

# Surgical stabilization for open tibial fractures in children External fixation or elastic stable intramedullary nail - which method is optimal?

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## ABSTRACT

**Background:** Management of open tibial fractures is well documented in adults, with existing protocols outlining detailed treatment strategies. No clear guidelines exist for children. Surgical stabilization of tibial fractures in the pediatric population requires implants that do not disrupt the open epiphyses (growth plate). Both elastic stable intramedullary nails and external fixation can be used. The objective of this study was to identify the optimal method of surgical stabilization in the treatment of open tibial fractures in children.

**Materials and Methods:** MEDLINE and Embase were searched from their inception to March 2014 using the following advanced search terms (Key words): “open tibia fracture,” “fracture fixation,” “external fixation,” “intramedullary,” and “bone nail.” Only studies in English and pertaining to children with open fractures treated with elastic stable intramedullary nails or external fixation between 1994 and 2014 were included. Twelve clinical studies were critically appraised.

**Results:** Due to a paucity in the literature coupled with a nonsystematic presentation of results, it proved to be very difficult in extracting relevant results from the studies. This was further added by a variation in outcome measures. Consequently, the results we obtained were difficult to draw conclusions from.

**Conclusion:** There is no conclusive evidence or best practice guidelines for their management. Thus, as is highlighted in this study, more research is needed to determine the optimum treatment strategy for this common pediatric injury. The existing literature is of poor quality; consisting mainly of retrospective reviews of patients’ medical records, charts, and radiographs. Carefully designed, high-quality prospective cohort studies utilizing a nationalized multi-hospital approach are needed to improve understanding before protocols and guidelines can be developed and implemented.

**Key words:** Children, elastic, external fixator, fracture, open, tibia

**MeSH terms:** Open fractures, tibial fractures, pediatrics, fracture fixation, external fixator, intramedullary nailing

## INTRODUCTION

A 1997 national pediatric database in the United States was reviewed and found that 84,202 children were hospitalized with orthopedic trauma and tibia and/or fibula fracture accounted for 18,111 (21.5%). This indicates that in the pediatric orthopedic trauma setting,

fractures of the tibia and/or fibula are the second most common, after femoral fractures.<sup>1,2</sup> The average age for such fractures was 13 years, and the majority were males (71.0%). 9% of the pediatric tibial fractures are open and the most frequent concomitant injuries are fractures of the foot and ankle, followed by humeral, femoral, and radio-ulnar fractures.<sup>3,4</sup> There is a huge variation of injury patterns with open tibial fractures and this has made it difficult to standardize treatment due to altering severity, tissue involvement, and risk of complication, namely infection.<sup>5</sup>

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Even though fractures of the tibia and fibula are relatively common in children,<sup>6</sup> operative stabilization is not always required as they are usually treated conservatively with a plaster cast or a functional brace.<sup>5</sup> Indications for surgical stabilization include open fractures, children of age 10 years and above, those with an associated compartment syndrome, polytrauma, unstable fracture patterns, and those who do not maintain acceptable position after closed reduction.<sup>7</sup> Open fractures are associated with high energy injury, subsequently involving unstable fracture patterns, and significant soft tissue damage; hence, the increased indication for surgical intervention.<sup>8</sup> Open fractures are classified according to the Gustilo-Anderson classification.<sup>9-11</sup>

In adults, one of the first line treatment options is reamed locked intramedullary nail fixation. However, in children, this is contraindicated to preserve the proximal tibial epiphysis. External fixators have traditionally been used when surgical stabilization is required in pediatric tibial fractures. However, due to their high complication rates, elastic stable intramedullary nails which do not cross the epiphysis have emerged as an alternative.<sup>2,12</sup> However, there is no conclusive evidence or best practice guidelines for their management. We reviewed the available literature to determine if a preferable method of surgical stabilization could be found.

## MATERIALS AND METHODS

A database search was carried out using “Ovid MEDLINE(R) 1946 to Present with Daily Update” on March 16, 2014, and “Embase 1974 to March 14, 2014.” The following advanced search terms (Key words) were used: “open tibia fracture,” “fracture fixation,” “external fixation,” “intramedullary,” and “bone nail.” The “Map to subject heading” tool was used on the sophisticated Ovid search for both databases [Tables 1 and 2]. This facilitated the literature search through Medical Subject Headings, known as MeSH terms. The MeSH terms differed slightly between the two databases, so the most similar and appropriate was used. An additional limit was put in place, “all child (0–18 years)” and “child” for MEDLINE and Embase, respectively.

Tables 1 and 2 show the searches using Ovid MEDLINE(R) 1946 to Present with Daily Update and searches using Embase 1974–2014 March 14, respectively.

The search produced 380 and 66 journal articles from MEDLINE and Embase, respectively. The total of 446 results were exported to Refworks. These journal articles were first screened for duplicates. Next, a title screen was performed. The remaining journal articles were then

**Table 1: Searches using Ovid MEDLINE (R) 1946 to present day**

Number	MeSH terms	Results
1	Fractures, open, and tibial fractures	1577
2	Fracture fixation	15,954
3	External fixators	4618
4	Fracture fixation, intramedullary	7022
5	Bone nails	8708
6	2 or 3	19,408
7	2 or 4 or 5	27,612
8	6 or 7	30,547
9	1 and 8	810
10	Limit 9 to “all child (0-18 years)”	380

**Table 2: Searches using Embase 1974 March 14, 2014**

Number	MeSH terms	Results
1	Open fracture and tibia fracture	1118
2	Fracture fixation	20,921
3	External fixator	3557
4	Fracture external fixation	5527
5	Intramedullary nailing	10,534
6	Intramedullary nail	1748
7	Bone nail	3623
8	2 or 3 or 4	28,345
9	2 or 5 or 6 or 7	33,003
10	8 or 9	39,192
11	1 and 10	615
12	Limit 11 to child <unspecified age>	66

screened using the abstract, with the application of inclusion criteria. The following inclusion criteria were used: (1) English language only; (2) studies focused on children only; (3) studies in which either external fixation or elastic stable intramedullary nailing was used; (4) studies published in the past 20 years (1994 – present). The journal articles retrieved were further analyzed and the following exclusion criteria were implemented: (1) studies not focused on tibial fractures only (2) studies performed in a warzone environment [Figure 1].

As a result of this literature search and methodology, 12 journal articles<sup>2,7,8,13,16-23</sup> have been selected to undergo systematic review and critical appraisal.

To determine which method of surgical stabilization is superior, outcome measures can be used to compare the efficacy of the two treatments. Outcome measures used in the literature<sup>8,13-16</sup> include: time for fracture healing, time to mobility, time elapsed before the removal of device, incidence of compartment syndrome, incidence of infection, incidence of mal-union, delayed union and nonunion, rate of amputation, measuring limb function using scores such as the Enneking score, patient health status questionnaires such as sickness impact profile and Medical Outcomes Study short form provide a useful assessment of patients.

## RESULTS

Eleven studies (excluding the systematic review) carried out between 1996 and 2012 reported on 294 open fractures of the tibia occurring in the pediatric population, treated between 1979 and 2010, were analyzed. Of those open fractures, 157/294 (53.4%) were treated by surgical stabilization, including 74/157 (47%) managed by elastic stable intramedullary nailing and 83/157 (53%) by external fixation. We used Gustilo grading in these open fractures. There were 26 Grade I, 38 Grade II, and 56 Grade III fractures; of the Grade III fractures, 22 Grade IIIA, 21 Grade IIIB, and 4 Grade IIIC were recorded; and the remaining 9 were recorded simply as Grade III. Of those open fractures treated by external fixation, there were 8 Grade I, 17 Grade II, and 31 Grade III; of the Grade III fractures, 10 Grade IIIA, 15 Grade IIIB, and 4 Grade IIIC were recorded, the remaining 2 were recorded simply as Grade III. Of those open fractures treated by elastic stable intramedullary nailing, there were 18 Grade I, 21 Grade II, and 21 Grade III; and of the Grade III fractures, 12 Grade IIIA and 6 Grade IIIB were recorded. Average age was recorded specifically to open fractures in only 3 of the studies, it was found to be 11 years and

3 months. Average time to union in open fractures only was also recorded in just 3 of the studies, it was found to be 23.4 weeks. Healing complications recorded in those open fractures treated by elastic stable intramedullary nailing were 10 delayed unions, 4 leg length discrepancies, 1 mal-union, and 1 nonunion. Other complications in this group included 1 deep infection, 2 superficial infections, 1 case of cellulitis, 2 cases of compartment syndrome, and 7 secondary procedures. In those patients with open fractures treated by external fixation, healing complications included 15 delayed unions, 2 leg length discrepancies, 2 mal-unions, and 1 nonunion. Other complications in this group included 5 pin tract infections, 1 superficial infection, 1 deep infection, and 3 cases of osteomyelitis [Table 3].

### Critical appraisal of papers

As a product of the literature search and methodology, 9 case series, 1 case-control study, 1 cohort study, and 1 systematic review were finally used for review. All the studies were analyzed and subsequently assigned scores using the SIGN level of evidence table [Table 4].<sup>24</sup>

The high SIGN evidence level scores allocated to the studies under review are representative of the poor quality of scientific evidence available in the literature. Critical appraisal of the 12 studies have been performed systematically, according to the study design, following an initial assessment of two fundamental weaknesses in all the journal articles.

### Wide spread weaknesses found in every paper

Unfortunately, due to the nature of open fractures and the study designs associated with the journal articles documenting them, there are two inherent weaknesses in all the appraised papers. There is a consistently low sample size and an absence of randomization.

### Sample size

In 11 of the studies undergoing appraisal (excluding the systematic review), 157 open fractures were treated with either of the methods of surgical stabilization under investigation. A mean of 12.8 open fractures (range 4–31) were treated with either elastic stable intramedullary nailing or external fixation in the studies. Due to the small sample sizes used in the studies, they are underpowered and so, drawing any clinically significant findings has posed problems. Given the relatively low incidence of open fractures in children, it is hard to overcome this.

### Randomization

Ideally, randomization would be implemented in a study, determining which method of surgical stabilization to be utilized in the treatment of open tibial fractures in

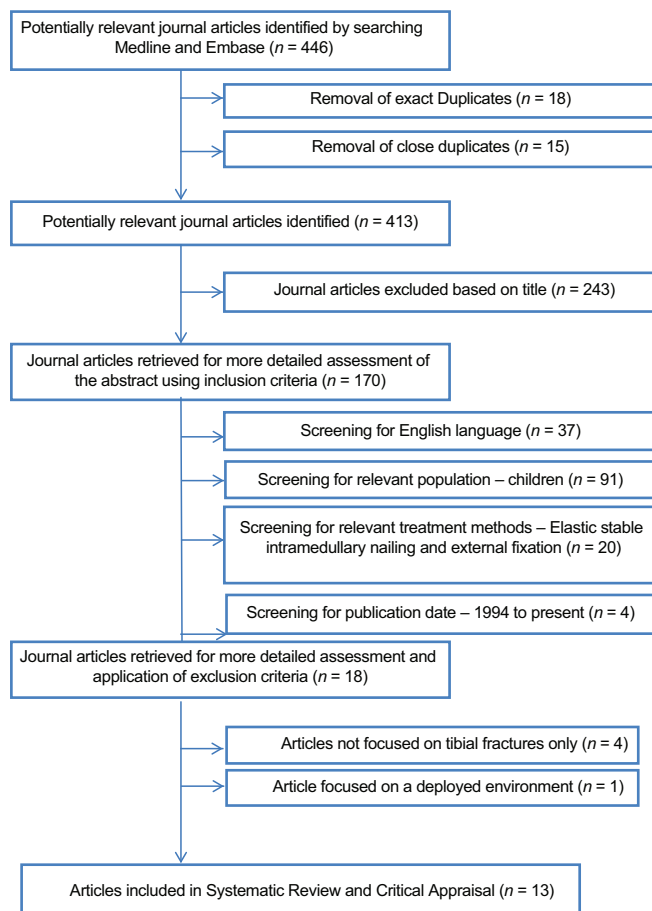


Figure 1: Methodology flow chart

Table 3: Results (pooled data from 12 papers appraised in discussion)

References	Type of study	Number of open fractures in the study	Number of open fractures treated with external fixation	Number of open fractures treated with ESIN	Total number of open fractures treated with surgical stabilization	Number of each Gustilo grade	Mean age	Average healing time	Mean time of treatment	Healing complications	Other complications
Pandya and Edmonds, (2012) <sup>2</sup>	Case-control study	14	-	14	14	-	-	7 months	-	5 delayed unions/ mal-unions 3 leg length discrepancies	1 infection 2 compartment syndrome 7 required secondary procedure
Kubiak <i>et al.</i> , (2005) <sup>7</sup>	Cohort study	13	8	5	13	-	-	-	-	3 nonunions 1 mal-union (in external fixator patients)	-
Vallamshetha <i>et al.</i> , (2006) <sup>17</sup>	Retrospective case series	13	-	13	13	I-8 II-2 III-3	-	-	-	-	1 deep infection 1 cellulitis
Srivastava <i>et al.</i> , (2008) <sup>18</sup>	Retrospective case series	16	-	16	16	I-2 II-5 IIIA-5 IIIB-4	10 years, 2 months	20.2 weeks	-	5 delayed union	1 compartment syndrome 1 infection
Gordon <i>et al.</i> , (2007) <sup>19</sup>	Retrospective case series	26	-	26	26	I-8 II-12 IIIA-4 IIIB-2 II-2 IIIA-3	-	-	-	1 nonunion 2 mal-unions 1 overgrowth of 1.5 cm	-
AL-Sayyad, (2006) <sup>20</sup>	Retrospective case series	5	5	-	5	II-2 IIIA-3	-	22 weeks	-	-	-
Monsell <i>et al.</i> , (2012) <sup>8</sup>	Case series	10	10	-	10	-	11.5 years	-	114 days i.e., 16.29 weeks	-	-
Zenios, (2013) <sup>21</sup>	Retrospective case series	4	4	-	4	IIIB-4	12.5 years	-	24.25 weeks	1 delayed union	1 pin site infection
Grimard <i>et al.</i> , (1996) <sup>13</sup>	Retrospective case series	90	31	-	31	I-7 II-15 IIIA-6 IIIB-2 IIIC-1	-	6.6 months	-	5 delayed union 7 nonunion	3 pin site infection 1 superficial infection

Contd...

Table 3: Contd...

References	Type of study	Number of open fractures in the study	Number of open fractures treated with external fixation	Number of open fractures treated with ESIN	Total number of open fractures treated with surgical stabilization	Number of each Gustilo grade	Mean age	Average healing time	Mean time of treatment	Healing complications	Other complications
Cullen <i>et al.</i> , (1996) <sup>22</sup>	Retrospective case series	83	9	-	9	I-1 II-2 III-6	-	21 weeks	-	5 delayed union	1 pin tract infection Bone resorption and subsequent external fixation removal in 1 patient
Buckley <i>et al.</i> , (1996) <sup>23</sup>	Case series	20	16	-	16	IIIA-4 IIIB-9 IIIC-3	-	-	-	2 leg length discrepancy 4 delayed union 1 mal-union	3 osteomyelitis 1 deep soft tissue infection

ESIN=Elastic stable intramedullary nailing

children. This would reduce bias and enable us to make a fair comparison between the two treatment options. In the studies under review, the decision regarding the choice of stabilization method has either been subjected to a set of criteria, left at the treating surgeon's discretion, or not mentioned. There is a trend in the literature, which is displayed well in the cohort study conducted by Kubiak *et al.*<sup>7</sup> that higher grade fractures, particularly those of Gustilo Grade IIIB and IIIC, are usually treated with external fixation. It is well understood that higher grade fractures have worse outcomes, and subsequently, this is reflected by more complications and a longer time to union in those treated by external fixation. Consequently, the results are biased against external fixation. However, with a random assignment of treatment method, this selection bias could be avoided. Unfortunately, randomization is not appropriate in the treatment of open fractures for a number of reasons. Most importantly, it would probably be considered unethical. This is because open tibial fractures are severe injuries which can be limb and life threatening. Optimal treatment should always be given, and randomization may be perceived as experimentation. In addition, open tibial fractures are relatively uncommon injuries and so, enrolling sufficient patients to enable randomization in a study would pose a major problem.<sup>25,26</sup>

**Case series**

Case series are studies conducted with relatively small populations, all of whom receive the same exposure. Case series are regarded as low quality of scientific evidence studies for a number of reasons. The biggest drawback is the absence of a control group. The lack of a control group means there is no group of patients without the specified condition or a group not receiving the same treatment to draw comparisons with. Case series are also prone to bias, and in particular, selection bias.

In general, the study protocols of the case series' appraised were poorly defined, and often very vague. Most of the studies were retrospective reviews of patients' medical records, notes, and radiographs from the databases at their respective institutions, within a time period.<sup>13,17-19,21-23</sup>

The use of consecutive patients is very important in a case series, as it prevents the selective use of cases, depending on their results. Unfortunately, only one of the case series under review, by Monsell *et al.*,<sup>8</sup> has stated clearly the use of consecutive patients. Most of the other case series have stated that they included "all" of the patients meeting their criteria, so although consecutive use of patients is implied, it cannot be confirmed.<sup>13,17,19-21</sup> The remaining studies have not used consecutive patients.<sup>18,22,23</sup> This suggests selective use of patients, and consequently, selection bias must be considered.



**Table 4: SIGN evidence level score for appraised journals**

References	Journal	Study design	SIGN evidence level
Vallamshetla, (2006)	The Journal of Bone and Joint Surgery	Retrospective case series	3
Srivastava, (2008)	Journal of Pediatric Orthopaedics	Retrospective case series	3
Gordon, (2007)	Journal of Pediatric Orthopaedics	Retrospective case series	3
AL-Sayyad, (2006)	Journal of Pediatric Orthopaedics	Retrospective case series	3
Monsell, (2012)	The Journal of Bone and Joint Surgery	Case series	3
Zenios, (2013)	The Journal of Orthopaedic Trauma	Retrospective case series	3
Grimard, (1996)	Clinical Orthopaedics and Related Research	Retrospective case series	3
Song, (1996)	Journal of Pediatric Orthopaedics	Case Series	3
Cullen, (1996)	The Journal of Bone and Joint Surgery	Retrospective case series	3
Buckley, (1996)	Journal of Pediatric Orthopaedics	Retrospective case series	3
Kubiak, (2005)	The Journal of Bone and Joint Surgery	Cohort study	2 <sup>-</sup>
Pandya, (2012)	Journal of Pediatric Orthopaedics	Case-control study	2 <sup>+</sup>
Gougoulias, (2009)	British Medical Bulletin	Systematic review	2 <sup>++</sup>

Another aspect of the study design prone to bias is the criteria, or more so the lack of criteria, used to determine what method of surgical stabilization was implemented. Given the nature of a case series, and in particular, those which review retrospectively, randomization is not possible. However, the use of strict criteria to determine what method to use would prevent selection bias to an extent. Five of the case series appraised make no mention of how the decision was made.<sup>13,18-21</sup> However, this may have actually been due to a lack of information in the medical records, given their retrospective nature. In a study by Buckley *et al.*,<sup>23</sup> the decision was left to the treating surgeon's discretion. In studies by Vallamshetla *et al.*<sup>17</sup> and Cullen *et al.*,<sup>22</sup> there was usage of criteria to make the decision, but it lacked clarity and specificity. Only the prospective case series written by Monsell *et al.*<sup>8</sup> accurately documented strict criteria to determine their method of surgical stabilization.

In summary, the case series reviewed were of low methodological quality. The majority of study protocols were poorly defined, with minimal information given on the inclusion and exclusion criteria used to acquire the populations used, and a retrospective approach to acquire information was used. Furthermore, strict criteria to decide on treatment options were only explicitly stated in one of the case series.

However, it is important to mention that clinically relevant outcomes were recorded in many of these case series, and although they are neither validated outcomes nor possess the specificity to the question posed in this dissertation, they can still be used effectively.

### Case-control

In the case-control study by Pandya and Edmonds,<sup>2</sup> a computerized search of an institution's billing database (Department of Pediatric Orthopaedics, Children's Hospital and Research Centre Oakland, University of California

San Francisco, Oakland) was used to acquire the records which were reviewed retrospectively. Using this search, patients were classified into 2 groups. A case group of those with open fractures was compared with a control group of those with closed fractures, and all the patients were treated with elastic stable intramedullary nails. Identical patient selection and exclusion criteria were applied to both groups, indicating that the study was designed in a way aimed at minimizing bias. However, it is not fair to say that the cases and controls have been taken from comparable populations, as there was a significantly greater incidence of polytrauma in the case group containing open fractures (71% vs. 25%) with  $P = 0.04$ .

Consecutive patients have been reviewed in this study, which reflects favorably in terms of selection bias, as it indicates that all patients treated with elastic stable intramedullary nails have been included regardless of the desired outcomes. On the contrary, the initial choice to use elastic stable intramedullary nails for fracture treatment was left to the treating surgeon's discretion, as opposed to strict criteria, which in turn infers a risk of selection bias. Expected outcomes based on age, fracture severity, and associated injuries may have allowed the surgeon to choose patients where the result would be favorable to the study's desired findings to reflect on flexible nailing positively. For example, no open fractures above Grade IIIA were treated, and 10 of the 14 open fractures were Grade II. If the study was compiled of patients with high-grade fractures and associated vascular injuries, then the results may have been less favorable for flexible nailing.

In addition, the study is retrospective and thus, all results obtained are dependent on the availability and accuracy of the medical records and so are subjected to scrutiny.

### Cohort study

The cohort study conducted by Kubiak *et al.*<sup>7</sup> targets both open and closed fracture. Unfortunately, it does not

separate the two groups in its results, thus limiting the study's usefulness as extracting data explicitly relating to open fractures was not possible.

The same inclusion and exclusion criteria were used for both cohorts, the only difference being the two surgical stabilization methods being compared. However, the external fixation group had a considerably higher proportion of open fractures, and although it was not significant, this indicates an unfair comparison between the groups. In addition to this, the Gustilo grading of the open fractures in either group has not been mentioned. Open fractures, and particularly those with a higher grade fractures are known to have less desirable outcomes and these have been treated by external fixation. This may have led to the more favorable results for the elastic stable intramedullary nailing cohort, indicating selection bias. This idea of selection bias is further emphasized as the method of surgical stabilization was chosen by a senior pediatric orthopedic surgeon or a senior orthopedic trauma surgeon, instead of a strict criterion.

### Systematic review

The systematic review by Gougoulias *et al.*<sup>16</sup> aims to identify management strategies applied to treating open tibial fractures in children and summarize the outcomes. Independent quality scoring of the studies was performed by two authors, using the Coleman methodology score.<sup>27,28</sup>

The literature search carried out was comprehensive, using MEDLINE, Embase, Cochrane, CINAHL, and Google Scholar, by the following key words: "open," "tibia," "fracture," "children," "paediatric," "pediatric," "external fixation," and "nailing." Inclusion and exclusion criteria have been stated specifically, amounting to an accurate and reproducible methodology.

This systematic review conducted by Gougoulias *et al.*<sup>16</sup> has succeeded in combining the data from the studies effectively, with the pooled results revealing some useful information. However, the low quality of the studies must be considered as the majority are case series as well, and no definitive conclusions can be drawn regarding the preferable method of surgical stabilization.

### DISCUSSION

The literature describing the treatment of open tibial fractures in children, specifically using elastic stable intramedullary nailing or external fixation, is scarce. There are a finite number of papers addressing open tibial fractures only, and a separate set focusing on either of the two surgical stabilization methods mentioned. However, there

is a paucity in the literature, with regards to papers relating to open tibial fractures only (not closed), in combination with external fixation or elastic stable intramedullary nailing. This is furthered by a trend in the studies focusing on the treatment methods under question, where the number of open and closed fractures in a population is stated, but presentation of the results has not been performed separately for the open and closed groups. Consequently, extracting truly relevant data from the results of the chosen papers has proven to be difficult and largely unsuccessful.

This review focused on 12 journal articles, following a literature search and an appropriate set of inclusion and exclusion criteria. Only two of the articles contain the desired focus, looking at one of the chosen surgical stabilization methods, simultaneously with open fractures only.<sup>2,8</sup> Six of the articles target either one or both of the chosen surgical treatment methods for tibial fractures in the pediatric population, but neglect specificity to open fractures.<sup>7,17-21</sup> Four of the articles target open tibial fractures in the pediatric population, but do not focus on our chosen surgical treatment methods.<sup>13,16,22,23</sup> The paucity of true relevance to the question posed in this review limits the usefulness of the studies under review to varying extents.

As previously mentioned, extracting truly relevant data from the results of the chosen papers has proven to be largely unsuccessful. The biggest difficulty was the nonsystematic presentation of data. Very few papers displayed results explicitly relating to open fractures, with a focus on surgical intervention. The combination of open and closed fractures in a results' section was commonplace in the literature. For example, giving a single figure for time to union representing both open and closed groups and not two separate figures was a theme-repeated throughout. This meant that only a fraction, if any at all, of the results in the majority of the studies was appropriate for inclusion in our pooled set of results. Consequently, the pooled results' table contains a substantial amount of gaps. The omission of so many results across a number of the studies has rendered the results obtained unrepresentative, unreliable, and brings their validity into question.

With regards to the results that were successfully extracted from the studies, a number of shortcomings were encountered. An absence of validated outcome measures within the literature presented difficulties for comparison. Studies, including those conducted by Pandya and Edmonds<sup>2</sup> and Srivastava *et al.*,<sup>18</sup> measured "time to union" as the main outcome measure. Alternatively, the study carried out by Al-Sayyad<sup>20</sup> utilized the healing time of the fractures and another by Monsell *et al.*<sup>8</sup> recorded time elapsed from implementation of the fixation device

to removal as their respective principal outcome measures. This was furthered by an inconsistency in the units of measurement, altering between days, weeks, and months across the literature. With regard to complications, there were major discrepancies in the recording of infection. Most studies divided infection into pin tract, superficial, and deep including those carried out by Vallamshetla *et al.*,<sup>17</sup> Grimard *et al.*,<sup>13</sup> and Cullen *et al.*<sup>22</sup> However, the study by Pandya and Edmonds<sup>2</sup> neglected this desired level of specificity and recorded all variants under the single broad term, infection. There was also an inconsistency between studies regarding the recording of osteomyelitis as infection or as a separate entity. Studies by Buckley *et al.*<sup>23</sup> and Cullen *et al.*<sup>22</sup> recorded osteomyelitis separately, whereas the study performed by Srivastava *et al.*<sup>18</sup> recorded a patient with osteomyelitis as simply having an infection, disregarding the considerable difference in severity between a pin tract infection and a case of osteomyelitis.

Unfortunately, due to a lack of desired focus and the nonsystematic presentation of results in the literature, any efforts at answering the question posed in this review, “What is the preferable method of surgical stabilization for open tibial fractures in children, external fixation or elastic stable intramedullary nailing?” have been largely unsuccessful.

## CONCLUSION

The literature describing open tibial fractures in children and the methods of surgical stabilization is of a low scientific evidence level and of poor methodological quality. It consists mainly of retrospective reviews of patients’ medical records, charts, and radiographs. There are no validated outcome measures, making comparison of results between difficult papers, furthered by a nonsystematic presentation of data. The use of patient assessment questionnaires was recorded in only one of the studies reviewed.

Although indications exist for the surgical stabilization of open fractures in children, there are no defined protocols in place as there are in the adult population. In agreement with the systematic review of the literature carried out by Gougoulias *et al.*,<sup>16</sup> it is obvious that further research is necessary.<sup>19</sup> Unfortunately, in the 5-year interim from 2009 to 2014, since the publication of this systematic review, only 2 papers of relevance with reliable standing have been published on this topic. Thus, our systematic review re-iterates the paucity of evidence mentioned by Gougoulias *et al.*<sup>16</sup> and calls for progress in research in the near future. We have shown that in 5 years, the apparent gap in the medical literature has not been remedied, and conclusive evidence and best practice protocols are still not in place.

Until the literature is improved, we are unable to draw scientifically based conclusions regarding the optimal management strategy of open tibial fractures using surgical stabilization.

## Future recommendations

It is difficult to perform randomized studies in open fracture management, and they would probably be considered unethical. Enrolling sufficient patients to enable randomization between different treatments would pose a problem, while the varying severity and concomitant injuries commonly associated with open fractures would prevent a fair comparison. Consequently, high-quality prospective cohort studies with a carefully designed study protocol utilizing a nationalized multi-hospital approach are needed. Clear criteria determining treatment methods should be used. Documentation of variables including age, soft tissue condition, associated injuries, fracture severity, and information on the surgery should be recorded. Validated outcome measures need to be implemented, to assert a consistency in the results of the literature, enabling comparison between studies. These should include time to union, complications, need for further operation, and the use of a universal patient outcomes questionnaire. Followup should be adequate to assess the long term effects on growth and development.

The suggested research would enhance knowledge, enabling the establishment of protocols for the management of open tibial fractures in children, in which factors such as age, soft tissue condition, concomitant injuries, and fracture severity have to be put into clinical practice. It would be of particular benefit in determining the preferable method of surgical stabilization.

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## Conflicts of interest

There are no conflicts of interest.

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