



Treatment of acute tibial shaft fractures with an expandable nailing system: A systematic review of the literature

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ABSTRACT

Locked Intramedullary Nailing is an established method of treatment for tibial shaft fractures. Locking of tibial nails is however not without its drawbacks. Locking is time consuming, and is associated with a noteworthy complication rate. The Fixion IM nailing system is an expandable nail designed to eliminate some of these drawbacks. We have performed a systematic review of the literature to determine the safety and efficacy of this system. Publications examining the use of the Fixion system were identified from the MEDLINE and the Cochrane databases.

Forty-one citations were generated by the MEDLINE search. Of these, two quasi-randomised trials and eight case series satisfied our selection criteria and were reviewed. Overall the average reoperation rate for the Fixion nail was 10.2%. Shortening occurred in 3% of cases and fracture propagation was reported in 2% of cases. The Fixion cohort united at an average of 12.2 weeks and the average operative time was 54 minutes. The Fixion system eliminated complications and reoperations associated with the use of locking screws. Further studies in the form of randomised controlled trials are needed to evaluate the Fixion system against conventional locked nails.

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Introduction

Fracture-fixation devices for tibial shaft fractures must maintain length, rotation and angular alignment and allow for early mobilisation of joints above and below the fracture. Intramedullary (IM) nails can satisfy these requirements whilst preserving the soft tissue envelope around the fracture.¹

Küntscher developed the clover leaf IM nail in the 1940s which represented a significant advancement in the treatment of tibial fractures. The IM nail provided resistance to deforming forces in the coronal and sagittal planes, and also provided a degree of torsional control through an interference fit of the nail with the diaphysis.² Axial control of the nail was however limited. Modification of the original Küntscher nail with locking screws was introduced in the 1970s which improved both the axial and torsional control of the nail and expanded the indications for IM nailing.³

The use of locking screws does however carry some disadvantages. It is associated with a 2% to 30% risk of neurological or vascular damage.^{4,5} The distal locking procedure itself is time consuming and also increases radiation exposure of both the patient and the surgeon.^{6,7} The use of locking screws increases the transmission of force through the nail and reduces bone load sharing,

which may contribute towards delayed union or even non-union.³ The re-operation rate required to obtain a union in patients with tibial fractures treated with a locked nail ranges from 11% to 57% with the most commonly performed procedure being dynamisation of the nail.^{8–10}

The Fixion expandable IM nail was developed by Disc-O-Tech to retain the mechanical characteristics of a large diameter locked nail, whilst obligating the necessity to ream and lock (Fig. 1). Expansion of the nail is believed to help aid fracture alignment and also achieved rotational stability of the fracture. The manufacturers do not recommend use of the nail for fractures less than 5 cm from the joint line.³

A systematic review of the literature to evaluate the safety and efficacy of the Fixion system has been conducted with re-operation rate as the primary outcome variable. Complication rate, union time and operative time associated with the use of the Fixion system were also examined as secondary outcomes.

Materials and methods

The MEDLINE database was searched from 1950 to September 2010 using the keyword “Fixion” OR (“Bone nail” AND “Expandable”). The Cochrane database was searched and a bibliographic review of selected papers was also performed.

Articles were considered for review if they satisfied specific pre-determined criteria (Table 1). Exclusion criteria were articles

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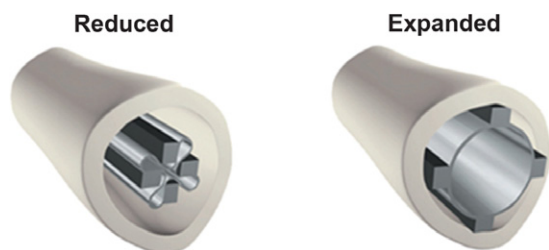


Fig. 1. Expansion of the Fixion nail. The Fixion nail is a stainless steel tube consisting of 4 longitudinal rectangular bars connected by 4 metallic membranes. The nail is introduced following reaming or not of the medullary canal, in its collapsed form having a diameter of either 8.5 mm or 10 mm. Once in the correct position it is expanded up to 160% of its original diameter with saline using a manually operated pump. During expansion it conforms to the intramedullary canal and provides an interference fit over the length of the canal.

Table 1
Selection rationale of the review

Target population	Skeletally mature patients with diaphyseal tibial fractures
Intervention	Fixion IM nail
Exclusion criteria	Language other than English Skeletally immature patients Indications as Non-Unions, Pathological fractures
Primary outcome	Reoperation rate
Secondary outcomes	Complication rate Union time Operative time
Studies methodology	Prospective or retrospective study

in other than English language, skeletally immature patients, and cases where the nail was used for the treatment of non-unions or for pathological fractures (Table 1). Such outcome parameters were examined as the length of the operative procedure, re-operation rates, union rates and complications (Table 1).

Results

The Medline search produced 41 papers. The titles and abstracts of the 41 studies that satisfied our search criteria were reviewed with respect to the inclusion and exclusion criteria. The flowchart of the exclusion process is presented in Fig. 2. Ten papers remained for review. The characteristics of the remaining studies are shown in Table 2.

The search of the Cochrane database and bibliographic review generated no additional citations.

Pascarella et al.¹¹, in 2002 retrospectively reviewed a series of 12 tibial fractures treated with the Fixion nail at a district general hospital in Bologna between June 2000 and June 2001. All nails were inserted after reaming. AO type A1-3 and B1 were treated with the nail. Surgical time ranged from 30 to 50 minutes. Fracture consolidation was obtained at an average of 4 months. One case of failure of nail to expand was noted. No other complications were reported.

The period of follow up, the indications for fixation with the Fixion nail and the background characteristics of this sample were not defined, making the interpretation of the results difficult. The authors concluded that the Fixion system was easy to use with few complications, however its indications are limited to stable fractures where excellent stability and early rehabilitation are guaranteed.

Capelli et al.¹², in 2003 retrospectively reviewed the results of 22 patients with diaphyseal tibial fractures treated with an unreamed Fixion nail at a Milan teaching hospital in between January 2000 and December 2001. Only AO type A fractures were included. At a

minimum of 3 months follow up the only complication noted was a superficial infection that responded to oral antibiotics. No nails were removed. The mean consolidation time was 16 weeks. Clinical results were judged to be excellent in 16 cases and good in 3.

Given the low complication rate and high union rate the authors concluded that the Fixion nail satisfied their requirement for a tibial intramedullary fixation system. The period of follow-up at a minimum of three months was however short, late complications such as late nail deflation or incarceration could not be excluded. The background characteristics of the group were not well defined and methods of assessing clinical outcome are not given. The selection criteria for treatment with Fixion nail at the authors' institution were not well defined. Only closed AO type A fractures were treated with the Fixion nail and as such one would expect the results to be good.

Smith et al.¹³, in 2006 reported the results of a prospective series of 27 tibial fractures treated with the Fixion system at two level-one trauma centres in Ohio and Denver during a six month period in 2002. The main outcome measures were the incidence of perioperative complication and union rates. Inclusion criteria were adult patients with acute OTA types A1, A2, A3, B1, and B2 diaphyseal fractures of the tibia who were candidates for intramedullary fixation. Two experienced fellowship trained surgeons performed all procedures. All nails were inserted after reaming. Nailing was performed in a young (average age 25.5 years) and predominantly multiply injured (injury severity score 17.4) cohort of patients. Six (22%) of the fractures were open. Excluding nonunions, the mean time to healing was 15 weeks (range 10 to 24 weeks). There was one non-union (3.7%) and two delayed unions (7.4%). Despite the fact that the nailing was performed in mostly length stable fracture configurations, five tibial shaft fractures (18.5%) were shortened by 1.0 cm or more postoperatively. In three tibias (11%) shortening occurred after fractures that were originally considered as length-stable, became unstable due to fracture propagation during nail expansion. Five tibias were converted to standard locked nails because of this issue. The expandable nail resulted in complications in eight (30%) of patients and unplanned reoperation in seven cases (26%). The study was designed as a multicentre pilot study to develop the preliminary data for a randomised trial comparing expandable to standard locked intramedullary nailing. The study was however stopped early due to the unacceptably high rate of complications. The authors concluded that expandable nails could not be used predictably even in stable fracture patterns, and that standard locked intramedullary nailing is more appropriate and a more reliable treatment for tibial diaphyseal fractures.

Steinberg et al.¹⁴, presented a retrospective case series of 54 consecutive patients treated with the Fixion nail system at two level-1 trauma centres. Patients were eligible for retrospective review if they had been treated by one of two surgeons with the Fixion nail between January 2000 and September 2002. Indication for treatment using the Fixion nail was an acute midshaft fracture of the tibia. Patients with non unions, pathological fractures and metaphyseal fractures were excluded.

All fractures healed in an average time of 72 days (range 21 to 204). Average operative time was 103 minutes if the nail was inserted reamed and 56 minutes if inserted unreamed. There were 11 complications (20.4%) related to the nailing: 3 deep infections, 2 superficial infections, 2 bone shortenings of 1 cm secondary to nail protrusion in the knee, 1 compartment syndrome, 1 fracture propagation, 1 distal malalignment, and 1 delayed union. Hardware was removed in 6 patients (3 infections, 2 patients' request and 1 protrusion into the knee), and 1 additional patient underwent exchange nailing due to a delayed union.

It is of note that two cases of significant shortening of the tibia were reported, one of which resulted in protrusion of the nail into

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