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Complications and subsequent surgery after intra-medullary nailing for tibial shaft fractures: Review of 8110 patients

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ABSTRACT

Background: Intramedullary nailing of tibial shaft fractures has been common practice for decades. Nevertheless, complications occur frequently, and subsequent surgery is often required. To improve our understanding on how we may improve trauma care for patients with tibial shaft fractures, this study systematically reviewed all currently available evidence to assess the incidence of complications and rate of re-operations following intramedullary nailing of traumatic tibial fractures.

Methods: Trip Database, Medline, Scopus and Cochrane Library were searched on September 7th, 2018. Searches were limited to English studies published after January 1st, 1998. Studies were included if authors included more than 50 patients treated with intramedullary nailing for traumatic tibial fractures. Inclusion of studies and critical appraisal of the evidence was performed by two independent authors. Incidence of complications and rate of re-operations were reported with descriptive statistics.

Results: Fifty-one studies involving 8110 patients treated with intramedullary nailing for traumatic tibial fractures were included. Mean age of patients was 37.5 years. The most frequent complication was anterior knee pain (23%), followed by non-union (11%). Eighteen percent of patients required at least one subsequent surgery. The most frequent indication of subsequent surgery was screw removal due to pain or discomfort (9%). Dynamization of the nail to promote union was reported in 8% of the cases. Nail revision and bone-grafting to promote union were applied in 4% and 2% respectively.

Discussion & Conclusion: Patients treated with intramedullary nailing for tibial fractures need to be consented for high probability of adverse events as anterior knee pain, subsequent surgical procedures and bone healing problems are relatively common. However, based on current data it remains difficult to identify specifiers and determinants of an individual patient with specific fracture characteristics at risk for complications. Future studies should aim to establish patient specific risks models for complications and re-operations, such that clinicians can anticipate them and adjust and individualize treatment strategies.

Level of Evidence
Therapeutic Level III

Introduction

Tibial shaft fractures are common long bone injuries with 16.9–21.5 cases per 100.000 per year [1,2]. Intramedullary nailing is widely considered the primary operative treatment for traumatic tibial shaft fractures [3,4]. The first use of the tibial nail on which the current technique is based was reported by Küntscher in 1940 [5]. The past century has seen a substantial evolution in technique: reaming and interlocking screws were introduced in the 1950′s, with the 1990′s bringing about the development of the titanium nail [6].

Despite the fact that the procedure has been in existence for several decades now, the nature of the traumatic tibial fractures and complications relating to intramedullary fixation allow opportunities for further improvement: patients frequently have to

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Table 1
Inclusion and Exclusion Criteria.

Inclusion criteria	Exclusion criteria
Studies assessing the outcome of intramedullary nailing in ≥50 patients with traumatic tibia fractures.	Follow-up of less than three months.
Studies must detail whether reamed/unreamed nailing was applied.	No description of duration of follow-up.
Cohorts must be consistent on at least one of the following surgical characteristics: reamed/unreamed; surgical approach; type of nail.	Studies making use of atypical locking methods.
Studies must describe the incidence of at least one of the following complications: Compartment syndrome, non-union, malunion, deep infection, rotational malalignment, anterior knee pain, nail breakage, screw breakage.	Studies assessing the outcome of intramedullary nailing in: floating knee injuries, pathological fractures, non-union, revision nailing.

Table 2
Literature search databases.

Database(s)	Search terms
Pubmed	*((("Fracture Fixation, Intramedullary"[Mesh]) OR "Bone Nails"[Mesh]) OR ((nail* [tiab]) OR (intramed* [tiab]))) AND (("Tibial Fractures"[Mesh]) OR (tibia* [tiab])) AND (complicat*)*
Trip database	*(tibia*) AND ((nail*) OR (intramed*)) AND complic**
Scopus, Cochrane database	*(TITLE-ABS-KEY ((tibia*) AND ((nail*) OR (intramed*))) AND ALL (complicat*))*

undergo subsequent surgical procedures; anterior knee pain has been reported in over half of the patients [7,8]; two-in-three patients have a screw penetrating in the proximal or distal tibiofibular joint [9]; and non-union has been reported in one-in-ten patients [10,11].

This study was set out to systematically review all currently available evidence to assess the incidence of complications and rate of re-operations following intramedullary nailing of traumatic tibial fractures. The knowledge derived from this systematic review can be used to educate both patients and clinicians. It may contribute to our understanding on how we can improve current techniques, so future treatment may result in fewer complications and lower rates of re-operation.

Methods

Protocol

This systematic review adhered to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines [12]. An unregistered review protocol was created prior to commencement of the study.

Selection criteria

All studies assessing the outcome of tibial IMN were included provided they reported on at least fifty patients treated with intramedullary nailing for traumatic tibia fractures. Studies had to consist of a follow up of at least three months. The study cohorts had to be consistent on either surgical approach, the use of reaming or the type of intramedullary nail used. Studies not reporting on complications or use of reaming were excluded. Both inclusion and exclusion criteria are displayed in Table 1.

Literature search strategy

In collaboration with a clinical librarian, 'Trip Database', 'Medline', 'Scopus' and 'Cochrane Library' were searched on 7 September 2018 to gather all available evidence. The searches were limited to English studies published after January 1st, 1998. This limitation in time was applied so only contemporary evidence was included. Search details are displayed in Table 2.

Screening for eligibility

Two authors (LH and JV) independently screened title, abstracts and full texts of the studies for eligibility. Disagreement was resolved by re-evaluation. If no agreement could be reached a senior author (JD) was consulted for a final decision.

Assessment of quality

Two authors (LH and JV) independently assessed the quality of the studies using a modified version of the 'Coleman Methodology Score' (Supplemental Digital Content 1). The total score on the "Coleman Methodology Score" ranges from 0–100, corresponding to either poor (0–49 points), fair (50–69 points), good (70–84 points) or excellent (85–100 points) quality. Disagreement was resolved by discussion. If no agreement could be reached a senior author (JD) was consulted for a final decision.

Data extraction

The following data was extracted by one author (LH) and validated by a second author (JV): author names, title, publication year, journal, country, study design, length of follow up, sample size, type of approach, reamed/unreamed nailing, male/female ratio, age and ratio of open/closed fractures.

The rates of the following complications and subsequent surgeries were also extracted: postoperative compartment syndrome; non-union; malunion; deep infection; rotational malalignment; knee pain; nail breakage; screw breakage; fasciotomy; dynamization; revision malunion; revision non-union; revision deep infection; bone-grafting; removal or exchange of nail for other reasons; removal of screws only due to pain or irritation. The definitions of the complications are displayed in Table 3.

Statistical analysis

Descriptive statistics were calculated. Means were used for continuous variables and frequencies and percentages for categorical variables.

Results

Study selection

A total of 2891 unique records were identified of which 2678 were excluded based on title and abstract. The assessment of 213 full-texts resulted in the inclusion of 51 studies [13–63]. The flow chart of the selection process is displayed in Fig. 1.

Table 3
Definition complications.

Variable	Definition
Postoperative compartment syndrome	- *By index authors as postoperative compartment syndrome:* - *Clinical diagnosis* - *Absolute compartment pressures of* >30 mmHg [95] *or differential compartment pressures of* <30 mmHg [96]
Non-union	- *No union and/or no signs of progressive healing at 6 months* - *By index authors using bone-grafting, dynamization or nail exchange or removal to promote union.* - *By index authors as non-union*
Malalignment/Malunion	- *>1* cm *shortening* - *>5° angulation in coronal or sagittal plane* - *Indicated by index authors as malalignment/malunion*
Rotational malalignment	- *Rotational difference of >10° diagnosed on CT-scan or clinically*
Deep infection	- *By index authors as deep infection*
Knee pain	- *By index authors as knee pain*
Nail breakage	- *By index authors as nail breakage*
Screw breakage	- *By index authors as screw breakage*

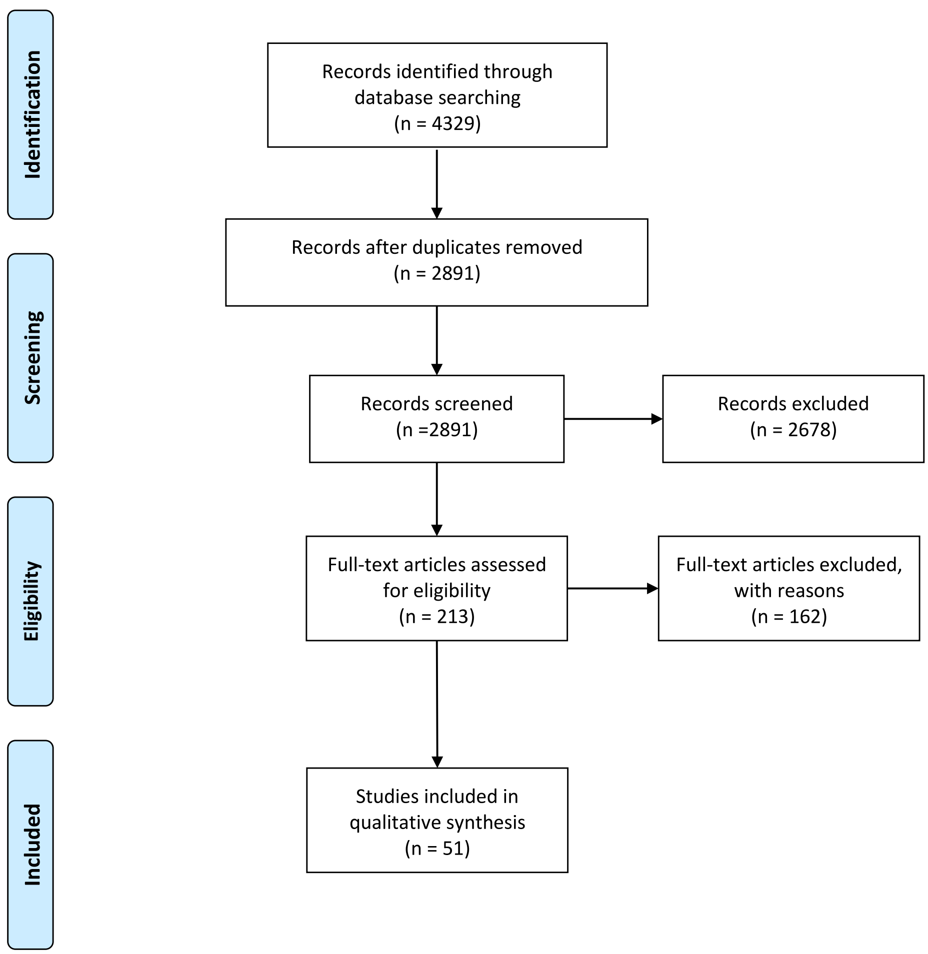

Fig. 1. Flow chart of the selection process.

Critical appraisal

The mean Coleman score was 60.2 (range 32 –91), indicating a fair overall quality of included studies. Thirteen studies [13,21,22,31,36,42,43,45,47,50,52,53,63] ranked poor, 23 studies [14–17,19,23,24,26,28,30,34,[37–40,44,46,49,51,54,60–62] ranked fair, 14 studies [18,25,27,29,32,33,35,41,48,55–59] were ranked good, and one study [20] ranked excellent.

Study characteristics

Eight randomized controlled trials [20,24,25,29,33,41,57,58], 9 prospective studies [18,23,27,39,48,49,55,56,60] and 34 retrospective studies [13–17,19,21,22,26,28,30–32,34–38,40,42–47,50–54,59,61–63] were included. Across studies there was a mean sample size of 161 patients (range 50–1226) and mean follow-up of 22 months (3–96). Nineteen studies were conducted in

Table 4
Patient demographics, fracture characteristics & surgery characteristics - total sample size $N = 8110$.

			N^{α}	Studies$^{\gamma}$
Age, years mean		37.5	5722	41 [13–15,17–23,25–34,36–41,43–45,48,49,53–55,57–63]
		n (%)	**N^{α}**	**Studies$^{\gamma}$**
Gender				
	Male	5030 (74%)	6830	44 [13–15,17–41,43–45,47–49,52–55,57–59,61–63]
	Female	1800 (26%)		
Fractures		8174	8110	51 [13–63]
Fracture characteristics		**n (%)**	**N^{β}**	**Studies$^{\gamma}$**
Open		2456 (33%)	7482	46 [13–35,37–40,43–45,47–49,51–63]
Closed		5026 (67%)		
location			3555	29[13,16–22,24–28,30,32,33,35,37–39,41,44,51,52,54,59,61–63]
	Proximal 1/3rd	330 (9%)		
	Middle 1/3rd	1305 (37%)		
	Distal 1/3rd	1920 (54%)		
Type			5333	24[15,19,20,22,23,25,27–30,32,33,36,40,43–45,47,49,51,54,55,57,62]
	42A	2934 (55%)		
	42B	1630 (31%)		
	42C	769 (14%)		
Surgery characteristics		**n (%)**	**N^{β}**	**Studies$^{\gamma}$**
Reaming			8174	51 [13–63]
	Reamed	4939 (60%)		
	Unreamed	3235 (40%)		
Approach			1815	19 [14,15,18,21,22,25,27,28,32,33,35–37,41,44,55,56,61,62]
	Transpatellar	690 (38%)		
	Parapatellar	960 (53%)		
	Suprapatellar/Semi extended	165 (9%)		

$^{\alpha}$ Total number of patients for which a variable was reported.
$^{\beta}$ *Total number of fractures for which a variable was reported.*
$^{\gamma}$ *Number of studies in which a variable was reported.*

Table 5
Incidence complications.

	% (n)	N^{α}	Studies$^{\beta}$
Early complications			
Compartment syndrome	3.8% (145)	3858	20 [15,20,22,29–31,34,39,40,42,50–56,58,62,63]
Deep infection	3.2% (196)	6067	36 [13–25,27–30,33,38,39,41,44,46–49,51–57,61–63]
Late complications			
Malunion	7.5% (251)	3351	30 [13,15,18,19,21,23,24,26–30,33,35,37,38,41,43,44,48,51,54–60,62,63]
Rotational malalignment	1.3% (22)	1699	12 [15,25,29,30,33,35,43,44,51,54,55,58]
Non-union	10.7% (747)	6969	45 [13–19,21–27,29–32,36–44,46–49,51–57,59–63]
Anterior knee pain	22.9% (427)	1862	17 [14,15,22,27–29,32,35–37,41,45,52,55,60–62]
Implant failure			
Screw breakage	7.1% (288)	4041	23 [13–15,18,20,22,25,29,30,38,44,48,49,51,52,54–56,58–60,62,63]
Nail breakage	0.7% (23)	3428	20 [13–15,20,22,25,29,30,38,44,48,51,52,55–60,63]

$^{\alpha}$ *Total number of fractures for which a variable was reported.*
$^{\beta}$ *Number of studies in which a variable was reported.*

Europe [2,14,15,27–29,31,32,40,42–44,47,49–51,54,55,59], 16 studies in Asia [13,18,21,22,24–26,33,36,39,41,45,52,57,60,62], 13 studies in North-America [16,17,19,23,35,37,46,48,53,56,58,61,64] and one study in Africa [30]. Two studies were conducted across more than one continent [20,38].

Patient-, fracture- and surgery-characteristics (Table 4)

Combined the studies consisted of 8110 patients who had a total of 8174 traumatic tibial fractures treated with intramedullary nailing. The mean age of patients was 37.5 years with 74% being male. Follow-up ranged from 1–172 months, with a reported mean follow-up of 28 months. Sixty-seven percent of the fractures were closed. The fracture was located in the proximal-, middle- and distal-tibia in 9%, 37% and 54% of the cases respectively. Distribution according to AO/OTA-type [64,65] was 55% 42A, 31% 42B and 14% 42C.

Sixty percent of the fractures were treated with reamed intramedullary nailing whilst 40% were unreamed. Studies from North America (83%) more often used reamed intramedullary nailing when compared to studies from Europe (67%) and Asia (57%) (Supplemental Digital Content 2). Reaming was furthermore more frequently used in studies originating from 2009–2018 (73%) when compared to 1998–2008 (50%). There was no clear pattern with regards to fracture characteristics and the use of reamed or unreamed intramedullary nailing.

The parapatellar approach was used in 53% of the cases, the transpatellar approach in 38% and the suprapatellar/semi-extended approach in 9%.

Complications (Table 5)

The incidence of compartment syndrome was 3.8%. Deep infection occurred in 3.2% of the cases. The incidence of malunion and rotational malalignment were 7.5% and 1.3% respectively. The incidence of non-union was 10.7%. Anterior knee pain was reported in 22.9% of the cases. Screw breakage and nail breakage were reported in 7.1% and 0.7% of the cases respectively.

Table 6
Subsequent surgery rates.

	% (*n*)	N^{α}	Studies$^{\beta}$
Any subsequent surgery	17.8% (1081)	6088	43 [13–15,17–32,34,36–41,43,44,46,48–57,59,61–63]
Fasciotomy	3.8% (145)	3858	20 [15,20,22,29–31,34,39,40,42,50–56,58,62,63]
Dynamization	8.4% (296)	3515	23 [13–15,17,19–21,24,25,28,30,32,39,44,46,51–54,56,57,59,61,62]
Bone grafting	2.4% (93)	3830	22 [13–15,17,20–22,27–29,37,39,46,48,49,51–53,56,59,62,63]
Revision to promote union	4.2% (204)	4814	32 [13–15,17–22,24–27,29,32,37,38,41,43,44,46,48,49,51–57,61,63]
Revision deep infection	1.2% (38)	3222	32 [13–15,17,18,21,22,24–29,33,37–39,41,43,44,46,48,51,53–57,59,61–63]
Revision due to malunion	1.3% (23)	1724	14 [13,15,26,[29,[35,[37,[38,[40,[51,[55,[57–59,[62]
Nail exchange or removal other reasons	8.2% (119)	1446	12 [17–19,22,23,28,36,51,53,57,61,63]
Screw removal pain or discomfort	8.9% (53)	598	7 [17,19,23,28,53,61]

$^{\alpha}$ *Total number of fractures for which a variable was reported.*
$^{\beta}$ *Number of studies in which a variable was reported.*

Subsequent surgery (Table 6)

Out of the 6088 patients in whom subsequent surgery was reported, a total of 1081 patients required subsequent surgery (17.8%, range 0–63%). One of the most frequent indications of subsequent surgery was dynamization of the nail, which was reported in 8.4% of the cases. Nail revision and bone-grafting to promote union were applied in 4.2% and 2.4% respectively.

Revision due to malunion and revision due to infection were seen in 1.3% and 1.2% respectively. In 3.8% of the cases, patients had to undergo fasciotomies due to compartment syndrome.

The most frequent indication of subsequent surgery was screw removal due to pain or discomfort (8.9%). Nail removal or nail exchange due to reasons other than failed union or infection occurred in 119 cases (8.2%): 108 nail removals due to pain and discomfort; 8 nail removals or exchanges due to implant failure or nail migration; and three removals or exchanges due to other reasons.

Discussion

Although intramedullary nailing of tibial shaft fractures has been common practice for decades there is room for improvement: complications occur frequently, and subsequent surgery is often required [40]. This study systematically reviewed a total of 8110 patients in order to summarize contemporary evidence on the incidence of complications and re-operations following intramedullary nailing of traumatic tibial fractures. Patients treated with intramedullary nailing for tibial fractures need to be consented for high probability of adverse events as anterior knee pain, subsequent surgical procedures and bone healing problems, whilst surgeons may use this compiled information to manage expectations and improve shared decision making. However, based on current data it remains difficult to identify specifiers and determinants of individual patients at risk of complications. In order to individualize treatment, trauma care should focus on generating large (multicentre) datasets, or merge existing ones, to establish patient specific risk models to estimate probabilities of adverse events.

Limitations of this study include (1) fair overall methodological quality of included studies; and (2) heterogeneity of study designs, which did not allow for any quantitative analysis. Furthermore, one could argue that the inclusion of non-reamed intramedullary nailing may cause for ‘pollution’ of the results. However, when we compared the rates of complications and subsequent surgeries of the included studies that used non-reamed nailing to those that used reamed nailing, we could not demonstrate any beneficial effect of reamed intramedullary nailing. This is in line with the findings of the most recent Cochrane review on this matter [66]. Strengths of this study include (1) large number of studies and patients, making it the most comprehensive review of the literature on this subject to date; (2) strict inclusion and exclusion of studies and critical appraisal of the evidence by two independent authors; and (3) similarity of patient demographics and fracture characteristics to other epidemiological studies [67,68]. Given these strengths we believe that the incidences of complications and rates of subsequent surgical procedures we have reported are representative of true incidences in tibial fractures managed operatively with intramedullary nailing.

Anterior knee pain was the most prevalent complication occurring in 23% of cases. This incidence is only half of what has previously been described by Katsoulis and colleagues, reporting an incidence of 47% in their review of the literature published in 2006 [69]. Differences may be accounted for by ongoing improvements in operative technique and postoperative rehabilitation regimes over time: in this review the incidence of anterior knee pain declined from 27% (1998–2008) [14,15,45,52,55] to 21% (2009–2018) [22,27–29,32,35–37,41,60–62]. Recent adaptations of technique that are thought to result in a lower incidence of anterior knee pain include the suprapatellar approach [71], and oblique incisions for the infrapatellar approach [70]. In this review, two studies were included that compared a suprapatellar approach to an infrapatellar approach [35,41]. Sun and colleagues demonstrated significantly lower pain scores for the suprapatellar approach [41], whilst Ryan and colleagues found no significant difference in the incidence of anterior knee pain [35]. Other studies in literature are also contradictory on this matter: some suggest a lower incidence of anterior knee pain for the suprapatellar approach [71,72], whilst others did not find any difference compared to the infrapatellar approach [73–75]. Further research is required to assess whether the incidence of anterior knee pain can be reduced using a suprapatellar approach.

Non-union was found to be the second most prevalent complication with an incidence of 11%. This is in line with the 12% that Dailey and colleagues have recently demonstrated in a large retrospective series including 1003 patients treated with intramedullary nailing [47]. Various risk factors for non-union after intramedullary nailing of tibial fractures have been reported, including fracture gap, fracture type (open/closed) and fracture morphology (OA/OTA-classification) [11,47,76,77]. O'Halloran and colleagues have recently developed a non-union prediction score based on odds ratios of a multiple variable logistic regression model [76]. This score allows for the calculation of patient-specific non-union risks. Despite this, the clinical value of the score remains unclear as (external) validation of performance, by means of discrimination and calibration, is lacking [78,79]. Future studies should not only aim to develop, but also validate prediction scores. Machine learning algorithms may prove a valuable adjunct as has been demonstrated in previous orthopaedic studies [80,81]. Of the above-mentioned risk factors, fracture gapping is the only one that surgeons can potentially modify in order to avoid non-union. Avoiding non-union furthermore relies on surgeons remaining critical about issues like implant choice and surgical technique.

The rate of subsequent surgeries to promote union was relatively high as well, consisting of bone grafting in 2%, revision in

Table 7
Clinical assessment versus CT assessment of rotational malalignment.

Clinical assessment of rotational malalignment		
Study	% (*n*)	*N**
Djahangiri et al. [15]	2.1% (2)	96
Hapa et al. [25]	0% (0)	57
Ramos et al. [29]	0% (0)	86
Salem [30]	4.8% (7)	145
Prasad et al. [33]	16.7% (10)	60
Ryan et al. [35]	0% (0)	185
De Santos de la Fuente et al. [43]	0.6% (1)	167
Greitbauer et al. [44]	0% (0)	66
Gaebler et al. [51]	0% (0)	467
Drosos et al. [54]	0.6% (1)	161
Babis et al. [55]	0% (0)	115
Finkemeier et al. [58]	1.1% (1)	94
Total	1.3% (22)	1699
CT assessment of rotational malalignment		
Study	% (n)	N*
Say et al. [86]	19.2% (5)	26
Puloski et al. [87].	22.7% (5)	22
Jafarinejad et al. [88]	30.0% (18)	60
Theriault et al. [85]	41.4% (29)	70
Prasad et al. [89]	27.3% (6)	22
Total	31.5% (63)	200

* *Total number of fractures for which a variable was reported.*

4% and dynamization in 8% of the cases. Eighteen percent of patients underwent at least one subsequent procedure. We believe this to be an underestimation, as various studies have not reported on each subsequent surgical procedure included in this rate. For instance, the SPRINT trial had a subsequent surgery rate of 15%, however, did not report on removal of screws or nail due to pain or irritation [20]. Stavrou and colleagues reported 21% of patients undergoing subsequent surgery in a retrospective analysis of 151 cases. They found AO/OTA type 42B-C fractures and alcohol abuse to be risk factors [40]. Prediction scores further identifying individual patients at risk of additional surgical procedures could aid clinicians in managing these patients' expectations, which may improve postoperative satisfaction [82–84].

Twelve studies [15,25,29,30,35,43,44,50,51,54,55,58] reported the incidence of rotational malalignment, with a weighted mean incidence of 1.3%. This is likely an underrepresentation of the true incidence of rotational malalignment, as all twelve studies based diagnosis on unreliable [85] clinical assessment. Studies using Computed-Tomography (CT) scanning to screen for rotational malalignment have reported much higher incidences ranging from 19–41% [85–89] (Table 7). These studies were excluded from this review on account of not meeting inclusion criteria because they were either based on small series [86,87,89], did not disclose reaming status [85] or made no report on duration of follow up [88]. The landmark paper on rotational malalignment after tibial intramedullary nailing, by Theriault and colleagues, reported an incidence as high as 41% [85]. We believe this to be a more accurate estimate of the true incidence. Future studies should further investigate the incidence of malrotation as well as the discrepancy between clinical and CT-based assessment of rotational malalignment. Various studies have demonstrated that malalignment in the coronal and sagittal plane may be avoided with certain surgical techniques such as Poller screws [90,91,92] or a suprapatellar approach [35,71,90]. It is less evident how rotational malalignment can be avoided. One study reported that by using an external tibial aiming device, commonly found in knee arthroplasty sets, they significantly reduced the incidence of rotational malalignment after tibial intramedullary nailing [93]. The personal experience from the authors is that the contralateral side should not be hidden under the drapes but also prepped and draped to serve as a reference during the operation. Whether this will indeed reduce the incidence of rotational malalignment will be subject of future study. As rotational malalignment is a common reason for litigation [94], research investigating the effect of rotational malalignment on functional outcome is also required.

In conclusion, this study reports a high incidence of adverse events and subsequent surgeries after nailing of tibial fractures. However, based on current data it remains difficult to identify specifiers and determinants of an individual patient, with specific fracture characteristics, at risk for complications. Future studies should aim to establish patient specific risk models for complications and re-operations, such that clinicians can anticipate these and individualize treatment strategies. To allow such studies in trauma care, multicentre collaborations are needed to generate large datasets or merge existing ones.

Declaration of Competing Interest

The authors, their immediate relatives, and any research foundations with which they are affiliated have not received any financial payments or other benefits from any commercial entity related to the subject of this article.

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Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.injury.2020.04.021.

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