP (25.2 weeks); Infection rates measured cumulatively until final FUP (25.2 weeks between groups)	21.3 ± 3.5	23.1 ± 3.6					9.0 ± 1.4	11.1 ± 1.7					No significant differences in anterior knee pain or malalignment. No cases of nonunion, implant failure or delayed union. No significant differences in mean postoperative varus/valgus angulation, ante-/recurvatum alignment.
			p = 0.047* (paired t-test)						P = 0.000* (paired t-test)						
Seyhan et al., 2013	Time to union; Time to full weight-bearing; Deep and superficial infection; Overall complications (inc. deep & superficial infections, nonunion & malunion, implant irritation)	Time to union = mean weeks; Time to full weight-bearing = mean weeks; Infections= measured cumulatively until final FUP (mean 21.4 months)	15.74 ± 3.92	17.24 ± 3.05					12.95 ± 2.95	15.21 ± 2.80					No statistically significant difference in rates of nonunion, malunion or implant irritation. Rate of secondary procedures significantly higher in plate compared to IMN.
			p = 0.113 (independent t-test)						P = 0.005* (independent t-test)						
Fadel et al., 2014	Time to union; Time to partial weight-bearing; Time to full weight-bearing; AOFAS	Time to union = mean weeks; Time to partial weight-bearing = mean days; Time to full weight-bearing = mean weeks; AOFAS = measured at final FUP (24 weeks)		28	18.5					From 28.24	From 0.14 (day 1)				No cases of delayed union or nonunion in the CF group (significant difference).
			p = 0.003* (Mann-Whitney test)						No statistical significance test performed						

SI2.2.2 – Radiographically assessed data from the non-randomised studies (continued)

Ali et al., 2015	Time to union; Time to full weight-bearing; AOFAS; Superficial infection; Deep infection	Time to union = mean weeks; Time to full weight-bearing = mean weeks; AOFAS = at final FUP?; Superficial + Deep infection cumulative to final follow-up (mean FUP was 34.2 months between groups)	15.74 (range 10-25)	17.2 (range 11-30)					6.66	11.4					No difference in rotational malalignment and insignificantly greater angular malalignment in the MIPO group vs IMN. None of these malalignments required secondary operation.
			p = 0.2209 (paired t-test)						p = 0.0154* (paired t-test)						
Jöstl et al., 2015	Time to union; Overall complication rate (inc. malunion, compartment syndrome, painful/broken interlocking screw, painful scar, Sudeck's disease, post-traumatic arthritis and refracture)	Time to union = days; Overall complication rate = cumulative at final FUP	21.05 ± 13.02	19.39 ± 15.82	23.30 ± 13.83										No significant differences in malunion, post-traumatic arthritis, refracture, painful/broken interlocking screw, or range of motion in the knee joint between the three groups.
			IMN vs CF p = 0.001* Plate vs CF p = 0.01* Plate vs IMN p = 0.293 (Kruskal-Wallis test)												
Ali et al., 2016	Time to Union; Time to partial weight-bearing; Time to full weight-bearing; Teeny and Wiss; Deep/superficial infection	Time to Union = mean weeks; Time to partial weight-bearing = mean weeks; Time to full weight-bearing = mean weeks; Teeny and Wiss = final FUP 9 months post-op; Deep/superficial infection = cumulative FUPs until 9 months	18.8 ± 6.0	20.5 ± 4.8		6.0 ±1.4	6.1 ±1.6		16.2 ± 4.2	15.0 ± 3.8		86.9 ±10 at 9 months	88.6 ±6.6 at 9 months		Malunion, Delayed union, Ankle stiffness, Anterior knee pain, and Nonunion were measured. None of these were statistically significant using Fisher's test.
			p = 0.25 (independent t-test)			p = 0.87 (independent t-test)			p = 0.24 (independent t-test)			p = 0.451 (independent t-test)			

SI2.2.2 – Radiographically assessed data from the non-randomised studies (continued)

Barcak et al., 2016	AOFAS; SF-36; Time to union; Superficial infections	Time to union = weeks; AOFAS, SF-36 = at minimum of 1 year follow up; Infection = cumulative at final FUP	23.2 (range 8-60)	23.4 (range 9-60)											Quantitatively higher scores in Short Form 36 scores in the IMN group but no significant difference. No significant difference in malalignment (rotational not measured).
			P = 0.84 (independent t-test)												
Shen et al., 2016	Wound complicatio ns	Cumulative until final FUP at 12 months (FUP 6, 10, 14 weeks, then every 6–8 weeks)													Malreduction / deformity (inc. valgus/varus, ante-/recurvation, rotation): significantly higher in IMN. No cases of shortening or nonunion.
Beytemur et al., 2017	Time to Union; OMAS; Deep/superf icial infection	Time to Union = mean weeks; OMAS = final FUP mean 29.4 months; Deep infection = cumulative FUPs until mean 29.4 months	16.4 ± 2.7 (range 12-24)	15.2 ± 1.8 (range 12-20)					16.4 ± 2.7 (range 12-24)	15.2 ± 1.8 (range 12-20)					Anterior knee pain, Varus malunion, Valgus malunion, and Recurvatum malunion were significantly greater with IMN. Ankle dorsiflexion was significantly decreased with IMN.
			p = 0.079 (independent t-test)						p = 0.079 (independent t-test) *N.B. Weight-bearing was permitted upon union, so values are the same for both outcomes*						
Imren et al., 2017	Time to union; Complicatio ns (inc. infection, hardware removal, delayed union); AOFAS; Time to full weight-bearing	Time to union, time to full weight-bearing = weeks; AOFAS = 1, 2 and 3 years; Delayed union = 6 months; Complications = not specified (likely reviewed cumulatively at routine follow up appointments - see "POI")		19.4±2.9	22.1±1.7					25.6 ±1.85	19.3				
			P = 0.001* (Mann-Whitney U test)						No statistical significance test performed						
Chandrakant et al., 2018	Time to Union; Time to partial weight-bearing; AOFAS; Overall complicatio ns	Time to Union = mean weeks; Time to partial weight-bearing = mean weeks; AOFAS = final FUP at a minimum of 12 months; Overall complications = Cumulative over at least 12 months	18 (range 14-24)	19 (range 16-28)		8	12								Greater nonunion with plate but greater malunion with IMN.
			p = 0.85 (independent t-test)			p = 0.01* (independent t-test)									

SI2.2.2 – Radiographically assessed data from the non-randomised studies (continued)

Mahendra et al., 2018	Time to Union; Time to partial weight-bearing (callus formation); OMAS; Deep/superficial infection	Time to Union = mean weeks; Time to partial weight-bearing = mean weeks; OMAS = final FUP 2 years post-op; Deep/superficial infection = cumulative FUPs until 2-year mark	25.64 ± 4.07	26.60 ± 7.14		12.00 ± 2.14	13.00 ± 6.34								No significant difference in mean angulation or shortening between groups. IMN group had mild anterior knee pain & discomfort when kneeling, and mild pain over screw head. Malunion rates higher in IMN group.
			p = 0.594 (independent t-test)			P = > 0.05 (independent t-test)									
Vaienti et al., 2019	Time to union; Wound problems; Infection; Malunion; Anterior knee pain; Time to full weight-bearing; OMAS; DRI	Time to union, time to full weight-bearing = weeks; DRI, OMAS = 3, 6, 12 months; Infection, anterior knee pain, wound problems, secondary operations = cumulative at final FUP (see "POI")	20.2 (range 16.8-24.2)	24.8 (range 18.1-27.5)					10.3±2.6	13.7±4.2					No significant difference in malunion/misalignment (including rotational). Greater proportion of knee pain in IMN group but not statistically significant.
			p = 0.271 (Mann-Whitney U test)						P = 0.019* (Maan-Whitney U test)						
Say et al., 2020	Time to union; Median AOFAS; Infection; overall complications (inc. infection, implant irritation, malunion and nonunion)	Time to union = weeks; AOFAS / Infection = likely cumulative at final FUP	18 (range 12-22)	15 (range 11-20)											No significant difference in malunion, nonunion, or implant irritation
			p = 0.06 (independent t-test)												
El Zohairy et al., 2021	OMAS; Time to full weight-bearing; Time to union; Deep infection rate	OMAS = 6 months; Time to full weight-bearing = Not specified; Deep infection rate = Not specified													No significant differences noted in OMAS. Nor in time to union, time to weight bearing or deep infections, despite not reporting any values for these outcomes.

SI2.2.2 – Radiographically assessed data from the non-randomised studies (continued)

Keerio et al., 2021	Time to Union; Time to full weight-bearing; OMAS; Deep infection	Time to Union = mean weeks; Time to full weight-bearing = mean weeks; OMAS = final FUP 1 year after fracture; Deep infection = cumulative FUPs after 6,12,18,24 weeks and every 3 months until final FUP (1 year)	18.91 ± 1.20 (range 19-23)	24.08 ± 1.17 (range 22-30)					14.4 ± 1.21 (range 14-18)	17.5 ± 0.95 (range 17- 20)					Significantly greater range of ankle movement in both plantar- and dorsi-flexion for IMN. Some cases of misalignment in IMN, but not plate group. Cases of delayed union higher in plate group.
			P = 0.001* (independent t-test)						P = 0.001* (independent t-test)						
Kumar et al., 2021	Time to union; Time to full weight-bearing; Superficial infection; Deep infection	Cumulative follow ups until 1-year post-op	17.12 ± 1.57	21.28 ± 1.78					8-10 weeks (70%) 11-12 weeks (30%)	8-10 weeks (15%) 11-12 weeks (30%) 13-14 weeks (40%) >14 weeks (15%)					More knee stiffness and pain reported in IMN. More ankle stiffness reported in plate.
			P = <0.001* (independent t-test)						No statistical significance test performed						
Almishri et al., 2022	Time to Union; Teeny and Wiss functional score; Infection	Time to Union = mean months; Teeny and Wiss = after 9-month FUP; Infection = measured cumulatively every 4 weeks until final 9-month FUP	25.07 ± 6.13	26.55 ± 6.30								84.22 ±20.13	80.77 ±18.32		More nonunion in IMN but more deformities and delayed union in plate.
			p = 0.654 (independent t-test)									P =0.767 (independent t-test)			

SI2.2.2 – Radiographically assessed data from the non-randomised studies (continued)

Bleeker et al., 2022	Complications (infection, malalignment, secondary operations); Median time to full weight bearing; Median time to union	Median time to union = months; Median time to full weight bearing = months; Infection (and secondary operations, anterior knee pain, range of motion) = not specified (likely reviewed cumulatively at routine follow up appointments - see "POI")	28.6 median (IQR 29.9)	24.7 median (IQR 15.7)					14.73 median (IQR 13.43)	16.47 median (IQR 12.13)					Insignificant differences in malalignment (rotational + angular)
			p = 0.03* (Mann-Whitney U test)						P = 0.57 (Mann-Whitney U test)						
Sharma et al., 2022	Time to Union; Teeny and Wiss functional score; Superficial infection; Deep Infection	Time to Union = mean weeks; Teeny and Wiss functional score; Superficial infection; Deep Infection	22.8 ± 5.40 (range 15-24)	23.74 ± 6.85 (range 16-24)								84.36 ±8.78 at 9 months	84.12 ±9.65 at 9 months		Very minor differences in malunion and delayed union.
			P = >0.05 (Mann-Whitney U test)									P = >0.05 (Mann-Whitney U test)			
Bastías et al., 2023	Overall complications (inc. Superficial & deep infection, malunion/ malalignment, nonunion, amputation); Time to union; Superficial & deep infection	Overall complications = Cumulative over 2 years post-op; Time to union = mean weeks		18.4 (range 9.8 - 52)	27.3 (range 13.2 - 39.2)										More malunion/misalignment in plate compared to frame.
			p = 0.009* (independent t-test)												

SI2.2.2 – Radiographically assessed data from the non-randomised studies (continued)

Kaya et al., 2023	Time to union; Overall complications rate (inc. superficial & deep infection, iatrogenic tibia fractures, cutaneous necrosis, Sudeck atrophy, anterior knee pain); AOFAS; Teeny-Wiss radiological score; Time to full weight bearing	Wound problems = Last-follow up (time not specified); Time to union = weeks; Time to full weight bearing and return to daily life = days; Complications, Teeny-Wiss score = not specified (likely reviewed cumulatively at routine follow up appointments - see "POI")	16 median (IQR 7)	12 median (IQR 7.5)					4.29 median (IQR 3.43)	6.79 median (IQR 2.14)		47.8% anatomic at final follow up (12 month)	33.3 % anatomic at final follow up (12 month)		
			p = 0.104 (Mann-Whitney U test)						P = <0.001* (Mann-Whitney U test)			P = 0.03* (Chi-squared test)			
Kumar et al., 2023	Time to weight bearing; Ankle score; Deep/superficial infection	Time to weight bearing = delayed vs immediate; Ankle score = not recorded; Deep infection = cumulative FUPs (mean FUP 10 months)				4.2	7.12		9.6	13.42					Entire plating group had delayed union and much less in the IMN group. Malunion rate higher in the nail group. Nonunion was higher in the plating group.
						Reported significant difference without explicit p values (independent t-test)			Reported significant difference without explicit p values (independent t-test)						
Nath et al., 2023	Time to union; AOFAS; Infection	Time to union = weeks; AOFAS, Infection = 1 year (cumulative appointments at 6 weeks, 12 weeks, 6 months and 1 year)	18.29 ± 2.13	21.07 ± 2.05											Nonunion had insignificant difference.
			p = > 0.05 (independent t-test)												

SI2.2.2 – Radiographically assessed data from the non-randomised studies (continued)

M. Singh et al., 2023	Time to union; Time to partial weight-bearing; Time to full weight-bearing; AOFAS	Time to union = mean weeks; Time to partial weight-bearing = mean days; Time to full weight-bearing = mean weeks; AOFAS = measured at final FUP (24 weeks)	14.93	18		1.47	2.65		2.87	6.07					
			p = < 0.05* (statistical significance test not stated)			p = < 0.05* (statistical significance test not stated)			p = < 0.05* (statistical significance test not stated)						
S. Singh et al., 2023	Superficial infection; Deep infection	Both recorded cumulatively until final FUP at 24-weeks													Varus/valgus angulation, knee stiffness, ankle stiffness, nonunion, delayed union, and malunion all had insignificant differences. Deep infection and anterior knee pain the only significantly different complications.
Taori et al., 2023	Time to Union; AOFAS; Overall complications	Time to Union = not reported; AOFAS = final FUP 12 months; Overall complications = cumulative FUPs (minimum 12 months)													Ankle stiffness, nonunion, varus deformity, and valgus deformity were compared. There was no significant difference in overall complications of deformities.
Tukade, 2023	Time to union; Time to weight bearing; OMAS; Deep/superficial infection	Time to union = mean weeks; Time to weight bearing = mean weeks; OMAS = measured at final FUP (1-year); Deep/superficial infection = cumulative until final FUP (1-year)	19.36 ± 2.42	21 ± 1.92	24 ± 1.63				11.09 ± 1.57	13.86 ± 2.13	12 ± 0				No cases of nonunion. No cases of delayed union. No cases of malunion. Ankle stiffness was IMN<CF<Plate
			p = 0.002* (ANOVA test)						P = <0.000001* (ANOVA test)						

SI2.2.2 – Radiographically assessed data from the non-randomised studies (continued)

Wang et al., 2023	AOFAS; Time to union; Superficial and deep infection	AOFAS = 12 months; Time to union = days; Superficial and deep infection = not specified (likely reviewed cumulatively at routine follow up appointments - see "POI")	19.83 ±1.57	21.93 ±2.44											Insignificant differences in malalignment (rotational + angular)
			p = 0.000* (independent t-test)												
Jang et al., 2024	Infection; PROs (PROMIS)	Reduction loss = 6 weeks; Nonunion = 6 months; PROs (PROMIS) = 2 weeks, 6 weeks, 12 weeks, 6 months, and 12 months; Infection = not specified													No significant difference in Patient Reported Outcomes (PROMIS).
Liu et al., 2024	Time to union; Time to full weight-bearing; AOFAS; Overall complicatio n rate (inc. nonunion, delayed union, superficial & deep infection, implant failure); Superficial & deep infection rate	Time to union, time to full weight-bearing = weeks; AOFAS = not specified (at final follow up); Complications = not specified (likely reviewed cumulatively at routine follow up appointments - see notes)	14.9 ± 2.3	15.4 ± 2.3					9.9±1.3	11.5 ±1.5					Significantly more people with fair and poor AOFAS scores in MIPO group.
			p = 0.46 (independent t-test)						P = 0.001* (independent t-test)						

SI2.2.2 – Radiographically assessed data from the non-randomised studies (continued)

Rafiq et al., 2024	Time to Union; AOFAS; Overall complication rate (inc. deep & superficial infections, nonunion, hardware irritation/implant removal); Deep & superficial infection rate	Time to Union = mean weeks; AOFAS = final FUP minimum 12 months; Deep infection = cumulative FUPs (minimum 12 months)	15.1 ± 2.1	16.2 ± 2.4											Malalignment: Plate<IMN. Delayed union: Plate<IMN. Nonunion: Plate<IMN. Alignment control was significantly better in the plating group.
			p = 0.12 (independent t-test)												
Shaikh et al., 2024	DRI; Patient satisfaction (SF-12); AOFAS; Malalignment; Time to union; Complications (inc. infection, secondary operations, malunion, nonunion, secondary arthritis, amputations, DVT, CRPS)	DRI, SF12, AOFAS = 3, 6, 12 months; Complications = not specified (likely reviewed cumulatively at routine follow up appointments - see "POI")		16.00 ± 1.85	15.92 ± 1.74										Greater proportion of malunion and secondary operations in the Illizarov group.
			p = 0.89 (statistical significance test not stated)												
Singh et al., 2025	AOFAS	AOFAS = minimum of 6-month follow-up													Nonunion: IMN<CF=Plate. Ankle stiffness: Plate<CF=IMN. Varus deformity: Plate<CF<IMN. Valgus deformity: IMN<Plate<CF.

SI2.2.3 – Patient-assessed data from the non-randomised studies

Study	Main relevant Outcomes	Outcome Timepoints	AOFAS			OMAS			Other			Points of interest
			IMN	Plate	Circular frame	IMN	Plate	Circular frame	IMN	Plate	Circular frame	
Harris et al., 2006	Deep & superficial infection rate; Overall complications rate (inc. deep & superficial infections, nonunion, malunion, wound complications)	Complications = cumulative to final FUP								**FFI:** 0.23; **MFA:** 20.9 at mean 88 months after surgery	**FFI**: 0.40; **MFA:** 34.0 at mean 88 months after surgery	ORIF associated with fewer complications and less post-traumatic arthritis
									FFI: p = 0.03* **MFA:** statistical significance test not used to compare between fixation types			
Yang et al., 2006	OMAS; Time to union; Overall infection rate	Time to union = weeks; OMAS, Malalignment, Malunion, Anterior knee pain = not specified (final FUP ≈ 33months)				86.2±3.2 at final follow up (mean ≈ 33 months	83.9 ±7.1 at final follow up (mean ≈ 33 months		**Iowa Ankle Score:** Excellent = 38.5% Good = 53.8% Fair = 7.7%	**Iowa Ankle Score:** Excellent = 35.5% Good = 42.9% Fair = 21.4%		No significant difference in Iowa ankle score nor malunion/misalignment (rotational was not measured). Anterior knee pain reported in some IMN patients compared none in the Plate group.
						P = 0.476 (Mann-Whitney U test)			P = 0.594 (Chi-Squared test)			
Janssen et al., 2007	Time to union; Infection; Time to weight-bearing	Time to union, time to weight-bearing = mean weeks; Infection (likely cumulative at final FUP - see points of interest ["POI"])							**Knee Society Score (KSS):** 139	**Knee Society Score (KSS):** 146		Main reason for plate removal was because patients "felt it there". Main reason for IMN removal was knee pain. Insignificant differences in malalignment/malunion (including rotational), despite their hypotheses. IMN had low-grade infection around locking screw. Could not distinguish between superficial or deep so overall infection rate extracted.
									No statistical significance test performed			
Koulouvaris et al., 2007	Time to union; Infection	Time to union = months; Infection = 1 week, 1 month, monthly for 12 months & annual follow-up (cumulative)										Significant relationship with the type of fracture and infection. No malunions or nonunions.

SI2.2.3 – Patient-assessed data from the non-randomised studies (continued)

Vallier et al., 2008	Complications (inc. infection)	Infection = cumulative at final FUP										Significantly greater malunion following IMN malalignment. IMN also had significantly greater procedures other than hardware removal (reasons including malalignment).
Li et al., 2012	Time to Union; Time to full weight-bearing; OMAS; Deep infection; Superficial infection	Time to union = mean weeks; Time to full weight-bearing = mean weeks; OMAS = measured at final FUP (25.2 weeks); Infection rates measured cumulatively until final FUP (25.2 weeks between groups)				89.0 ± 7.1	87.6 ± 8.4					No significant differences in anterior knee pain or malalignment. No cases of nonunion, implant failure or delayed union. No significant differences in mean postoperative varus/valgus angulation, ante-/recurvatum alignment.
						P = 0.478 (independent t-test)						
Seyhan et al., 2013	Time to union; Time to full weight-bearing; Deep and superficial infection; Overall complications (inc. deep & superficial infections, nonunion & malunion, implant irritation)	Time to union = mean weeks; Time to full weight-bearing = mean weeks; Infections= measured cumulatively until final FUP (mean 21.4 months)										No statistically significant difference in rates of nonunion, malunion or implant irritation. Rate of secondary procedures significantly higher in plate compared to IMN.
Fadel et al., 2014	Time to union; Time to partial weight-bearing; Time to full weight-bearing; AOFAS	Time to union = mean weeks; Time to partial weight-bearing = mean days; Time to full weight-bearing = mean weeks; AOFAS = measured at final FUP (24 weeks)								**Modified Mazur Ankle Score:** Excellent = 10% Good = 40% Fair = 20% Poor = 30%	**Modified Mazur Ankle Score:** Excellent = 50% Good = 50%	No cases of delayed union or nonunion in the CF group (significant difference).
									No statistical significance test performed			

SI2.2.3 – Patient-assessed data from the non-randomised studies (continued)

Ali et al., 2015	Time to union; Time to full weight-bearing; AOFAS; Superficial infection; Deep infection	Time to union = mean weeks; Time to full weight-bearing = mean weeks; AOFAS = at final FUP?; Superficial + Deep infection cumulative to final follow-up (mean FUP was 34.2 months between groups)	92.9 (75–98)	89.8 (70–96)								No difference in rotational malalignment and insignificantly greater angular malalignment in the MIPO group vs IMN. None of these malalignments required secondary operation.
			P = 0.0219* (paired t-test)									
Jöstl et al., 2015	Time to union; Overall complication rate (inc. malunion, compartment syndrome, painful/broken interlocking screw, painful scar, Sudeck's disease, post-traumatic arthritis and refracture)	Time to union = days; Overall complication rate = cumulative at final FUP										No significant differences in malunion, post-traumatic arthritis, refracture, painful/broken interlocking screw, or range of motion in the knee joint between the three groups.
Ali et al., 2016	Time to Union; Time to partial weight-bearing; Time to full weight-bearing; Teeny and Wiss; Deep/superficial infection	Time to Union = mean weeks; Time to partial weight-bearing = mean weeks; Time to full weight-bearing = mean weeks; Teeny and Wiss = final FUP 9 months post-op; Deep/superficial infection = cumulative FUPs until 9 months										Malunion, Delayed union, Ankle stiffness, Anterior knee pain, and Nonunion were measured. None of these were statistically significant using Fisher's test.
Barcak et al., 2016	AOFAS; SF-36; Time to union; Superficial infections	Time to union = weeks; AOFAS, SF-36 = at minimum of 1 year follow up; Infection = cumulative at final FUP	88.4±11.0 at final follow up (minimum 1 year)	86.6±11.0 at final follow up (minimum 1 year)								Quantitatively higher scores in Short Form 36 scores in the IMN group but no significant difference. No significant difference in malalignment (rotational not measured).
			P = 0.24 (independent t-test)									

SI2.2.3 – Patient-assessed data from the non-randomised studies (continued)

Shen et al., 2016	Wound complications	Cumulative until final FUP at 12 months (FUP 6, 10, 14 weeks, then every 6–8 weeks)										Malreduction / deformity (inc. valgus/varus, ante-/recurvation, rotation): significantly higher in IMN. No cases of shortening or nonunion.
Beytemur et al., 2017	Time to Union; OMAS; Deep/superficial infection	Time to Union = mean weeks; OMAS = final FUP mean 29.4 months; Deep infection = cumulative FUPs until mean 29.4 months				87.2 ± 8.1	81.5 ± 11.8					Anterior knee pain, Varus malunion, Valgus malunion, and Recurvatum malunion were significantly greater with IMN. Ankle dorsiflexion was significantly decreased with IMN.
						P = 0.013* (independent t-test)						
Imren et al., 2017	Time to union; Complications (inc. infection, hardware removal, delayed union); AOFAS; Time to full weight-bearing	Time to union, time to full weight-bearing = weeks; AOFAS = 1, 2 and 3 years; Delayed union = 6 months; Complications = not specified (likely reviewed cumulatively at routine follow up appointments - see "POI")		12 months = 86.38±2.06 24 months = 79.47±1.03 36 months = 77.95±0.80	12 months = 86.57±1.69 24 months = 82.09±0.77 36 months = 79.67±1.06							
			Year 1: p = 0.745 (independent t-test) Year 2: p = 0.001* (independent t-test) Year 3: p = 0.001* (independent t-test)									
Chandrakant et al., 2018	Time to Union; Time to partial weight-bearing; AOFAS; Overall complications	Time to Union = mean weeks; Time to partial weight-bearing = mean weeks; AOFAS = final FUP at a minimum of 12 months; Overall complications = Cumulative over at least 12 months	91.10% at 12 months	88.90% at 12 months								Greater nonunion with plate but greater malunion with IMN.
			P = 0.31 (independent t-test)									
Mahendra et al., 2018	Time to Union; Time to partial weight-bearing (callus formation); OMAS; Deep/superficial infection	Time to Union = mean weeks; Time to partial weight-bearing = mean weeks; OMAS = final FUP 2 years post-op; Deep/superficial infection = cumulative FUPs until 2-year mark				82.4±11.5 (range 60-95) at 24 months	81.5±12.9 (range 40-95) at 24 months					No significant difference in mean angulation or shortening between groups. IMN group had mild anterior knee pain & discomfort when kneeling, and mild pain over screw head. Malunion rates higher in IMN group.
						P = 0.802 (independent t-test)						

SI2.2.3 – Patient-assessed data from the non-randomised studies (continued)

Vaienti et al., 2019	Time to union; Wound problems; Infection; Malunion; Anterior knee pain; Time to full weight-bearing; OMAS; DRI	Time to union, time to full weight-bearing = weeks; DRI, OMAS = 3, 6, 12 months; Infection, anterior knee pain, wound problems, secondary operations = cumulative at final FUP (see "POI")				3 months = 49.8 (range: 40-62) 6 months = 68.3 (range: 56-81) 12 months = 79.6 (range: 67-89)	3 months = 34.2 (range: 28-51) 6 months = 59.1 (range: 49-70) 12 months = 34.2 (range: 65-91)		**DRI:** 3 months = 40.6 (range: 32-59) 6 months = 21.5 (range: 13-38) 12 months = 11.8 (range: 6-18)	**DRI:** 3 months = 56.7 (range: 42-65) 6 months = 30.3 (range: 18-39) 12 months = 14.3 (range: 8-24)		No significant difference in malunion/misalignment (including rotational). Greater proportion of knee pain in IMN group but not statistically significant.
						OMAS 3 months: P = 0.008* OMAS at 6 months: p = 0.074 OMAS at 12 months = 0.244 (Mann-Whitney U test)			DRI 3 months: p = 0.005* DRI 6 months = 0.098 DRI 12 months = 0.326 (Mann-Whitney U test)			
Say et al., 2020	Time to union; Median AOFAS; Infection; overall complications (inc. infection, implant irritation, malunion and nonunion)	Time to union = weeks; AOFAS / Infection = likely cumulative at final FUP	82 (range, 65-90) at final follow up (median follow up period 10 months)	84 (range, 47-90) at final follow up (median follow up period 11 months)								No significant difference in malunion, nonunion, or implant irritation
			P = 0.974 (Mann-Whitney U test)									
El Zohairy et al., 2021	OMAS; Time to full weight-bearing; Time to union; Deep infection rate	OMAS = 6 months; Time to full weight-bearing = Not specified; Deep infection rate = Not specified				6 months = 80.42 ± 28.4	6 months = 85.42 ± 23.98					No significant differences noted in OMAS. Nor in time to union, time to weight bearing or deep infections, despite not reporting any values for these outcomes.
						P = 0.646 (independent t-test)						
Keerio et al., 2021	Time to Union; Time to full weight-bearing; OMAS; Deep infection	Time to Union = mean weeks; Time to full weight-bearing = mean weeks; OMAS = final FUP 1 year after fracture; Deep infection = cumulative FUPs after 6,12,18,24 weeks and every 3 months until final FUP (1 year)				84.50%	75.30%					Significantly greater range of ankle movement in both plantar- and dorsi-flexion for IMN. Some cases of misalignment in IMN, but not plate group. Cases of delayed union higher in plate group.
						P = 0.383 (independent t-test)						

SI2.2.3 – Patient-assessed data from the non-randomised studies (continued)

Kumar et al., 2021	Time to union; Time to full weight-bearing; Superficial infection; Deep infection	Cumulative follow ups until 1 year post-op										More knee stiffness and pain reported in IMN. More ankle stiffness reported in plate.
Almishri et al., 2022	Time to Union; Teeny and Wiss functional score; Infection	Time to Union = mean months; Teeny and Wiss = after 9-month FUP; Infection = measured cumulatively every 4 weeks until final 9-month FUP										More nonunion in IMN but more deformities and delayed union in plate.
Bleeker et al., 2022	Complications (infection, malalignment, secondary operations); Median time to full weight bearing; Median time to union	Median time to union = months; Median time to full weight bearing = months; Infection (and secondary operations, anterior knee pain, range of motion) = not specified (likely reviewed cumulatively at routine follow up appointments - see "POI")										Insignificant differences in malalignment (rotational + angular)
Sharma et al., 2022	Time to Union; Teeny and Wiss functional score; Superficial infection; Deep Infection	Time to Union = mean weeks; Teeny and Wiss functional score; Superficial infection; Deep Infection										Very minor differences in malunion and delayed union.
Bastías et al., 2023	Overall complications (inc. Superficial & deep infection, malunion/ malalignment, nonunion, amputation); Time to union; Superficial & deep infection	Overall complications = Cumulative over 2 years post-op; Time to union = mean weeks										More malunion/misalignment in plate compared to frame.

SI2.2.3 – Patient-assessed data from the non-randomised studies (continued)

Kaya et al., 2023	Time to union; Overall complications rate (inc. superficial & deep infection, iatrogenic tibia fractures, cutaneous necrosis, Sudeck atrophy, anterior knee pain); AOFAS; Teeny-Wiss radiological score; Time to full weight bearing	Wound problems = Last-follow up (time not specified); Time to union = weeks; Time to full weight bearing and return to daily life = days; Complications, Teeny-Wiss score = not specified (likely reviewed cumulatively at routine follow up appointments - see "POI")	95.8 ± 5.0 at final follow up (mean follow up period 13.3±6.0 months)	91.9 ± 14.3 at final follow up (mean follow up period 13.3±6.0 months)								
			P = 0.019* (Mann-Whitney U test)									
Kumar et al., 2023	Time to weight bearing; Ankle score; Deep/superficial infection	Time to weight bearing = delayed vs immediate; Ankle score = not recorded; Deep infection = cumulative FUPs (mean FUP 10 months)										Entire plating group had delayed union and much less in the IMN group. Malunion rate higher in the nail group. Nonunion was higher in the plating group.
Nath et al., 2023	Time to union; AOFAS; Infection	Time to union = weeks; AOFAS, Infection = 1 year (cumulative appointments at 6 weeks, 12 weeks, 6 months and 1 year)	92.6±5.41 mean score taken at 6, 12 weeks, 6, 12 months & 1 year	91.2±6.81 mean score taken at 6, 12 weeks, 6, 12 months & 1 year								Nonunion had insignificant difference.
			P = > 0.05 (independent t-test)									
M. Singh et al., 2023	Time to union; Time to partial weight-bearing; Time to full weight-bearing; AOFAS	Time to union = mean weeks; Time to partial weight-bearing = mean days; Time to full weight-bearing = mean weeks; AOFAS = measured at final FUP (24 weeks)	Score 90-99 = 53.34% Score 80-89 = 33.33% Score 70-79 = 13.33%	Score 90-99 = 6.67% Score 80-89 = 20.00% Score 70-79 = 73.33%								
			No statistical significance test performed									

SI2.2.3 – Patient-assessed data from the non-randomised studies (continued)

S. Singh et al., 2023	Superficial infection; Deep infection	Both recorded cumulatively until final FUP at 24-weeks										Varus/valgus angulation, knee stiffness, ankle stiffness, nonunion, delayed union, and malunion all had insignificant differences. Deep infection and anterior knee pain the only significantly different complications.
Taori et al., 2023	Time to Union; AOFAS; Overall complications	Time to Union = not reported; AOFAS = final FUP 12 months; Overall complications = cumulative FUPs (minimum 12 months)	77.5 ± 8.9 at 12 months	88.3 ± 9.1 at 12 months	70.2 ± 6.4 at 12 months							Ankle stiffness, nonunion, varus deformity, and valgus deformity were compared. There was no significant difference in overall complications of deformities.
			P = < 0 .001* (one-way ANOVA test)									
Tukade, 2023	Time to union; Time to weight bearing; OMAS; Deep/superficial infection	Time to union = mean weeks; Time to weight bearing = mean weeks; OMAS = measured at final FUP (1-year); Deep/superficial infection = cumulative until final FUP (1-year)				87.27±5.17 (timeframe not specified)	85±5.97 (timeframe not specified)	85±7.07 (timeframe not specified)				No cases of nonunion. No cases of delayed union. No cases of malunion. Ankle stiffness was IMN<CF<Plate
						P = 0.59 (ANOVA test)						
Wang et al., 2023	AOFAS; Time to union; Superficial and deep infection	AOFAS = 12 months; Time to union = days; Superficial and deep infection = not specified (likely reviewed cumulatively at routine follow up appointments - see "POI")	87.3±7.7 at 12 months	86.3±6.9 at 12 months								Insignificant differences in malalignment (rotational + angular)
			P = 0.057 (independent t-test)									

SI2.2.3 – Patient-assessed data from the non-randomised studies (continued)

Jang et al., 2024	Infection; PROs (PROMIS)	Reduction loss = 6 weeks; Nonunion = 6 months; PROs (PROMIS) = 2 weeks, 6 weeks, 12 weeks, 6 months, and 12 months; Infection = not specified										No significant difference in Patient Reported Outcomes (PROMIS).
Liu et al., 2024	Time to union; Time to full weight-bearing; AOFAS; Overall complication rate (inc. nonunion, delayed union, superficial & deep infection, implant failure); Superficial & deep infection rate	Time to union, time to full weight-bearing = weeks; AOFAS = not specified (at final follow up); Complications = not specified (likely reviewed cumulatively at routine follow up appointments - see notes)	84.5±4.7 at final follow up (mean follow up period 15.7 months):	82.6±5.8 at final follow up (mean follow up period 15.6 months)								Significantly more people with fair and poor AOFAS scores in MIPO group.
			P = 0.24 (independent t-test)									
Rafiq et al., 2024	Time to Union; AOFAS; Overall complication rate (inc. deep & superficial infections, nonunion, hardware irritation/implant removal); Deep & superficial infection rate	Time to Union = mean weeks; AOFAS = final FUP minimum 12 months; Deep infection = cumulative FUPs (minimum 12 months)	84.7 ± 7.5 at 12 months	87.3 ± 6.8 at 12 months								Malalignment: Plate<IMN. Delayed union: Plate<IMN. Nonunion: Plate<IMN. Alignment control was significantly better in the plating group.
			P = 0.21 (independent t-test)									
Shaikh et al., 2024	DRI; Patient satisfaction (SF-12); AOFAS; Malalignment; Time to union; Complications (inc. infection, secondary operations, malunion, nonunion, secondary arthritis, amputations, DVT, CRPS)	DRI, SF12, AOFAS = 3, 6, 12 months; Complications = not specified (likely reviewed cumulatively at routine follow up appointments - see "POI")		3 months = 41.70±7.97 6 months = 45.97±10.33 9 months = 57.14±4.66 12 months = 60.98±11.49	3 months = 44.52±13.52 6 months = 48.26±7.28 9 months = 53.62±7.61 12 months = 63.93±10.58					**DRI:** 3 months = 45.89±4.69 6 months = 42.64±5.27 9 months = 39.60±6.90 12 months = 39.82±6.26	**DRI:** 3 months = 48.69±8.36 6 months = 40.95±7.633 9 months = 40.69±5.61 12 months = 36.55±6.98	Greater proportion of malunion and secondary operations in the Illizarov group.
			3 months: p = 0.46 6 months: p = 0.41 9 months: p = 0.11 12 months: p = 0.41 (statistical significance test not stated)						DRI 3 months: p = 0.24 DRI 6 months: p = 0.45 DRI 9 months: p = 0.58 DRI 12 months: p = 0.14 (statistical significance test not stated)			

SI2.2.3 – Patient-assessed data from the non-randomised studies (continued)

Singh et al., 2025	AOFAS	AOFAS = minimum of 6-month follow-up	74.2 at final follow up (min. 6 months)	89.2 at final follow up (min. 6 months)	70.5 at final follow up (min. 6 months)							Nonunion: IMN<CF=Plate. Ankle stiffness: Plate<CF=IMN. Varus deformity: Plate<CF<IMN. Valgus deformity: IMN<Plate<CF.
			P = 0.05* (independent t-test)									

SI2.2.4 – Clinician-assessed data from the non-randomised studies

Study	Main relevant Outcomes	Outcome Timepoints	Superficial Infections (%)			Deep infections (%)			Infections (%)			Overall complication rate (%)			Points of interest
			IMN	Plate	Circular frame	IMN	Plate	Circular frame	IMN	Plate	Circular frame	IMN	Plate	Circular frame	
Harris et al., 2006	Deep & superficial infection rate; Overall complications rate (inc. deep & superficial infections, nonunion, malunion, wound complications)	Complications = cumulative to final FUP		0%	12.5%		0%	6.25%					7.94%	37.5%	ORIF associated with fewer complications and less post-traumatic arthritis
			No statistical significance test performed			No statistical significance test performed						P = 0.007* (Fisher's exact test)			
Yang et al., 2006	OMAS; Time to union; Overall infection rate	Time to union = weeks; OMAS, Malalignment, Malunion, Anterior knee pain = not specified (final FUP ≈ 33months)							0%	0%					No significant difference in Iowa ankle score nor malunion/misalignment (rotational was not measured). Anterior knee pain reported in some IMN patients compared none in the Plate group.
									No statistical test performed						
Janssen et al., 2007	Time to union; Infection; Time to weight-bearing	Time to union, time to weight-bearing = mean weeks; Infection (likely cumulative at final FUP - see points of interest ["POI"])	0%	8.33%		0%	0%		8.33%	8.33%					Main reason for plate removal was because patients "felt it there". Main reason for IMN removal was knee pain. Insignificant differences in malalignment/malunion (including rotational), despite their hypotheses. IMN had low-grade infection around locking screw. Could not distinguish between superficial or deep so overall infection rate extracted.
			No statistical significance test performed			No significant difference found but no statistical test performed			No statistical significance test performed						
Koulouvaris et al., 2007	Time to union; Infection	Time to union = months; Infection = 1 week, 1 month, monthly for 12 months & annual follow-up (cumulative)					7.69%	0%		7.69%	9.09%				Significant relationship with the type of fracture and infection. No malunions or nonunions.
						No statistical significance test performed			P = 0.37 – included comparison with monolateral external fixation (Chi-Squared test)						
Vallier et al., 2008	Complications (inc. infection)	Infection = cumulative at final FUP				5.26%	2.70%								Significantly greater malunion following IMN malalignment. IMN also had significantly greater procedures other than hardware removal (reasons including malalignment).
						P = 0.46 (Fisher's exact test)									

SI2.2.4 – Clinician-assessed data from the non-randomised studies (continued)

Li et al., 2012	Time to Union; Time to full weight-bearing; OMAS; Deep infection; Superficial infection	Time to union = mean weeks; Time to full weight-bearing = mean weeks; OMAS = measured at final FUP (25.2 weeks); Infection rates measured cumulatively until final FUP (25.2 weeks between groups)	4.35%	13.04%		0%	0%								No significant differences in anterior knee pain or malalignment. No cases of nonunion, implant failure or delayed union. No significant differences in mean postoperative varus/valgus angulation, ante-/recurvatum alignment.
			P = 0.608 (Fisher's two-sided exact test)			No statistical significance test performed									
Seyhan et al., 2013	Time to union; Time to full weight-bearing; Deep and superficial infection; Overall complications (inc. deep & superficial infections, nonunion & malunion, implant irritation)	Time to union = mean weeks; Time to full weight-bearing = mean weeks; Infections= measured cumulatively until final FUP (mean 21.4 months)	0.00%	11.10%		0%	5.60%		0%	16.7%		20%	52.8%		No statistically significant difference in rates of nonunion, malunion or implant irritation. Rate of secondary procedures significantly higher in plate compared to IMN.
			No statistical significance test performed			P = 0.508 (Fisher's exact chi-squared test)			P = 0.073 (Fisher's exact test)			No statistical test performed			
Fadel et al., 2014	Time to union; Time to partial weight-bearing; Time to full weight-bearing; AOFAS	Time to union = mean weeks; Time to partial weight-bearing = mean days; Time to full weight-bearing = mean weeks; AOFAS = measured at final FUP (24 weeks)		10%	0%		0%	0%							No cases of delayed union or nonunion in the CF group (significant difference).
			No statistical significance test performed			No statistical significance test performed									
Ali et al., 2015	Time to union; Time to full weight-bearing; AOFAS; Superficial infection; Deep infection	Time to union = mean weeks; Time to full weight-bearing = mean weeks; AOFAS = at final FUP?; Superficial + Deep infection cumulative to final follow-up (mean FUP was 34.2 months between groups)	3.33%	6.67%		0%	0%								No difference in rotational malalignment and insignificantly greater angular malalignment in the MIPO group vs IMN. None of these malalignments required secondary operation.
			No statistical significance test performed			No statistical significance test performed									
Jöstl et al., 2015	Time to union; Overall complication rate (inc. malunion, compartment syndrome, painful/broken interlocking screw, painful scar, Sudeck's disease, post-traumatic arthritis and refracture)	Time to union = days; Overall complication rate = cumulative at final FUP										12.12%	13.33%	25%	No significant differences in malunion, post-traumatic arthritis, refracture, painful/broken interlocking screw, or range of motion in the knee joint between the three groups.
												No statistical significance found but no p value provided			

SI2.2.4 – Clinician-assessed data from the non-randomised studies (continued)

Ali et al., 2016	Time to Union; Time to partial weight-bearing; Time to full weight-bearing; Teeny and Wiss; Deep/superficial infection	Time to Union = mean weeks; Time to partial weight-bearing = mean weeks; Time to full weight-bearing = mean weeks; Teeny and Wiss = final FUP 9 months post-op; Deep/superficial infection = cumulative FUPs until 9 months	6.67%	6.67%		0%	3.33%								Malunion, Delayed union, Ankle stiffness, Anterior knee pain, and Nonunion were measured. None of these were statistically significant using Fisher's test.
			P = 1.0 (Fisher's exact test)			P = 1.0 (Fisher's exact test)									
Barcak et al., 2016	AOFAS; SF-36; Time to union; Superficial infections	Time to union = weeks; AOFAS, SF-36 = at minimum of 1 year follow up; Infection = cumulative at final FUP	3.60%	0.00%											Quantitatively higher scores in Short Form 36 scores in the IMN group but no significant difference. No significant difference in malalignment (rotational not measured).
			P = 0.82 (Fisher's exact test)												
Shen et al., 2016	Wound complications	Cumulative until final FUP at 12 months (FUP 6, 10, 14 weeks, then every 6–8 weeks)													Malreduction / deformity (inc. valgus/varus, ante-/recurvation, rotation): significantly higher in IMN. No cases of shortening or nonunion.
Beytemur et al., 2017	Time to Union; OMAS; Deep/superficial infection	Time to Union = mean weeks; OMAS = final FUP mean 29.4 months; Deep infection = cumulative FUPs until mean 29.4 months	8.1%	19.4%		0%	2.8%								Anterior knee pain, Varus malunion, Valgus malunion, and Recurvatum malunion were significantly greater with IMN. Ankle dorsiflexion was significantly decreased with IMN.
			P = 0.159 (Fisher's exact test)			P = 0.493 (Fisher's exact test)									
Imren et al., 2017	Time to union; Complications (inc. infection, hardware removal, delayed union); AOFAS; Time to full weight-bearing	Time to union, time to full weight-bearing = weeks; AOFAS = 1, 2 and 3 years; Delayed union = 6 months; Complications = not specified (likely reviewed cumulatively at routine follow up appointments - see "POI")		23.81%	65.00%		0%	5%							
			No statistical significance test performed			No statistical significance test performed									

SI2.2.4 – Clinician-assessed data from the non-randomised studies (continued)

Chandrakant et al., 2018	Time to Union; Time to partial weight-bearing; AOFAS; Overall complications	Time to Union = mean weeks; Time to partial weight-bearing = mean weeks; AOFAS = final FUP at a minimum of 12 months; Overall complications = Cumulative over at least 12 months													Greater nonunion with plate but greater malunion with IMN.
Mahendra et al., 2018	Time to Union; Time to partial weight-bearing (callus formation); OMAS; Deep/superficial infection	Time to Union = mean weeks; Time to partial weight-bearing = mean weeks; OMAS = final FUP 2 years post-op; Deep/superficial infection = cumulative FUPs until 2-year mark	0%	10%		0%	5%								No significant difference in mean angulation or shortening between groups. IMN group had mild anterior knee pain & discomfort when kneeling, and mild pain over screw head. Malunion rates higher in IMN group.
			No statistical significance test performed			No statistical significance test performed									
Vaienti et al., 2019	Time to union; Wound problems; Infection; Malunion; Anterior knee pain; Time to full weight-bearing; OMAS; DRI	Time to union, time to full weight-bearing = weeks; DRI, OMAS = 3, 6, 12 months; Infection, anterior knee pain, wound problems, secondary operations = cumulative at final FUP (see "POI")							0.00%	3.70%					No significant difference in malunion/misalignment (including rotational). Greater proportion of knee pain in IMN group but not statistically significant.
									P = 0.084 (Fisher's exact test)						
Say et al., 2020	Time to union; Median AOFAS; Infection; overall complications (inc. infection, implant irritation, malunion and nonunion)	Time to union = weeks; AOFAS / Infection = likely cumulative at final FUP	11.10%	23.50%		0%	0%					50%	52.9%		No significant difference in malunion, nonunion, or implant irritation
			P = 0.33 (Chi-Squared test)			No statistical significance test performed						P = 0.862 (Chi-Squared test)			
El Zohairy et al., 2021	OMAS; Time to full weight-bearing; Time to union; Deep infection rate	OMAS = 6 months; Time to full weight-bearing = Not specified; Deep infection rate = Not specified													No significant differences noted in OMAS. Nor in time to union, time to weight bearing or deep infections, despite not reporting any values for these outcomes.
Keerio et al., 2021	Time to Union; Time to full weight-bearing; OMAS; Deep infection	Time to Union = mean weeks; Time to full weight-bearing = mean weeks; OMAS = final FUP 1 year after fracture; Deep infection = cumulative FUPs after 6,12,18,24 weeks and every 3 months until final FUP (1 year)				0%	26.70%								Significantly greater range of ankle movement in both plantar- and dorsi-flexion for IMN. Some cases of misalignment in IMN, but not plate group. Cases of delayed union higher in plate group.
						No statistical significance test performed									

SI2.2.4 – Clinician-assessed data from the non-randomised studies (continued)

Kumar et al., 2021	Time to union; Time to full weight-bearing; Superficial infection; Deep infection	Cumulative follow ups until 1 year post-op	0%	5%		0%	15%								More knee stiffness and pain reported in IMN. More ankle stiffness reported in plate.
			No statistical significance test performed			No statistical significance test performed									
Almishri et al., 2022	Time to Union; Teeny and Wiss functional score; Infection	Time to Union = mean months; Teeny and Wiss = after 9-month FUP; Infection = measured cumulatively every 4 weeks until final 9-month FUP							33.3%	55.6%					More nonunion in IMN but more deformities and delayed union in plate.
									P = 0.34 (Pearson's Chi-Square test)						
Bleeker et al., 2022	Complications (infection, malalignment, secondary operations); Median time to full weight bearing; Median time to union	Median time to union = months; Median time to full weight bearing = months; Infection (and secondary operations, anterior knee pain, range of motion) = not specified (likely reviewed cumulatively at routine follow up appointments - see "POI")	4.76%	4.17%		1.59%	8.33%		6.35%	12.5%					Insignificant differences in malalignment (rotational + angular)
			No statistical significance test performed			No statistical significance test performed			P = 0.21 (Fisher's exact test)						
Sharma et al., 2022	Time to Union; Teeny and Wiss functional score; Superficial infection; Deep Infection	Time to Union = mean weeks; Teeny and Wiss functional score; Superficial infection; Deep Infection	13.33%	0%		6.66%	13.33%								Very minor differences in malunion and delayed union.
			P = > 0.05 (Chi-Squared test)			No statistical significance test performed									
Bastías et al., 2023	Overall complications (inc. Superficial & deep infection, malunion/ malalignment, nonunion, amputation); Time to union; Superficial & deep infection	Overall complications = Cumulative over 2 years post-op; Time to union = mean weeks		20%	47.80%		20%	0%					56.6%	65.2%	More malunion/misalignment in plate compared to frame.
			P = 0.031* (Chi-Squared test)			P = 0.03* (Fisher's exact test)						P = 0.520 (Fisher's exact test)			

SI2.2.4 – Clinician-assessed data from the non-randomised studies (continued)

Kaya et al., 2023	Time to union; Overall complications rate (inc. superficial & deep infection, iatrogenic tibia fractures, cutaneous necrosis, Sudeck atrophy, anterior knee pain); AOFAS; Teeny-Wiss radiological score; Time to full weight bearing	Wound problems = Last-follow up (time not specified); Time to union = weeks; Time to full weight bearing and return to daily life = days; Complications, Teeny-Wiss score = not specified (likely reviewed cumulatively at routine follow up appointments - see "POI")	2.9%	2.9%		0.00%	2.9%					22.86%	29.41%		
			No statistical significance test performed			No statistical significance test performed						P = 0.908 (Pearson's Chi-Squared test)			
Kumar et al., 2023	Time to weight bearing; Ankle score; Deep/superficial infection	Time to weight bearing = delayed vs immediate; Ankle score = not recorded; Deep infection = cumulative FUPs (mean FUP 10 months)	10% (1/10)	20% (2/10)		0%	10% (1/10)								Entire plating group had delayed union and much less in the IMN group. Malunion rate higher in the nail group. Nonunion was higher in the plating group.
			No statistical significance test performed			No statistical significance test performed									
Nath et al., 2023	Time to union; AOFAS; Infection	Time to union = weeks; AOFAS, Infection = 1 year (cumulative appointments at 6 weeks, 12 weeks, 6 months and 1 year)							0%	15%					Nonunion had insignificant difference.
									P = < 0.05* (Chi-Squared test)						
M. Singh et al., 2023	Time to union; Time to partial weight-bearing; Time to full weight-bearing; AOFAS	Time to union = mean weeks; Time to partial weight-bearing = mean days; Time to full weight-bearing = mean weeks; AOFAS = measured at final FUP (24 weeks)													
S. Singh et al., 2023	Superficial infection; Deep infection	Both recorded cumulatively until final FUP at 24-weeks	6.67%	20%		0%	33.33%								Varus/valgus angulation, knee stiffness, ankle stiffness, nonunion, delayed union, and malunion all had insignificant differences. Deep infection and anterior knee pain the only significantly different complications.
			P = 0.4262 (statistical significance test not stated)			P = 0.0421* (statistical significance test not stated)									
Taori et al., 2023	Time to Union; AOFAS; Overall complications	Time to Union = not reported; AOFAS = final FUP 12 months; Overall complications = cumulative FUPs (minimum 12 months)													Ankle stiffness, nonunion, varus deformity, and valgus deformity were compared. There was no significant difference in overall complications of deformities.

SI2.2.4 – Clinician-assessed data from the non-randomised studies (continued)

Tukade, 2023	Time to union; Time to weight bearing; OMAS; Deep/superficial infection	Time to union = mean weeks; Time to weight bearing = mean weeks; OMAS = measured at final FUP (1-year); Deep/superficial infection = cumulative until final FUP (1-year)	9.09%	0%	0%	0%	6.67% (1/15)	0%							No cases of nonunion. No cases of delayed union. No cases of malunion. Ankle stiffness was IMN<CF<Plate
			No statistical significance test performed			No statistical significance test performed									
Wang et al., 2023	AOFAS; Time to union; Superficial and deep infection	AOFAS = 12 months; Time to union = days; Superficial and deep infection = not specified (likely reviewed cumulatively at routine follow up appointments - see "POI")	1.92%	8.18%		0.64%	0.90%								Insignificant differences in malalignment (rotational + angular)
			P = 0.031* (Pearson's chi-square test)			P = 1.000 (Fisher's exact test)									
Jang et al., 2024	Infection; PROs (PROMIS)	Reduction loss = 6 weeks; Nonunion = 6 months; PROs (PROMIS) = 2 weeks, 6 weeks, 12 weeks, 6 months, and 12 months; Infection = not specified							6.06%	14.3%					No significant difference in Patient Reported Outcomes (PROMIS).
									P = 0.17 (propensity-adjusted multivariate logistic regression model)						
Liu et al., 2024	Time to union; Time to full weight-bearing; AOFAS; Overall complication rate (inc. nonunion, delayed union, superficial & deep infection, implant failure); Superficial & deep infection rate	Time to union, time to full weight-bearing = weeks; AOFAS = not specified (at final follow up); Complications = not specified (likely reviewed cumulatively at routine follow up appointments - see notes)	4.76%	11.11 %		0.00%	7.41%					4.76%	29.63%		Significantly more people with fair and poor AOFAS scores in MIPO group.
			No statistical significance test performed			No statistical significance test performed						No statistical test performed			
Rafiq et al., 2024	Time to Union; AOFAS; Overall complication rate (inc. deep & superficial infections, nonunion, hardware irritation/implant removal); Deep & superficial infection rate	Time to Union = mean weeks; AOFAS = final FUP minimum 12 months; Deep infection = cumulative FUPs (minimum 12 months)	0%	11.10%		0%	5.60%					17.6%	22.2%		Malalignment: Plate<IMN. Delayed union: Plate<IMN. Nonunion: Plate<IMN. Alignment control was significantly better in the plating group.
			P = 0.23 (Fisher's exact test)			P = 0.33 (Fisher's exact test)						P = 0.66 (Fisher's exact test)			

SI2.2.4 – Clinician-assessed data from the non-randomised studies (continued)

Shaikh et al., 2024	DRI; Patient satisfaction (SF-12); AOFAS; Malalignment; Time to union; Complications (inc. infection, secondary operations, malunion, nonunion, secondary arthritis, amputations, DVT, CRPS)	DRI, SF12, AOFAS = 3, 6, 12 months; Complications = not specified (likely reviewed cumulatively at routine follow up appointments - see "POI")		0.00%	7.70%		0.00%	7.70%							Greater proportion of malunion and secondary operations in the Illizarov group.
			P = 0.52 (Fisher's exact test)			P = 0.52 (Fisher's exact test)									
Singh et al., 2025	AOFAS	AOFAS = minimum of 6-month follow-up													Nonunion: IMN<CF=Plate. Ankle stiffness: Plate<CF=IMN. Varus deformity: Plate<CF<IMN. Valgus deformity: IMN<Plate<CF.

Analyses of bias

Supplementary Information 3 (SI3)

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    - SI3.1.1.2 – Summary plot
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Quality assessment (RoB2)

(SI3.1)

*SI3.1.1.1 – **Traffic light plot for radiographically assessed outcomes**:*
RoB 2 domain-level judgements for each included study, with colours indicating low risk, some concerns, or high risk of bias.

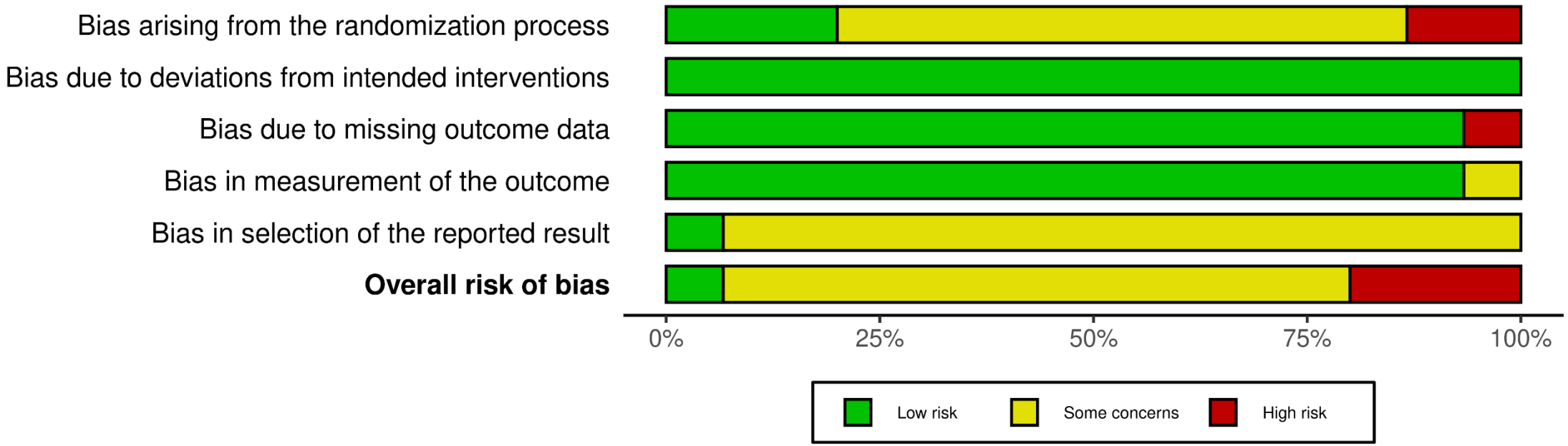
Risk of bias domains

Study	D1	D2	D3	D4	D5	Overall
Im et al., 2005	-	+	X	+	-	X
Guo et al., 2010	-	+	+	+	-	-
Vallier et al., 2011	+	+	+	+	-	-
Li et al., 2014	+	+	+	+	-	-
Polat et al., 2015	X	+	+	+	-	X
Imran et al., 2016	-	+	+	+	-	-
Wani et al., 2017	-	+	+	+	-	-
Costa et al., 2018	+	+	+	+	+	+
Ahmed et al., 2018	-	+	+	+	-	-
Sharma et al., 2018	-	+	+	+	-	-
KC et al., 2021	-	+	+	+	-	-
Kumar et al., 2022	-	+	+	-	-	-
Ahmed et al., 2023	X	+	+	+	-	X
Hamdy et al., 2024	-	+	+	+	-	-
Prabhat et al., 2025	-	+	+	+	-	-

Domains:
D1: Bias arising from the randomization process.
D2: Bias due to deviations from intended intervention.
D3: Bias due to missing outcome data.
D4: Bias in measurement of the outcome.
D5: Bias in selection of the reported result.

Judgement
X High
- Some concerns
+ Low

SI3.1.1.1 – ***Summary plot for radiographically assessed outcomes****:*
Proportion of studies rated low risk, some concerns, or high risk across RoB 2 domains.



*SI3.1.1.1 – **RoB2 decision process and notes** indicating decision pathways to come to a risk of bias judgement.*
Radiographically assessed outcomes

Study	Overall RoB 2 Judgment	Justification / Notes	1.1	1.2	1.3	2.1	2.2	2.3	2.4	2.5	2.6	2.7	3.1	3.2	3.3	3.4	4.1	4.2	4.3	4.4	4.5	5.1	5.2	5.3
Im et al., 2005	High risk	No significant differences in baseline characteristics, except there is no statistical test for smoking which does appear to be notably different between both groups (~15%). Does not specify from which intervention groups participants lost to follow up were from, or provide reasoning for why they were lost to follow up. Therefore, we cannot tell differences between interventions in proportions of missing outcome data or whether reasons for missingness differ between interventions. Could not locate pre-analysis plant/trial registration. Likely mITT analysis was completed, although no explicit mention of this.	Y	Y	PY	PY	Y	N			PY		N	N	Y	NI	N	N	Y	N		NI	N	N
Guo et al., 2010	Some concerns	No concealment of allocation process, however baseline characteristics were comparable. Although not explicitly mentioned, mITT can be assumed due to analysis of all participants post-randomisation except for those who had not been followed up at the time of publication. Data is missing (no evidence result is not biased), however missingness is due to the fact that they had not been follow-up at the time of publication.		NI	N	PY	Y	N			Y		N	N	N		N	N	Y	N		NI	N	N
Vallier et al., 2011	Some concerns	Whilst assessors would have had knowledge of the procedure, radiographic outcomes in this study are objective making it unlikely that awareness of the intervention would have influenced measurement of the outcome.	Y	Y	Y	PY	Y	N			PY		Y				N	N	Y	N		NI	N	N
Li et al., 2014	Some concerns	Although no explicit mention of mITT, all participants were analysed post-randomisation except for 15 lost to follow up. Whist data missing for around 15 participants, there are documented reasons for this. Could not identify trial registration or pre-analysis plan for this study.	Y	Y	N	PY	Y	N			PY		N	N	PN		N	N	Y	N		NI	N	N
Polat et al., 2015	High risk	Allocation sequence not concealed as method used was flip of a coin. No specific reference to ITT analysis, however all participants post-randomisation were analysed. Could not access trail registration/pre-analysis plan raising some concerns.		NI	PN	PY	Y	N			PY		Y				N	N	Y	N		NI	N	N
Imran et al., 2016	Some concerns	No information on concealment of allocation process, and no significance testing between baseline demographic characteristics. However, these characteristics appear to be balanced across both intervention groups. No explicit mention of ITT analysis, but all patients randomised were analysed. No available pre-analysis plan or trial registration could be found for this study raising some concerns.		NI	PN	PY	Y	N			PY		Y				N	N	Y	N		NI	N	N

SI3.1.1.1 – RoB2 decision process and notes (continued)

Radiographically assessed outcomes

Wani et al., 2017	Some concerns	No reference to whether the allocation sequences was concealed, however baseline characteristics were balanced. Whilst no explicit mention of ITT, all participants post-randomisation were analysed. Could not access trail registration/pre-analysis plan raising some concerns.		NI	N	PY	Y	N			PY		Y				N	N	Y	N		NI	N	N
Costa et al., 2018	Low risk	Sample size was inflated to account for loss of follow up of over 20%, and less than 20% were lost from the primary outcome analysis at every time point, making it unlikely that missing data had an overall impact on measured outcome.	Y	Y	Y	Y	Y	N			Y		N	Y			N	N	Y	N		Y	N	N
Ahmed et al., 2018	Some concerns	Allocation sequence random but no information on concealment. However, baseline characteristics appear balanced. Although no reference to mITT, all participants were analysed post-randomisation except for 3 who (refused treatment & lost to follow up) in their original intervention groups. 93.33% (<95/%) of original randomised population analysed due to 3 dropouts. However, one from each group dropped out due to insufficient follow up, and another due to treatment refusal. Therefore, unlikely that outcomes were biased as differences were reasonably even across both groups in missing data.		NI	PN	PY	Y	N			PY		N	N	PN		N	N	Y	N		NI	N	N
Sharma et al., 2018	Some concerns	No information provided on concealment of allocation process. However, baseline characteristics appeared balanced. No specific reference to ITT analysis, however all participants post-randomisation were analysed.		NI	N	PY	Y	N			PY		Y				N	N	Y	N		NI	N	N
KC et al., 2021	Some concerns	Allocation was random and concealed. However, there was no significance testing for differences in sex and fracture type between intervention groups, only for age, to assess baseline imbalances. Whilst there was no specific mention of ITT, all participants that were randomised were also analysed. Could not access pre-analysis plan/trail registration.	Y	Y	PY	PY	Y	N			Y		N				N	N	Y	N		NI	N	N
Kumar et al., 2022	Some concerns	Allocation sequence not concealed. No significance testing on baseline characteristics, however most differences in baseline characteristics are likely due to chance and not the randomisation process. Some concerns in distribution of patients 66-75 years old and types of fracture. No specific reference to ITT, however all participants post-randomisation were analysed. Teeny & Wiss score involves patient reported outcomes (e.g. pain) and therefore knowledge of intervention could influence assessment. However, there is no evidence to suggest this.		NI	PN	PY	Y	N			PY		Y				N	N	Y	Y	PN	NI	N	N

SI3.1.1.1 – RoB2 decision process and notes (continued)
Radiographically assessed outcomes

Ahmed et al., 2023	High risk	Patients alternately allocated an intervention ('every other one' basis). Sequence of allocations can be predicted in advance, therefore cannot be considered concealed. Unable to access pre-analysis plan/trial registration.		N		PY	Y	N			PY		Y				N	N	Y	N		NI	N	N
Hamdy et al., 2024	Some concerns	3 patients lost to follow up in the IMN group. However, >95% of original randomised participants still involved in final analysis. Therefore, nearly all outcome data was available. No mention of time to radiological union as an outcome measure in the pre-analysis plan. No explicit reference to mITT, however all participants were analysed in their original intervention groups apart from the 3 lost to follow up post-randomisation.		NI	N	PY	Y	N			PY		PY				N	N	Y	N		N	N	N
Prabhat et al., 2025	Some concerns	No information provided on concealment of allocation process. OFAS regarded as clinical measure (but included patient reported elements). Plausible that patient knowledge of intervention could influence certain criteria of the score (e.g. pain), however there is no evidence to suggest this.		NI	N	PY	Y	N			PY		Y				N	N	Y	N		NI	N	N

*SI3.1.2.1 – **Traffic light plot for patient-assessed outcomes**:*
RoB 2 domain-level judgements for each included study, with colours indicating low risk, some concerns, or high risk of bias.

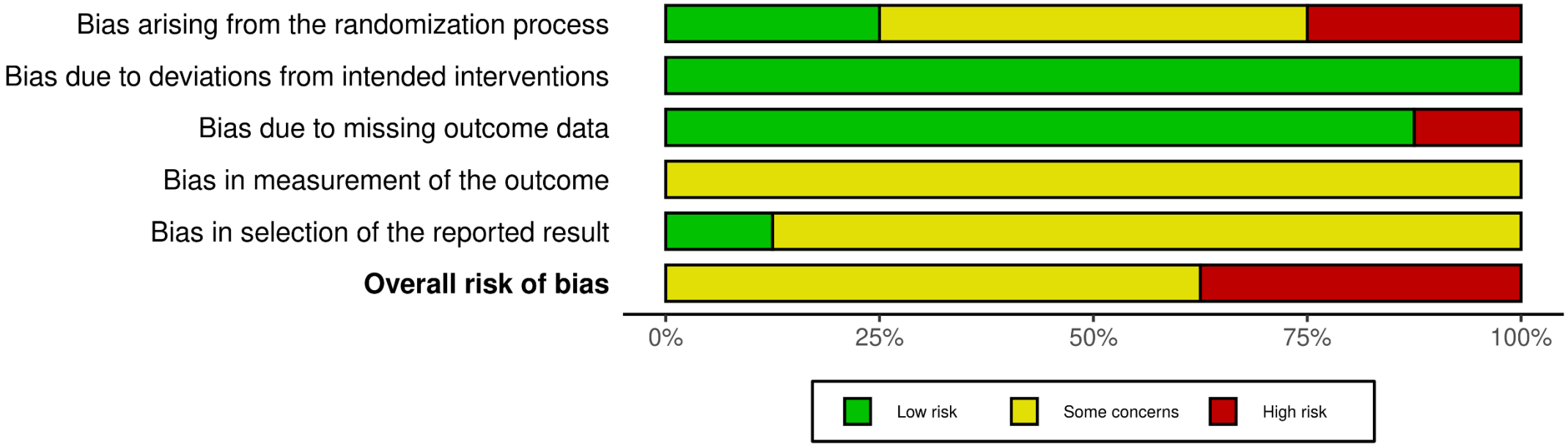
Risk of bias domains

Study	D1	D2	D3	D4	D5	Overall
Im et al., 2005	-	+	X	-	-	X
Li et al., 2014	+	+	+	-	-	-
Polat et al., 2015	X	+	+	-	-	X
Wani et al., 2017	-	+	+	-	-	-
Costa et al., 2018	+	+	+	-	+	-
Sharma et al., 2018	-	+	+	-	-	-
Ahmed et al., 2023	X	+	+	-	-	X
Hamdy et al., 2024	-	+	+	-	-	-

Domains:
D1: Bias arising from the randomization process.
D2: Bias due to deviations from intended intervention.
D3: Bias due to missing outcome data.
D4: Bias in measurement of the outcome.
D5: Bias in selection of the reported result.

Judgement
X High
- Some concerns
+ Low

*SI3.1.2.2 – **Summary plot for patient-assessed outcomes**:*
Proportion of studies rated low risk, some concerns, or high risk across RoB 2 domains.



*SI3.1.2.3 – **RoB2 decision process and notes** indicating decision pathways to come to a risk of bias judgement.*
Patient-assessed outcomes

Study	Overall RoB 2 Judgment	Justification / Notes	1.1	1.2	1.3	2.1	2.2	2.3	2.4	2.5	2.6	2.7	3.1	3.2	3.3	3.4	4.1	4.2	4.3	4.4	4.5	5.1	5.2	5.3
Im et al., 2005	High risk	Does not specify from which intervention groups participants lost to follow up were from or provide reasoning for why they were lost to follow up. Therefore, we cannot tell differences between interventions in proportions of missing outcome data or whether reasons for missingness differed between interventions. Knowledge of intervention could have influenced self-reported outcomes using OMAS, no evidence to suggest this was the case. Could not locate pre-analysis plant/trial registration. Likely mITT analysis was completed, although no explicit mention of this.	Y	Y	PY	PY	Y	N			PY		N	N	Y	NI	N	N	Y	Y	PN	NI	N	N
Li et al., 2014	Some concerns	Although no explicit mention of mITT, all participants were analysed post-randomisation except for 15 lost to follow up. Whist data missing for around 15 participants, there are documented reasons for this. Soft tissue irritation and anterior knee pain were recorded which could be influenced by knowledge of the intervention. There is no evidence to suggest that this is the case, however. Could not identify trial registration or pre-analysis plan for this study.	Y	Y	N	PY	Y	N			PY		N	N	PN		N	N	Y	Y	PN	NI	N	N
Polat et al., 2015	High risk	Allocation sequence not concealed as method used was flip of a coin. No specific reference to ITT analysis, however all participants post-randomisation were analysed. FFI, anterior knee pain and prominence of implants are patient reported outcomes. Therefore, knowledge of intervention could influence the assessment of these variables (e.g. pain). However, there is no evidence to suggest that this was the case. Could not access trail registration/pre-analysis plan raising some concerns.		NI	PN	PY	Y	N			PY		Y				N	N	Y	Y	PN	NI	N	N
Wani et al., 2017	Some concerns	No reference to whether the allocation sequences was concealed, however baseline characteristics were balanced. Whilst no explicit mention of ITT, all participants post-randomisation were analysed. FFI is a patient reported outcome; therefore knowledge of the intervention could have influenced assessment (e.g. pain). However, there is no evidence to suggest that this was the case. Could not access trail registration/pre-analysis plan raising some concerns.		NI	N	PY	Y	N			PY		Y				N	N	Y	Y	PN	NI	N	N

SI3.1.2.3 – RoB2 decision process and notes (continued)

Patient-assessed outcomes

Costa et al., 2018	Some concerns	Sample size was inflated to account for loss of follow up of over 20%, and less than 20% were lost from the primary outcome analysis at every time point, making it unlikely that missing data had an overall impact on measured outcome. Whilst knowledge of the intervention could influence patient assessment of patient reported outcomes, there is no evidence to suggest that this was the case.	Y	Y	Y	Y	Y	N			Y		N	Y			N	N	Y	Y	PN	Y	N	N
Sharma et al., 2018	Some concerns	No information provided on concealment of allocation process. However, baseline characteristics appeared balanced. No specific reference to ITT analysis, however all participants post-randomisation were analysed. LEFS (and associated POMF score) and pain score are both patient reported outcomes. Therefore, it is possible that knowledge of the intervention could influenced the assessment of these measures. However, there is no evidence to suggest that this was the case.		NI	N	PY	Y	N			PY		Y				N	N	Y	Y	PN	NI	N	N
Ahmed et al., 2023	High risk	Patients alternately allocated an intervention ('every other one' basis). Sequence of allocations can be predicted in advance, therefore cannot be considered concealed. This was completed for KSS which is not a PROM that we are analysing in our study. Whilst knowledge of the intervention could have influenced patient reported assessment, there is no evidence to suggest that it did. Unable to access pre-analysis plan/trial registration.		N		PY	Y	N			PY		Y				N	N	PY	Y	PN	NI	N	N
Hamdy et al., 2024	Some concerns	3 patients lost to follow up in the IMN group. However, >95% of original randomised participants still involved in final analysis. OMAS assessment could have been influenced by knowledge of intervention, but there is no evidence to suggest that it was. Pre-analysis plan stated a timeframe of 2 weeks for OMAS measurement; however it was measured at 3 and 6 months. No explicit reference to mITT, however all participants were analysed in their original intervention groups apart from the 3 lost to follow up post-randomisation.		NI	N	PY	Y	N			PY		PY				N	N	Y	Y	PN	N	N	N

*SI3.1.3.1 – **Traffic light plot for clinician-assessed outcomes**: RoB 2 domain-level judgements for each included study, with colours indicating low risk, some concerns, or high risk of bias.*

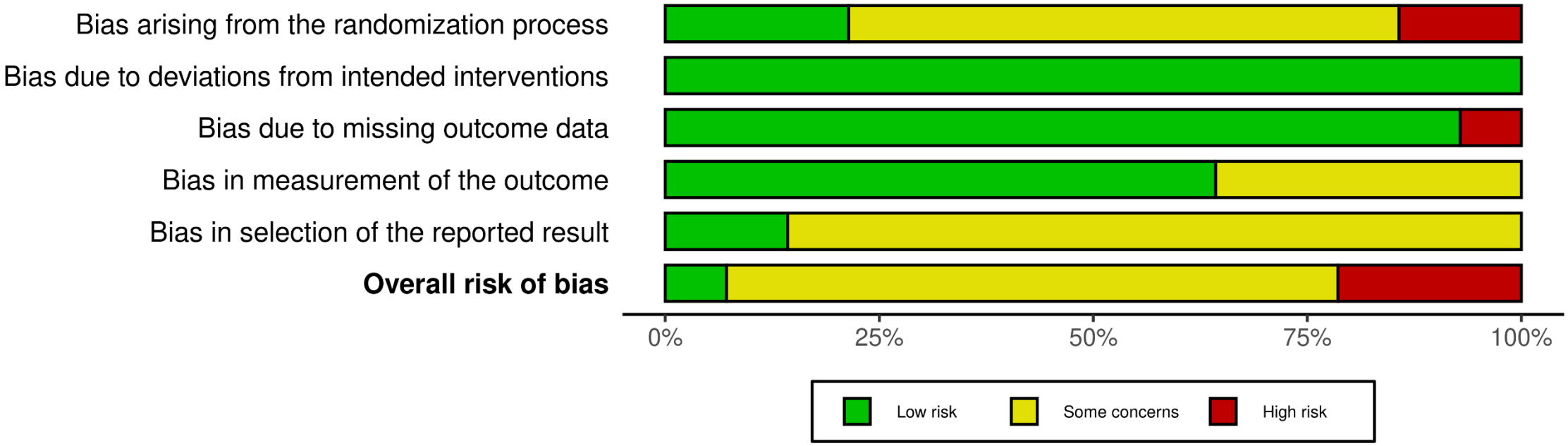
Risk of bias domains

Study	D1	D2	D3	D4	D5	Overall
Im et al., 2005	-	+	X	+	-	X
Guo et al., 2010	-	+	+	-	-	-
Vallier et al., 2011	+	+	+	+	-	-
Li et al., 2014	+	+	+	-	-	-
Polat et al., 2015	X	+	+	+	-	X
Wani et al., 2017	-	+	+	+	-	-
Costa et al., 2018	+	+	+	+	+	+
Ahmed et al., 2018	-	+	+	-	-	-
Sharma et al., 2018	-	+	+	+	-	-
KC et al., 2021	-	+	+	-	-	-
Kumar et al., 2022	-	+	+	+	-	-
Ahmed et al., 2023	X	+	+	+	-	X
Hamdy et al., 2024	-	+	+	+	+	-
Prabhat et al., 2025	-	+	+	-	-	-

Domains:
D1: Bias arising from the randomization process.
D2: Bias due to deviations from intended intervention.
D3: Bias due to missing outcome data.
D4: Bias in measurement of the outcome.
D5: Bias in selection of the reported result.

Judgement
X High
- Some concerns
+ Low

*SI3.1.3.2 – **Summary plot for clinician-assessed outcomes**:*
Proportion of studies rated low risk, some concerns, or high risk across RoB 2 domains.



*SI3.1.3.3 – **RoB2 decision process and notes** indicating decision pathways to come to a risk of bias judgement.*
Clinician-assessed outcomes

Study	Overall RoB 2 Judgment	Justification / Notes	1.1	1.2	1.3	2.1	2.2	2.3	2.4	2.5	2.6	2.7	3.1	3.2	3.3	3.4	4.1	4.2	4.3	4.4	4.5	5.1	5.2	5.3
Im et al., 2005	High risk	Does not specify from which intervention groups participants lost to follow up were from, or provide reasoning for why they were lost to follow up. Therefore, we cannot tell differences between interventions in proportions of missing outcome data or whether reasons for missingness differed between interventions. Could not locate pre-analysis plant/trial registration. Likely mITT analysis was completed, although no explicit mention of this.	Y	Y	PY	PY	Y	N			PY		N	N	Y	NI	N	N	Y	N		NI	N	N
Guo et al., 2010	Some concerns	No concealment of allocation process, however baseline characteristics were comparable. Although not explicitly mentioned, mITT can be assumed due to analysis of all participants post-randomisation except for those who had not been followed up at the time of publication. Data is missing (no evidence result is not biased), however missingness is due to the fact that they had not been follow-up at the time of publication. AOFAS used which included patient reported outcomes (e.g. pain). Therefore, knowledge of the intervention could influence assessment. However, there is no evidence to suggest that this was the case.		NI	N	PY	Y	N			Y		N	N	N		N	N	Y	Y	PN	NI	N	N
Vallier et al., 2011	Some concerns	Missing data from 4 participants in the analysis of those who needed a secondary procedure. This was because they had not reached the 12 month follow up period at the time of the study, meaning their missingness was not dependent on the intervention. Whilst assessors would have had knowledge of the procedure, clinical outcomes in this study (infection and secondary procedures) are objective making it unlikely that awareness of the intervention would have influenced measurement of the outcome.	Y	Y	Y	PY	Y	N			PY		N	N	N		N	N	Y	N		NI	N	N
Li et al., 2014	Some concerns	Although no explicit mention of mITT, all participants were analysed post-randomisation except for 15 lost to follow up. Whist data missing for around 15 participants, there are documented reasons for this. Clinical measures of interest included superficial and deep infection (which are objective and unlikely to be influenced by knowledge of intervention). Mazur ankle score is a clinical measure although includes subjective measures (e.g. pain) which could be influenced by knowledge of the intervention. There is no evidence to suggest that this is the case, however. Could not identify trial registration or pre-analysis plan for this study.	Y	Y	N	PY	Y	N			PY		N	N	PN		N	N	Y	Y	PN	NI	N	N

SI3.1.3.3 – RoB2 decision process and notes (continued)
Clinician-assessed outcomes

Polat et al., 2015	High risk	Allocation sequence not concealed as method used was flip of a coin. No specific reference to ITT analysis, however all participants post-randomisation were analysed. Could not access trail registration/pre-analysis plan raising some concerns.		NI	PN	PY	Y	N			PY		Y				N	N	Y	N		NI	N	N
Wani et al., 2017	Some concerns	No reference to whether the allocation sequences was concealed, however baseline characteristics were balanced. Whilst no explicit mention of ITT, all participants post-randomisation were analysed. Could not access trial registration/pre-analysis plan raising some concerns.		NI	N	PY	Y	N			PY		Y				N	N	Y	N		NI	N	N
Costa et al., 2018	Low risk	Sample size was inflated to account for loss of follow up of over 20%, and less than 20% were lost from the primary outcome analysis at every time point, making it unlikely that missing data had an overall impact on measured outcome.	Y	Y	Y	Y	Y	N			Y		N	Y			N	N	Y	N		Y	N	N
Ahmed et al., 2018	Some concerns	Allocation sequence random but no information on concealment. However, baseline characteristics appear balanced. Although no reference to mITT, all participants were analysed post-randomisation except for 3 who (refused treatment & lost to follow up) in their original intervention groups. 93.33% (<95/%) of original randomised population analysed due to 3 dropouts. However, one from each group dropped out due to insufficient follow up, and another due to treatment refusal. Therefore, unlikely that outcomes were biased as differences were reasonably even across both groups in missing data. AOFAS contains patient reported measures (e.g. pain) which could be influenced by knowledge of intervention, but there is no evidence to suggest this.		NI	PN	PY	Y	N			PY		N				N	N	Y	Y	PN	NI	N	N
Sharma et al., 2018	Some concerns	No information provided on concealment of allocation process. However, baseline characteristics appeared balanced. No specific reference to ITT analysis, however all participants post-randomisation were analysed.		NI	N	PY	Y	N			PY		Y				N	N	Y	N		NI	N	N
KC et al., 2021	Some concerns	Allocation was random and concealed. However, there was no significance testing for differences in sex and fracture type between intervention groups, only for age. AOFAS regarded as clinical measure (but included patient reported elements). Plausible that patient knowledge of intervention could influence certain criteria of the score (e.g. pain), however there is no evidence to suggest this. Whilst there was no specific mention of ITT, all participants that were randomised were also analysed. Could not access pre-analysis plan/trial registration.	Y	Y	PY	PY	Y	N			Y		N	N	PN		N	N	Y	PY	PN	NI	N	N

SI3.1.3.3 – RoB2 decision process and notes (continued)

Clinician-assessed outcomes

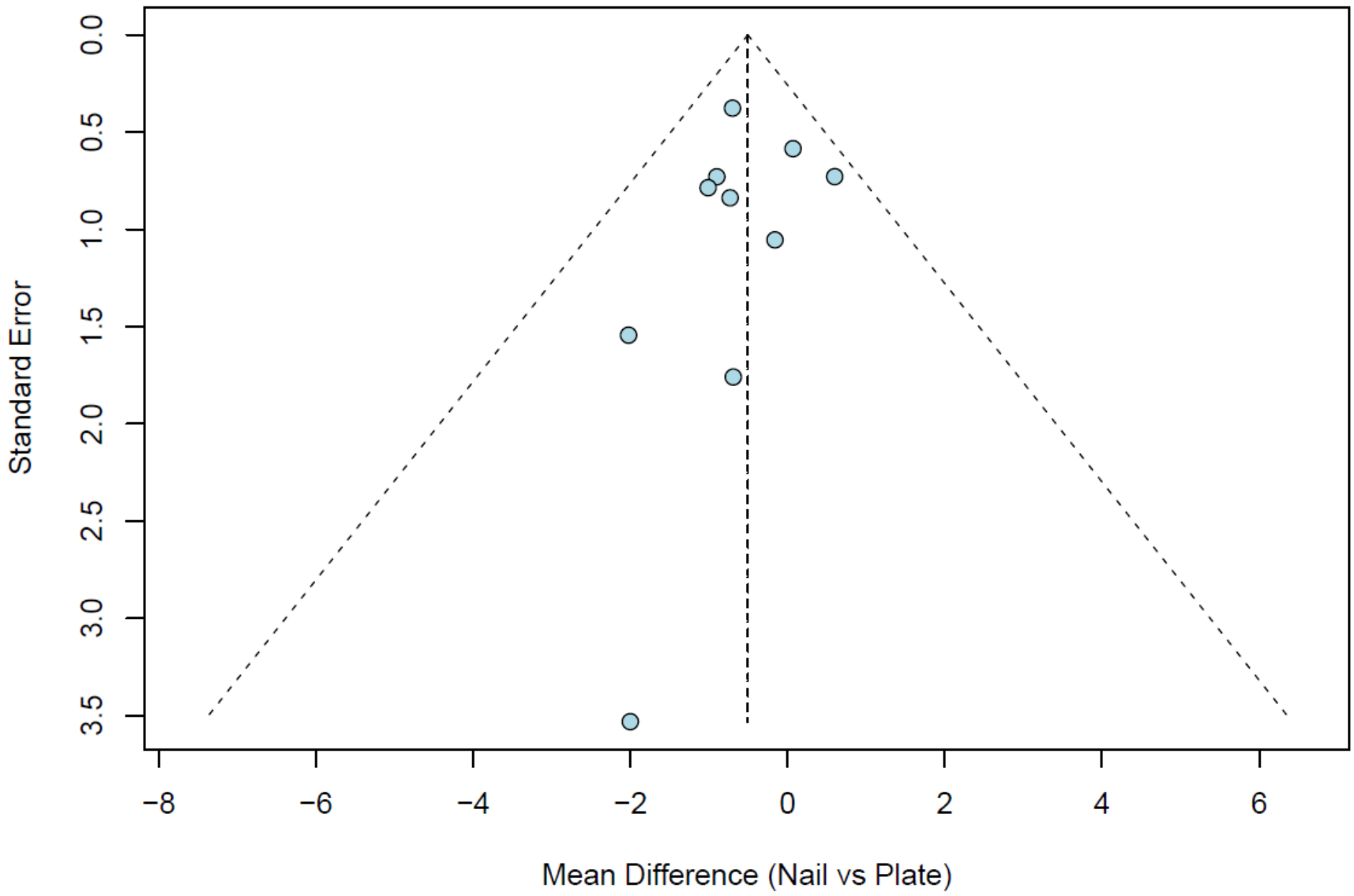
Kumar et al., 2022	Some concerns	Allocation sequence not concealed. No significance testing on baseline characteristics, however most differences in baseline characteristics are likely due to chance and not the randomisation process. Some concerns in distribution of patients 66-75 years old and types of fracture. No specific reference to ITT, however all participants post-randomisation were analysed.		NI	PN	PY	Y	N			PY		Y				N	N	Y	N		NI	N	N
Ahmed et al., 2023	High risk	Patients alternately allocated an intervention ('every other one' basis). Sequence of allocations can be predicted in advance, therefore cannot be considered concealed. Unable to access pre-analysis plan/trial registration.		N		PY	Y	N			PY		Y				N	N	Y	N		NI	N	N
Hamdy et al., 2024	Some concerns	3 patients lost to follow up in the IMN group. However, >95% of original randomised participants still involved in final analysis. Clinical outcome measures of complications outlined in pre-analysis plan. No explicit reference to mITT, however all participants were analysed in their original intervention groups apart from the 3 lost to follow up post-randomisation.		NI	N	PY	Y	N			PY		PY				N	N	Y	N		PY	N	N
Prabhat et al., 2025	Some concerns	No information provided on concealment of allocation process. OFAS regarded as clinical measure (but included patient reported elements). Plausible that patient knowledge of intervention could influence certain criteria of the score (e.g. pain), however there is no evidence to suggest this.		NI	N	PY	Y	N			PY		Y				N	N	Y	PY	PN	NI	N	N

Publication and reporting bias

(SI3.2)

Only *available for "**time to union**" as it was the only outcome with* ***≥10*** *studies reporting on it for* ***primary meta-analysis.***

SI3.2.1 – ***Funnel plot for time to union:***
Scatterplot of study effect estimates against standard error to assess small-study effects, with dashed lines indicating the expected distribution in the absence of bias.



*SI3.2.2 – **Egger's test calculation for time to union**:*
Linear regression of effect estimates on their standard error to evaluate small-study effects for the time-to-union analysis.

Linear regression test of funnel plot asymmetry

Test result: t = -0.54, df = 8, p-value = 0.6038

Bias estimate: -0.2994 (SE = 0.5543)

Details:

- multiplicative residual heterogeneity variance (tau^2 = 0.6721)
- predictor: standard error
- weight: inverse variance
- reference: Egger et al. (1997), BMJ

- *Insignificant publication bias (p=0.6038)*
- *Moderate heterogeneity was found (tau² = 0.67), so there was some variability among studies. However, it did not appear to be related to small-study effects and was probably due to large sample variances - not a true heterogeneity (I^2 = 0.00%).*

Primary meta-analyses & Sensitivity analyses

Supplementary Information 4

(SI4)

Contents:

Primary meta-analyses

- SI4.1 – Continuous outcomes……(76)
  - SI4.1.1 – Time to union
  - SI4.1.2 – Time to full weightbearing
  - SI4.1.3 – OMAS at 3 months
  - SI4.1.4 – OMAS at 6 months
  - SI4.1.5 – FFI at 12 months
  - SI4.1.6 – AOFAS at 12 months

- SI4.2 – Dichotomous outcomes……..…(79)
  - SI4.2.1 Overall complications
  - SI4.2.2 Superficial infections
  - SI4.2.3 Deep infections

Sensitivity analyses

- SI4.3 – Continuous outcomes……(81)
  - SI4.3.1 – Time to union

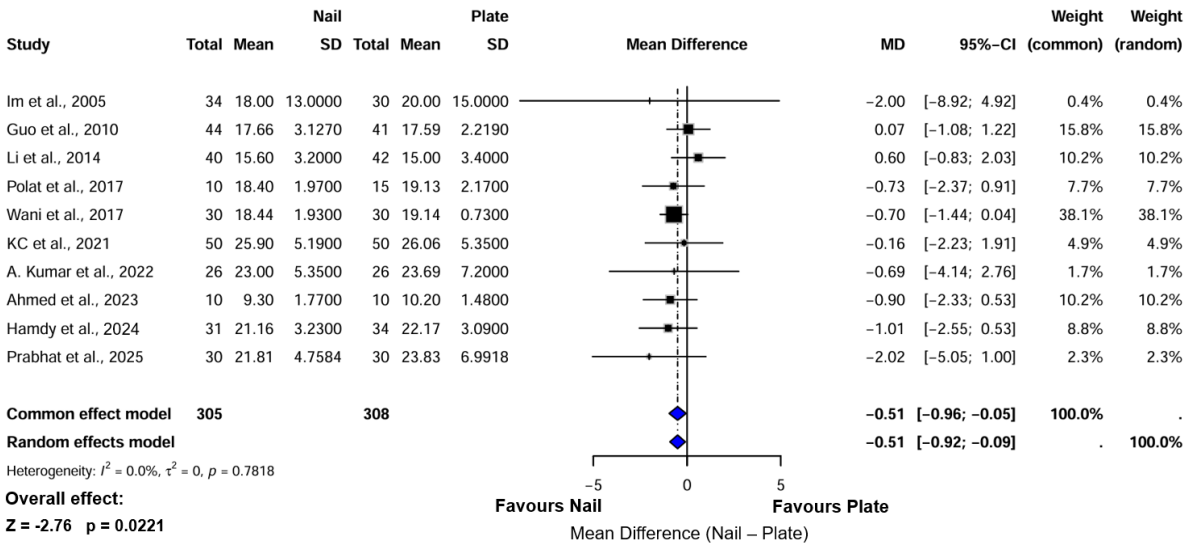
- SI4.4 – Dichotomous outcomes……..…(83)
  - SI4.4.1 Overall complications
  - SI4.4.2 Superficial infections
  - SI4.4.3 Deep infections

Primary meta-analyses

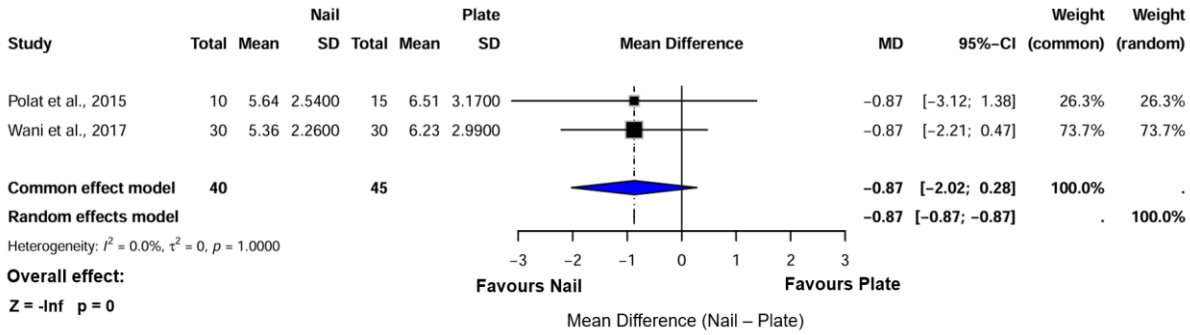
Continuous outcomes

(SI4.1)

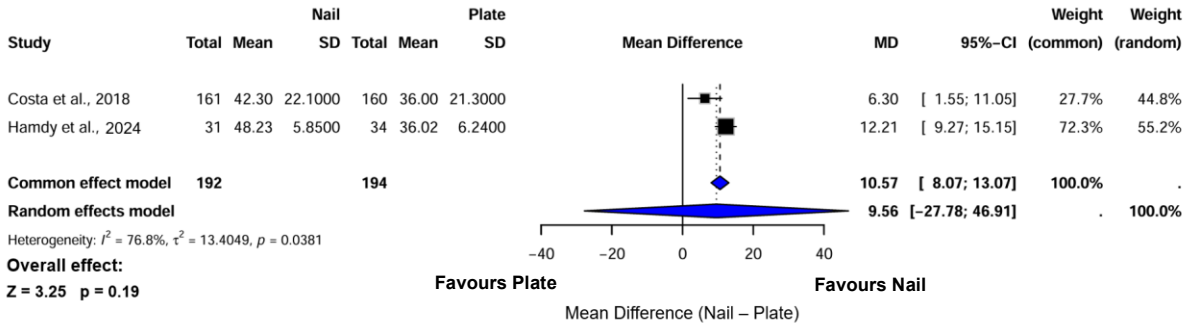
SI4.1.1 – Time to union



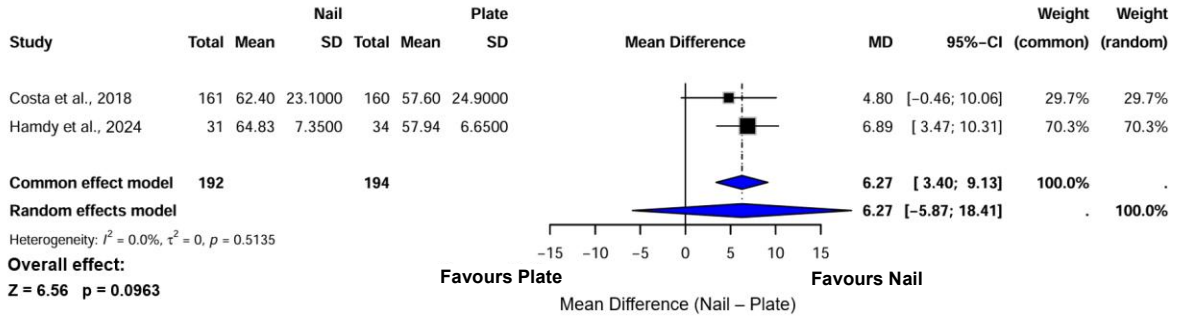
SI4.1.2 – Time to full weightbearing



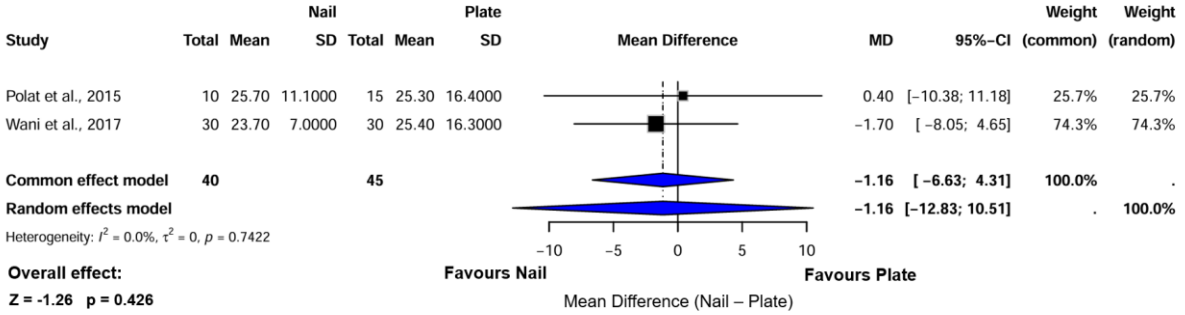
SI4.1.3 – OMAS at 3 months



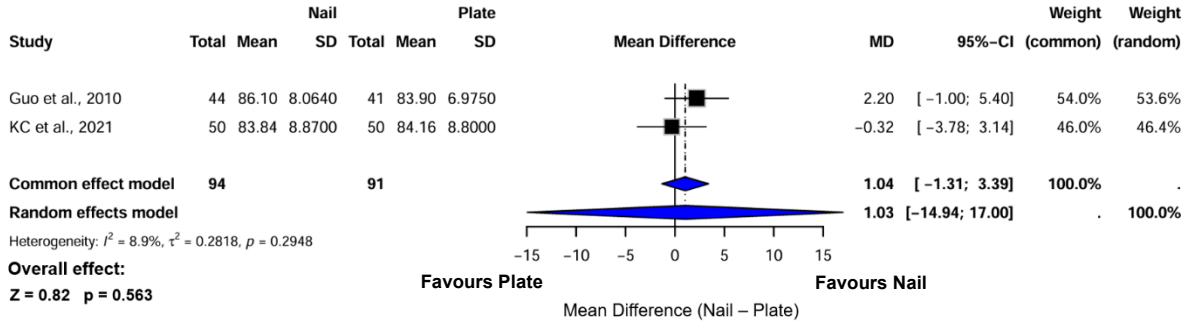
SI4.1.4 – OMAS at 6 months



SI4.1.5 – FFI at 12 months



SI4.1.6 – AOFAS at 12 months

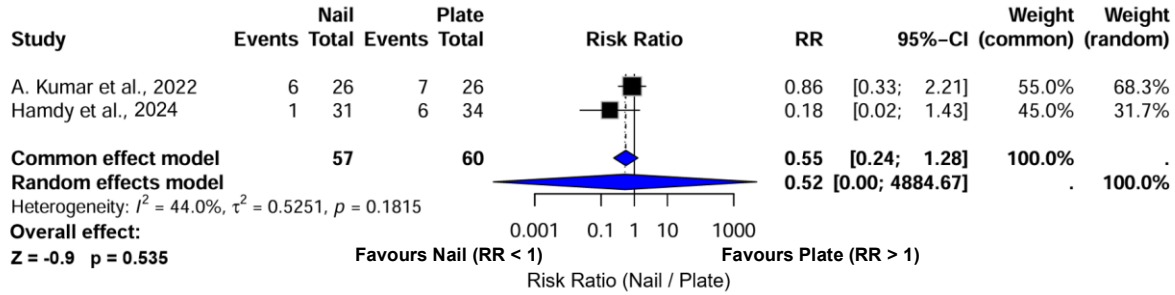


Primary meta-analyses

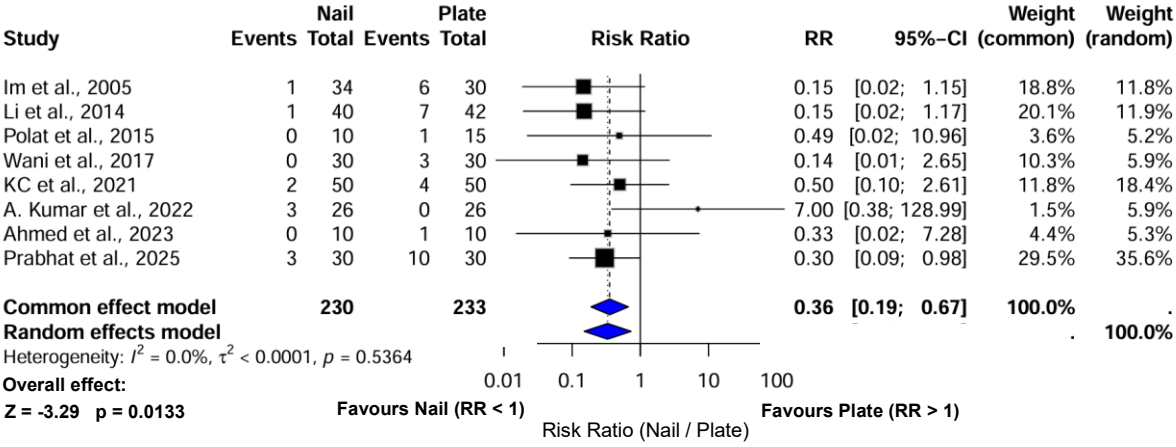
Dichotomous outcomes

(SI4.2)

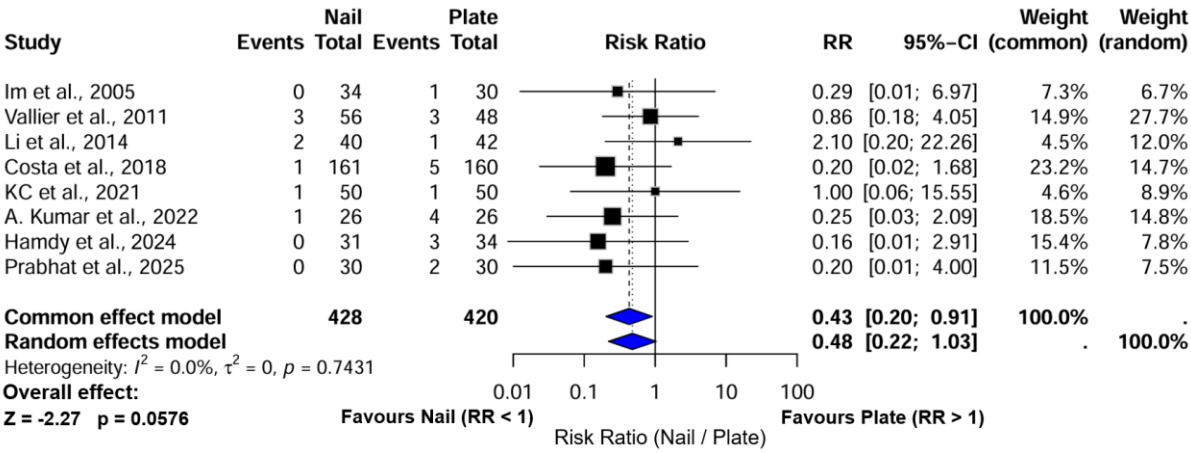
SI4.2.1 – Overall complications



SI4.2.2 – Superficial infections



SI4.2.3 – Deep infections

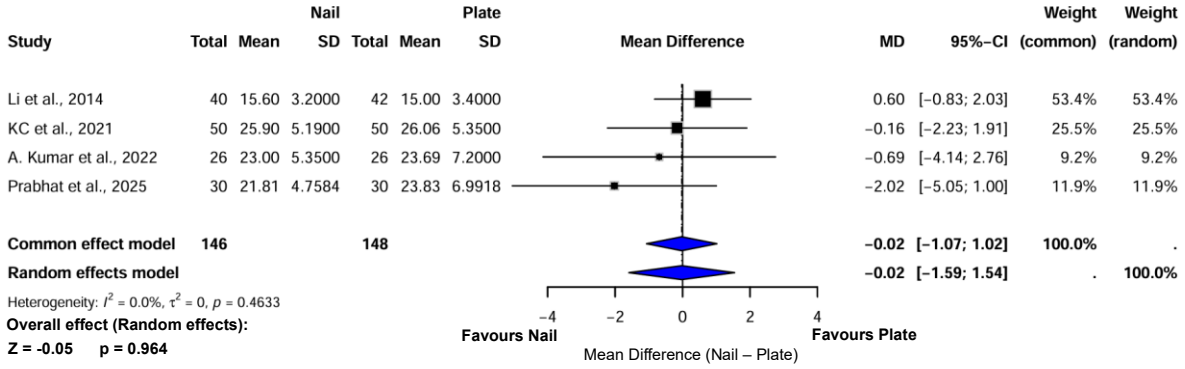


Sensitivity analyses

Continuous outcomes

(SI4.3)

SI4.3.1 – Time to union

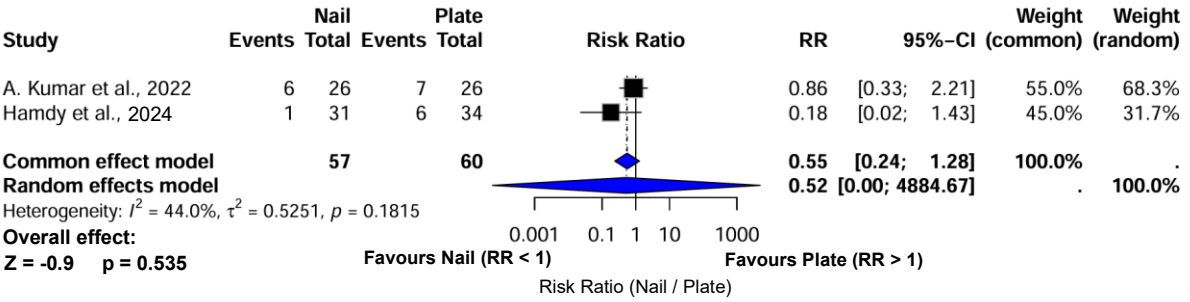


Sensitivity analyses

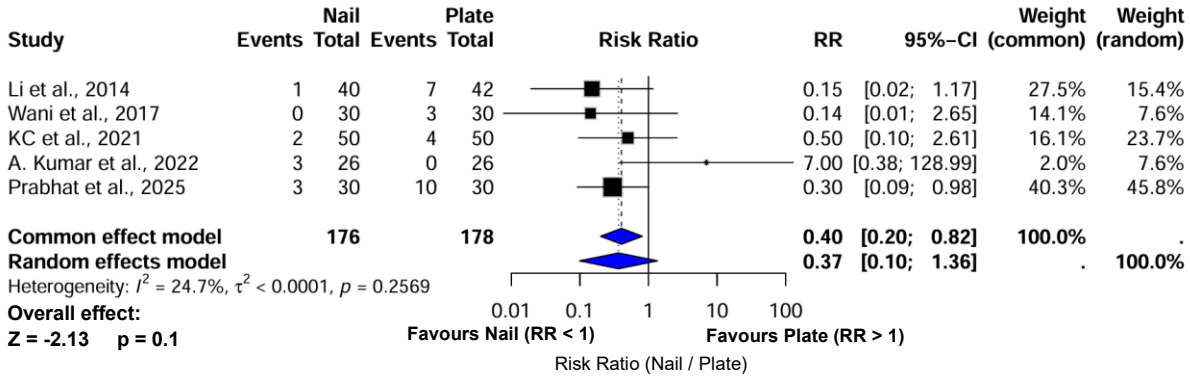
Dichotomous outcomes

(SI4.4)

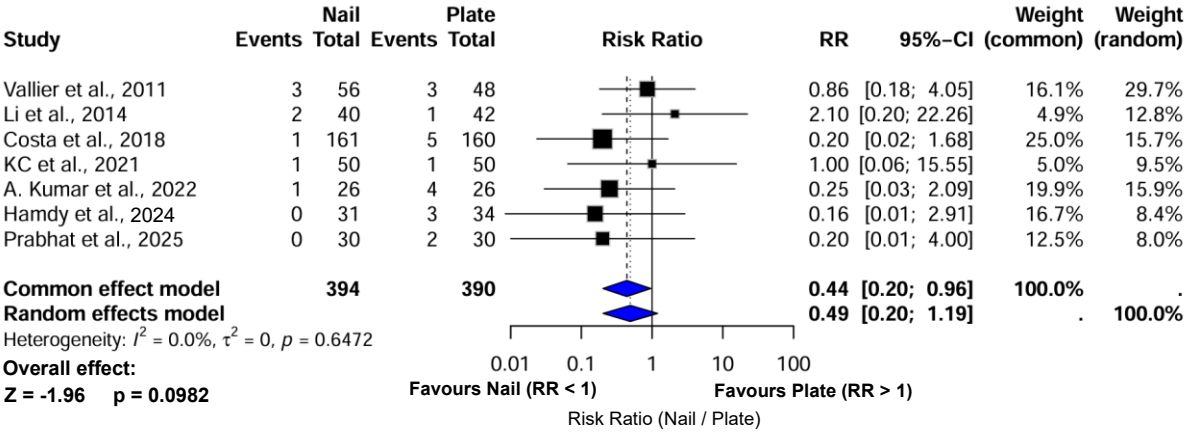
SI4.4.1 – Overall complications



SI4.4.2 – Superficial infections



SI4.4.3 – Deep infections



PRISMA 2020 Checklist

Section and Topic	Item #	Checklist item	Location where item is reported
TITLE			
Title	1	Identify the report as a systematic review.	Title page
ABSTRACT			
Abstract	2	See the PRISMA 2020 for Abstracts checklist.	Anonymized manuscript – pg. 1
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of existing knowledge.	Anonymized manuscript – pg. 2
Objectives	4	Provide an explicit statement of the objective(s) or question(s) the review addresses.	Anonymized manuscript – pg. 2
METHODS			
Eligibility criteria	5	Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.	Anonymized manuscript – pg. 3 & SI 1.1
Information sources	6	Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted.	Anonymized manuscript – pg. 2
Search strategy	7	Present the full search strategies for all databases, registers and websites, including any filters and limits used.	SI 1.2
Selection process	8	Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process.	Anonymized manuscript – pg. 3
Data collection process	9	Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process.	Anonymized manuscript – pg. 3
Data items	10a	List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcome domain in each study were sought (e.g. for all measures, time points, analyses), and if not, the methods used to decide which results to collect.	Anonymized manuscript – pg. 3
	10b	List and define all other variables for which data were sought (e.g. participant and intervention characteristics, funding sources). Describe any assumptions made about any missing or unclear information.	Anonymized manuscript – pg. 3-4
Study risk of bias assessment	11	Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process.	Anonymized manuscript – pg. 4
Effect measures	12	Specify for each outcome the effect measure(s) (e.g. risk ratio, mean difference) used in the synthesis or presentation of results.	Anonymized manuscript – pg. 3-4

Section and Topic	Item #	Checklist item	Location where item is reported
Synthesis methods	13a	Describe the processes used to decide which studies were eligible for each synthesis (e.g. tabulating the study intervention characteristics and comparing against the planned groups for each synthesis (item #5)).	Anonymized manuscript – pg. 3-4
	13b	Describe any methods required to prepare the data for presentation or synthesis, such as handling of missing summary statistics, or data conversions.	Anonymized manuscript – pg. 3-4
	13c	Describe any methods used to tabulate or visually display results of individual studies and syntheses.	Anonymized manuscript – pg. 3-5
	13d	Describe any methods used to synthesize results and provide a rationale for the choice(s). If meta-analysis was performed, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity, and software package(s) used.	Anonymized manuscript – pg. 4-5
	13e	Describe any methods used to explore possible causes of heterogeneity among study results (e.g. subgroup analysis, meta-regression).	Anonymized manuscript – pg. 5
	13f	Describe any sensitivity analyses conducted to assess robustness of the synthesized results.	Anonymized manuscript – pg. 5
Reporting bias assessment	14	Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases).	Anonymized manuscript – pg. 4
Certainty assessment	15	Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome.	Anonymized manuscript – pg. 4
RESULTS			
Study selection	16a	Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram.	Anonymized manuscript – pg.5/Fig.1
	16b	Cite studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded.	Anonymized manuscript – pg. 5
Study characteristics	17	Cite each included study and present its characteristics.	Anonymized manuscript – pg. 5, SI 2.1.1 & SI 2.2.1
Risk of bias in studies	18	Present assessments of risk of bias for each included study.	Anonymized manuscript – pg. 6 & SI 3.1
Results of	19	For all outcomes, present, for each study: (a) summary statistics for each group (where appropriate) and (b) an effect estimate and its	Anonymized

Section and Topic	Item #	Checklist item	Location where item is reported
individual studies		precision (e.g. confidence/credible interval), ideally using structured tables or plots.	manuscript – pg. 7 & SI 2
Results of syntheses	20a	For each synthesis, briefly summarise the characteristics and risk of bias among contributing studies.	Anonymized manuscript – pg. 5-6 & SI 2.1.1/2.2.1/3.1
	20b	Present results of all statistical syntheses conducted. If meta-analysis was done, present for each the summary estimate and its precision (e.g. confidence/credible interval) and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect.	Anonymized manuscript – pg. 7-9, SI 4 & Figures 2, 3, 4
	20c	Present results of all investigations of possible causes of heterogeneity among study results.	SI 4 & SI 3.1
	20d	Present results of all sensitivity analyses conducted to assess the robustness of the synthesized results.	Anonymized manuscript – pg. 7-8 & SI 4.3,4
Reporting biases	21	Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed.	Anonymized manuscript – pg. 7 & SI 3.2
Certainty of evidence	22	Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed.	Table 1
DISCUSSION			
Discussion	23a	Provide a general interpretation of the results in the context of other evidence.	Anonymized manuscript pg. 9-11
	23b	Discuss any limitations of the evidence included in the review.	Anonymized manuscript pg. 11-12
	23c	Discuss any limitations of the review processes used.	Anonymized manuscript pg. 12
	23d	Discuss implications of the results for practice, policy, and future research.	Anonymized manuscript pg. 12 & 13
OTHER INFORMATION			
Registration and protocol	24a	Provide registration information for the review, including register name and registration number, or state that the review was not registered.	Anonymized manuscript – pg. 13
	24b	Indicate where the review protocol can be accessed, or state that a protocol was not prepared.	Anonymized

Section and Topic	Item #	Checklist item	Location where item is reported
			manuscript – pg. 13
	24c	Describe and explain any amendments to information provided at registration or in the protocol.	Anonymized manuscript – pg. 13
Support	25	Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review.	Anonymized manuscript – pg. 13
Competing interests	26	Declare any competing interests of review authors.	Anonymized manuscript – pg. 13
Availability of data, code and other materials	27	Report which of the following are publicly available and where they can be found: template data collection forms; data extracted from included studies; data used for all analyses; analytic code; any other materials used in the review.	Anonymized manuscript – pg. 13 & SI 1-5

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