

Living FRIendly Summaries of the Body of Evidence using Epistemonikos (FRISBEE)

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Is intramedullary nailing superior to plating in patients with extraarticular fracture of the distal tibia?

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Abstract

Distal tibial metaphyseal fractures are generally produced by high-energy trauma such as car accidents and can cause severe disability due to pain and deformity. In the management of these fractures, there are multiple surgical alternatives, but it is uncertain which the best option is. Searching in Epistemonikos database, which is maintained by screening 30 databases, we identified six systematic reviews including three randomized trials. We combined the evidence using meta-analysis and generated a summary of findings table following the GRADE approach. We concluded it is not clear whether one surgical option is better than the other, because the certainty of the evidence is very low. Two ongoing randomized trials might help solving this uncertainty.

Problem

The distal tibial metaphysis is defined as a square construction in which the length of its sides equals the widest portion of the tibial plafond. Extraarticular fractures of the distal tibia (43A according to AO/OTA classification) have more soft tissue damage than diaphyseal fractures due to its relatively exposed position. Additionally, it is technically demanding to achieve an acceptable alignment for its proximity to the ankle joint. Intramedullary nailing is the treatment of choice for tibial diaphyseal fractures. Its advantages include the preservation of soft tissue and the possibility of early mobilization. However, the reduction of the fracture in the distal region may be difficult to maintain due to the size of the intramedullary canal at the metaphysis. Plate fixation could improve alignment but it is associated with a higher risk of surgical complications, such

as infection, inadequate coverage of soft tissue, and vascular damage during surgery. Thus, there is uncertainty regarding the optimal surgical treatment for distal tibial metaphyseal fractures.

Methods

We used Epistemonikos database, which is maintained by screening more than 30 databases, to identify systematic reviews and their included primary studies. With this information, we generated a structured summary using a pre-established format, which includes key messages, a summary of the body of evidence (presented as an evidence matrix in Epistemonikos), meta-analysis of the total of studies, a summary of findings table following the GRADE approach and a table of other considerations for decision-making.

Key messages

- It is unclear whether intramedullary nailing is superior to locking plate in the distal tibial metaphyseal fractures because of the certainty of the evidence is very low.

About the body of evidence for this question

<p>What is the evidence. See evidence matrix in Epistemonikos later</p>	<p>We found six systematic reviews [1],[2],[3],[4],[5],[6], including 22 primary studies [7],[8],[9],[10],[11],[12],[13],[14],[15],[16],[17],[18],[19],[20],[21],[22],[23],[24],[25],[26],[27],[28], of which three correspond to randomized controlled trials [17],[21],[23] This table and the summary in general are based on the latter.</p>
<p>What types of patients were included</p>	<p>All studies included adult patients with extraarticular fracture of the distal tibia AO/OTA 43-A1, A2 or A3 [17],[21],[23] with or without association of fibula fracture. One study also included undisplaced intraarticular fractures AO/OTA 43 -C1 [23]. All studies included patients with closed or Gustilo and Anderson type I fractures [17],[21],[23].</p>
<p>What types of interventions were included</p>	<p>One study used Stryker S2 tibial nails [21], one study used ACE tibial nails [23] and one study used tibial nails secured with at least two unlocked distal screws [17]. One study compared nails against locking plates (LCP) [21], one study compared nails against locking plates with variable angle screws [17] and one study compared against anatomical plates[23].</p>
<p>What types of outcomes were measured</p>	<p>The studies assessed the functional outcome reported by the patient with the American Orthopaedic Foot and Ankle Surgery (AOFAS) score or Functional Olerud and Molander Ankle Score (OMAS), need of reoperation, nonunion, malunion, time until consolidation, pain, wound complications including superficial infection, deep infection and osteomyelitis, time of surgery and radiation time.</p>

Summary of findings

The information about the effects of intramedullary nailing compared to plating is based on three randomized trials including 173 patients. All of the studies reported functionality scores, need for revision or secondary intervention, nonunion or malunion, superficial or deep infection, osteomyelitis and time until consolidation. Only one study evaluated pain after one year.

- It is unclear whether osteosynthesis with intramedullary nail is superior to the use of a locking plate in distal tibial metaphyseal fractures because the certainty of the evidence is very low.

Plate versus intramedullary nail for distal tibial metaphyseal fracture				
Patients		Adults with distal tibial metaphyseal fracture		
Intervention 1		Intramedullary nail		
Intervention 2		Locking plate		
Outcomes	Absolute effect*		Relative effect (95% CI)	Certainty of the evidence (GRADE)
	WITH nail	WITH plate		
	Difference: patients per 1000			
Functionality** a. OMAS at 12 months b. OMAS percentage of the normal side at 24 months c. AOFAS at 12 months	On average, functionality was better in patients with plate than in those with nail, although the margin of error does not exclude the possibility of no difference between the two options		SMD 0.29 (-0.03 to 0.6)	⊕○○○ Very low ¹
	Difference: SMD 0.29 *** (Margin of error: (-0.03 to 0.6))			
Review or secondary intervention	45 per 1000	120 per 1000	RR 0.37 (0.12 to 1.12)	⊕○○○ Very low ²
	Difference: 76 patients less per 1000 with nail (Margin of error: 106 less to 14 more)			
No union or symptomatic malunion	35 per 1000	48 per 1000	RR 0.72 (0.18 to 2.80)	⊕○○○ Very low ³
	Difference: 13 patients less per 1000 with nail (Margin of error: 40 less to 87 more)			
Superficial or deep infection	79 per 1000	169 per 1000	RR 0.47 (0.20 to 1.10)	⊕○○○ Very low ⁴
	Difference: 89 patients less per 1000 with nail (Margin of error: 135 less to 17 more)			
Pain at 12 months (0 a 40 points)	Average in the group with intramedullary nail was 32.5 points	Average in the group with plate was 31.5 points	MD 1.00 (-0.63 to 2.63)	⊕○○○ Very low ⁵
	Difference: 1 point more in average with nail (Margin of error: -0.63 to 2.63)			

RR: Risk ratio.
MD: Mean difference.
SMD: Standardized mean difference.
Margin of error = 95% confidence interval (CI).
GRADE: evidence grades of the GRADE Working Group (see later in this article).

* The risk **WITH locking plate** is based on the risk in this group of the trials. The risk **WITH nail** (and its margin of error) is calculated from relative effect (and its margin of error).

** The functionality was measured by OMAS in two studies, but in a different way, and AOFAS in one study.
a. OMAS (0-100) to 12 months: MD 15.80, 95% CI 0.80 to 30.80; 23 participants.
b. OMAS percentage of the normal side to 24 months: MD 0.30; 95% CI -1.27 to 1.87; 64 participants.
c. AOFAS score (0-100) to 12 months: nail favoring MD 2.20, 95% CI -0.97 to 5.37; 85 participants.

*** Standardized mean difference is calculated when the outcome is measured using different scales, and its clinical interpretation is difficult. A general rule is: values under 0.2 are of minor or no clinical importance, between 0.2 and 0.5 are of moderate clinical importance, and over 0.5 are of high clinical importance.

¹ The certainty of the evidence was downgraded in two levels for risk of bias and one level for inconsistency.
² The certainty of the evidence was downgraded in one level for risk of bias, one level for inconsistency and one level for imprecision.
³ The certainty of the evidence was downgraded in one level for risk of bias and in two levels for imprecision.
⁴ The certainty of the evidence was downgraded in two levels for risk of bias and in one level for inconsistency.
⁵ The certainty of the evidence was downgraded in two levels for risk of bias and in one level for imprecision.

About the certainty of the evidence (GRADE)*

⊕⊕⊕⊕

High: This research provides a very good indication of the likely effect. The likelihood that the effect will be substantially different† is low.

⊕⊕⊕○

Moderate: This research provides a good indication of the likely effect. The likelihood that the effect will be substantially different† is moderate

⊕⊕○○

Low: This research provides some indication of the likely effect. However, the likelihood that it will be substantially different† is high.

⊕○○○

Very low: This research does not provide a reliable indication of the likely effect. The likelihood that the effect will be substantially different† is very high.

*This concept is also called 'quality of the evidence' or 'confidence in effect estimates'.

† Substantially different = a large enough difference that it might affect a decision.

Other considerations for decision-making

To whom this evidence does and does not apply

- This evidence applies to adult patients with distal tibial metaphyseal fractures AO/OTA 43 - A1, A2, A3 or C1, closed or Gustilo type I.

About the outcomes included in this summary

- The outcomes presented in this summary are those considered critical for decision making by the authors of this summary.

Balance between benefits and risks, and certainty of the evidence

- In general, the certainty of the available evidence is very low so it is not possible to make a risk/benefit balance.

Resource considerations

- There are no reports of costs in the studies included in this summary. Furthermore, the evidence presented has a very low level of certainty, so it is not possible to make an estimation of the cost/benefit.

Differences between this summary and other sources

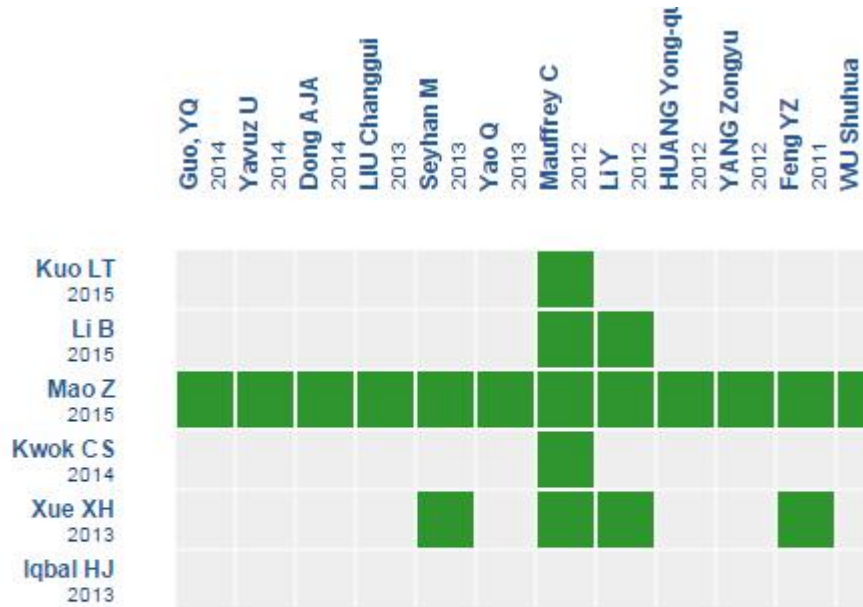
- The key messages of our summary are consistent with the findings of individual identified systematic reviews.
- We did not find clinical guidelines in this area making a recommendation of one intervention over another.

Could this evidence change in the future?

- The probability of change of the main findings of this summary in the future is very high due to the very low certainty of the evidence so far.
- There are at least two ongoing randomized controlled trials that could provide relevant information on this question [29],[30].

How we conducted this summary

Using automated and collaborative means, we compiled all the relevant evidence for the question of interest and we present it as a matrix of evidence.



Starting from any systematic review, Epistemonikos builds a matrix based on existing connections in the database.

The author of the matrix can select relevant information for a specific health question (typically in PICO format) in order to display the information set for the question.

The rows represent systematic reviews that share at least one primary study, and columns display the studies.

The boxes in green correspond to studies included in the respective reviews.

Follow the link to access the **interactive version**: [Plate fixation versus intramedullary nailing for extra-articular distal tibia fractures](#)

Notes

The upper portion of the matrix of evidence will display a warning of "new evidence" if new systematic reviews are published after the publication of this summary. Even though the project considers the periodical update of these summaries, users are invited to comment in *Medwave* or to contact the authors through email if they find new evidence and the summary should be updated earlier. After creating an account in Epistemonikos, users will be able to save the matrixes and to receive automated notifications any time new evidence potentially relevant for the question appears.

The details about the methods used to produce these summaries are described here <http://dx.doi.org/10.5867/medwave.2014.06.5997>.

Epistemonikos foundation is a non-for-profit organization aiming to bring information closer to health decision-

makers with technology. Its main development is Epistemonikos database (www.epistemonikos.org). These summaries follow a rigorous process of internal peer review.

Conflicts of interest

The authors do not have relevant interests to declare.

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