Intramedullary Fixation of Tibial Shaft Fractures Using an Expandable Nail

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Interlocking intramedullary nails are the gold standard for treating tibial fractures. We compared the clinical and economic factors associated with tibial fracture fixation using either interlocking intramedullary or expandable nails. From 2000 to 2002, 53 patients with 53 diaphyseal tibial fractures of similar characteristics (AO/OTA 42A1-B3) were randomly and prospectively treated with either interlocking (n = 26) or expandable nails (n = 27). Patients were followed for a minimum of 2 years. The mean surgical duration was 104 minutes with interlocking nails and 52.9 minutes with expandable nails. Rehospitalizations were required in 12 patients (46%) and reoperations were required in nine patients (35%) with interlocking nails. Only one patient (3%) with an expandable nail required rehospitalization and reoperation. Union was achieved after 17 weeks (mean) with interlocking nails and 11.5 weeks with expandable nails. The beneficial economic ramifications of using expandable nails were a 39% reduction in overall surgical and hospital expenses. Expandable nails showed important clinical advantages for tibial fracture fixation, and complications related to lengthy operations, reoperations, and rehospitalizations were substantially reduced. Overall treatment cost was substantially lower with expandable nails. Based on these advantages, simplicity in use, and short surgical time, we recommend an expandable nail for treating tibial (AO Type A, B) shaft fractures.

Kuntscher’s innovation of the cloverleaf-shaped intramedullary (IM) nailing technique brought about a breakthrough in fracture treatment. Advantages associated with IM nail fixation include a shorter time to union, substantially shorter hospitalization time and earlier patient ambulation, return to work, reduced incidence of malunion, and prompt resumption of joint movement.14 Court-Brown et al5 reported that the major advantage of the interlocking IM nail was functional, with 78% of their patients returning to most activities other than sports even before clinical union.

Although interlocking IM nailing is probably the first choice of treatment by many orthopaedic surgeons for long-bone fractures, it is associated with a spectrum of disadvantages including disruption of cortical vascularity,18,28 increased intracompartmental pressure,23,24 thermal necrosis associated with reaming,21 and neurologic and vascular insult.19 However, inserting larger-diameter nails (after reaming or insertion of large-diameter, tight-fitting unreamed nails) provides better stabilization of the fracture with resultant higher union rates and reduced hardware failure.5,17

Expandable nails were created to retain the advantages of large-diameter nails and improve the torsional stability while avoiding the biologic disadvantages of reaming and inserting tight-fitting large-diameter IM nails.

The expandable nail is a stainless steel sealed tube consisting of four longitudinal rectangular bars connected by four thinner metallic membranes. The nail is introduced into the medullary canal in its collapsed form. This allows for easy, less traumatic insertion. Once in its proper position, it is expanded gradually with physiologic saline solution using a manual hand-operated pump. The proximal end of the nail has a one-way valve that allows an influx
of saline into the internal nail compartment. Pressure is monitored with a built-in pressure gauge (Figs 1, 2). The surrounding steel membrane slowly expands under the guidance of an image intensifier and pressure barometer control (Fig 1). It is not necessary to expand the nail to its maximal diameter, but rather until its longitudinal bars abut against the cortical walls to stabilize the fracture. The target pressure for maximal expansion is up to 70 bar, which may expand the nail to approximately 160% of its original insertion diameter (Fig 1). During expansion the nail’s outer bars and stainless steel connecting membrane conform to the medullary canal’s individual shape (Fig 3), while the four longitudinal bars abut against the inner cortical walls. This provides an interference fit along the whole length of the tibial inner shaft on both sides of the isthmus. This technology has been used and examined with encouraging success in the treatment of femoral, tibial, and humeral shaft fractures.8,20,22,31

This study was done to evaluate the clinical outcomes of patients with diaphyseal tibia fractures after being treated with either expandable or conventional interlocking IM nails. We designed a prospective randomized comparative study to answer the following questions: (1) Does the use of expandable nails improve postoperative clinical outcomes as measured by rehospitalizations and reoperation rates; (2) Does the use of expandable nails improve postoperative clinical outcomes as measured by the rate of fracture union; (3) Does the use of expandable nails reduce the duration of surgical fixation; and (4) Is the use of expandable nails associated with a lower overall cost?

MATERIALS AND METHODS

We performed a prospective, randomized, comparative clinical trial involving all patients who were treated by IM nailing for acute, isolated midshaft diaphyseal tibial fractures from January 2000 to December 2002. Patients were treated randomly with either an interlocking nail (Mathys, Bettlach, Switzerland) or an expandable nail (Fixion, Disc-O-Tech, Hertzelia, Israel). The expandable nail (Fixion, Disc-O-Tech) is manufactured in two tibial nail diameters. An 8.5-mm folded diameter, which can be expanded to 13.5 mm and a 10 mm which can be expanded to 16 mm. Randomization was decided by day of admission; certain days were designated for expandable nail treatment while others were designated for conventional IM nail use.

We evaluated 26 patients (six females and 20 males) with a mean age of 37.5 years (range, 17–81 years) who were treated with conventional interlocking IM nails. Twenty-seven patients (eight females and 19 males) had expandable nail fixation. We included patients with acute, isolated midshaft diaphyseal fractures of the tibia without other associated injuries. Fractures included those with similar characteristics and configuration; 42-A1 to 42-B3 fractures according to the AO/OTA classification.23 We excluded patients treated for metaphyseal frac-
features, nonunions, pathologic fractures, and 42-C type fractures. We also excluded patients who refused to be treated with the new expandable nail.

The fractures were classified according to the AO classification. The interlocking nail group included A1-6, A2-5, A3-6, B1-2, B2-4, and B3-3 fractures, and the expandable nail group included A1-4, A2-5, A3-6, B1-2, B2-4, and B3-6 fractures (Table 1). Seventeen fractures (63%) in the expandable nail group were open fractures compared with 10 (38.5%) open fractures in the interlocking nail group (Table 2).

This study was approved by our institutional review board. All participating patients were informed of the study and the new implant and signed an informed consent form before treatment.

Surgical fracture fixation was preceded by preoperative radiographic assessment of IM length and diameter. We chose a nail diameter 2 to 3 mm less than the measured IM canal diameter at its narrowest point. Patients were positioned supine on a radiolucent fracture table. Fracture reduction, alignment, and surgical technique were obtained in standard fashion. Reaming was performed in cases where the surgeon thought the medullary canal would be too narrow and would preclude the use of larger-diameter nails. Expandable nails were expanded to a maximum

**Table 1. Fracture Types in Each Treatment Group (AO classification)**

<table>
<thead>
<tr>
<th>Fracture Types</th>
<th>Conventional Intramedullary Nail (n = 26)</th>
<th>Expandable Nail (n = 27)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A1</td>
<td>6</td>
<td>4</td>
</tr>
<tr>
<td>A2</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>A3</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>B1</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>B2</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>B3</td>
<td>3</td>
<td>6</td>
</tr>
</tbody>
</table>

**Table 2. Open Fracture Distribution According to the Gustilo-Anderson Classification**

<table>
<thead>
<tr>
<th>Classification</th>
<th>Conventional Interlocking Intramedullary Nail (n = 26)</th>
<th>Expandable Nail (n = 27)</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>2 (20%)</td>
<td>6 (35%)</td>
</tr>
<tr>
<td>II</td>
<td>6 (60%)</td>
<td>5 (30%)</td>
</tr>
<tr>
<td>III</td>
<td>2 (20%)</td>
<td>6 (35%)</td>
</tr>
<tr>
<td>Total</td>
<td>10 (38.5%)</td>
<td>17 (62.9%)</td>
</tr>
</tbody>
</table>
of 70 bars and interlocking nails were fixed by introducing interlocking screws in a standard fashion.

All patients with open fractures received 1 g cefazolin every 8 hours for 24 hours and were given prophylaxis against tetanus if necessary. Patients who had Grade III open fractures also were given gentamicin (one dose of 3 mg/kg body weight, but no more than 240 mg/day). Antibiotic therapy was maintained after surgery for 72 hours. Subcutaneous heparin was used as antithrombotic therapy.

Postoperative instructions were: active range of motion (ROM) of the knee and ankle and early weightbearing as tolerated. Protected weightbearing with crutches was begun in patients who had little cortical continuity. Patients were seen at followup at 4- to 6-week intervals.

The outcome measures included demographics (age and gender), type of fracture according to the AO fracture type classification and the Gustilo-Anderson open fracture classification, duration of surgical procedure measured as skin-to-skin time, intraoperative difficulties or complications, early postoperative complications (eg, neurologic deficits, compartment syndrome), incidence of readmissions and reoperations associated with late complications (eg, infections, delayed unions or nonunions, anterior knee pain, interlocking screw-related pain), and clinical followup and assessment of time to clinical and radiographic union. Patients were routinely followed in our outpatient clinic for a minimum of 2 years.

Bone union was defined as a combination of clinical and radiographic union. Radiographic bone union was defined as bone bridging of at least three cortical shaft walls on anteroposterior (AP) and lateral views of the bone as evaluated independently by two of the surgeons (PBG and ELS), and clinical union was determined when there was absence of pathologic movement or pain during full weightbearing.

The cost of the initial fracture-fixation surgery was not substantially different and was $3400 for interlocking IM nail surgery and $3420 for expandable nail surgery. The overall costs of the different operative procedures and hospital care for each group of patients were calculated using the actual prices effective at the time of treatment. We included the costs for all procedures and treatments during the initial treatment and for all reoperations and readmissions. The overall cost of treatment then was divided by the number of patients in each of the two treatment groups.

Comparison between the two treatment groups was performed using the Mann-Whitney nonparametric test and the t test for independent samples for continuous variables. We used the chi square test for categorical variables.

RESULTS

Patients treated with expandable nails had better clinical outcomes than the conventional IM nail group. Rehospitalizations were required in 12 patients with interlocking IM nails (46%) and reoperations were required in nine (35%), compared with one patient for each (3%) in the expandable nail group who required a nail exchange (p < 0.0001) (Table 3). Three patients (11.5%) had postoperative peroneal nerve-related neurologic deficits solely related to interlocking screw insertion (two of which required later microsurgical intervention).

Although bone union did not show a significant difference, there was a nonsignificant trend toward faster bone union for the expandable nail group (11.5 weeks) compared with the interlocking nail group (17 weeks).

The mean duration of surgery was shorter (p < 0.001) for the expandable nail group, with a mean surgical time of 52.9 minutes compared with 104 minutes for the interlocking nail group. Reaming was performed in seven of the 26 patients in the interlocking nail group and in five of the 27 patients in the expandable nail group.

The mean overall treatment price for patients treated with conventional interlocking nails was approximately 39% more expensive than treatment with an expandable nail. Prices in our community were $4850 versus $3480 average overall treatment per patient, respectively.

Although the hardware price was approximately 30% higher for the expandable nail than for the interlocking IM nail (depending on nail size and reamed or unreamed IM nail), the overall cost of treatment was substantially lower. Overall treatment price differences were related primarily to additional treatment and procedures that had to be performed after the initial fracture fixation.

Only one patient in the expandable nail group needed an additional hospital procedure (a nail exchange), whereas in the conventional interlocking IM nail group there were three nail exchange operations (one nail was exchanged intraoperatively and two were reoperations), three nail removals, four removals of interlocking screws, two reoperations for neurologic deficits, and three readmissions for infection (Table 3).

DISCUSSION

Interlocking IM nailing is the preferred treatment method for displaced long bone-shaft fractures. We had the oppor-
tunity to use expandable IM stainless steel nails that use a self-locking expansion technique without the need to insert interlocking screws and to compare their operative and clinical results with results of conventional interlocking nails. The two treatment groups involved patients with isolated, noncomminuted diaphyseal tibial fractures. Both groups were similar with respect to patient demographics (age and gender distribution), location, and fracture type according to the AO classification.25

The expandable nail was surgically advantageous as it resulted in a shorter operative time and the lack of complications (eg, neurologic damage to the peroneal nerves). Shorter surgical duration may be beneficial when considering risk of operative complications associated with longer surgical duration such as thromboembolic events, compartment syndrome, infection, bleeding, prolonged fluoroscopy radiation exposure, and decreased risk of anesthetic complications.10,19,35

The expandable nail group had reduced operative and postoperative complications including lower rates of re- current admissions and reoperations. These advantages are not surprising with a reported reoperation rate ranging from 27% to 57%, required to obtain union when using interlocking nails.2,3,6 The most commonly performed procedures in these reports and in our study were dynamization of a static locking nail (removal of locking screws) and exchange or removal of nails. These procedures are not required with the expandable nail. These advantages were maintained in the expandable nail even though the types of fractures in this group were of a more severe nature, according to the Gustilo-Anderson open fracture classification (Table 1).13

Reaming often is preferred for diaphyseal fractures because it may allow insertion of larger-diameter nails, which avoids mechanical problems related to less-durable nonreamed nails and affords more stable fracture fixation.9,12,30,32,33 However, reaming may be associated with an increased risk of infection in open fractures, severe soft tissue injury,3,7 and thermal injury to the bone.21,26 Nonreamed interlocking nails typically have diameters of 8 to 11 mm and reamed nails typically have diameters of 11 to 14 mm. The new expandable nail technology may bridge the small-diameter nonreamed nails and the larger diameter more solid reamed nails, combining the benefits of both. The expandable nail was designed to abut the endosteal bone, enabling rotational stability, and does not require interlocking screws. In vitro bending stiffness and strength and torsion stiffness studies of this system showed that the biomechanical properties of the expandable nail are similar or even superior to other commercially available intramedullary devices.29,31 This system is used for other long-bone fracture fixation and the reported results are favorable and encouraging.8,20,22,29,31 We performed reaming depending on the surgeon’s assessment of obtaining optimal nail fit hin the inner diameter of the cortex. Reaming was done whenever a surgeon thought that it would allow for a substantially larger-diameter nail fit. Reaming was performed if the tibial isthmic diameter was narrow.

We believe the expandable nail assists with fracture site reduction because of the process of nail expansion. During expansion, the nail’s bars fan out in a symmetric fashion and it becomes centralized with respect to both fracture ends, ensuring that both ends of the fracture edges become precisely aligned (Fig 1). Thus, if one gently slides the nail into the medullary canal, ensures rotational alignment (rotation is still possible with the deflated nail in place before locking the bone ends by expansion), then nail expansion will assist with transverse plane reduction.

Another unique feature of this nail is its ability to accommodate itself to the shape of the intramedullary canal. As the nail is expanded in the canal it assumes an hourglass shape (Fig 3). This happens because the expanded nail abuts against the inner-cortex hourglass shape (a smaller midshaft tibial cross section and a larger metaphyseal diameter). This locks the bone fragments against distraction forces along the length of the whole bone. In previous biomechanical studies this fixation was better than point fixation of the interlocking screws used with conventional interlocking IM nails.29,31

These unique technical advantages associated with the use of an expandable nail and its simplicity help to avoid common difficulties encountered when using interlocking nails such as difficult intramedullary insertion and passage of the wide, conventional IM nails, which carries a risk of iatrogenic fracture propagation.16 Large nails also cause considerable torque during their passage which makes maintenance of rotational reduction difficult. The expandable nail completely avoids the need for precise interlocking screw insertion. Insertion of interlocking screws increases the operative time significantly and necessitates more radiation exposure. Insertion of interlocking screws requires drilling holes in unaffected bone and creates stress risers which have been shown to decrease bone strength.4,5,11 Although fracture propagation also may occur with expandable nail insertion and expansion, this complication was not encountered in any of the patients in our study.

The shorter time to bone union and earlier ambulation with use of the expandable nail may be associated with the decreased endosteal vascular striping related to gentle, loose-fitted IM insertion. Expandable nails are inserted in a very loose-fitting manner and reaming is optional, thus damage to the membranous endosteum is minimized. The expandable nail compresses the endosteum and cortical wall only along the apexes of its four longitudinal bars and

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acts as a low-contact hardware device sparing areas of endosteum, cancellous bone, and some cortical vascular supply in the recesses between the longitudinal bars (Fig 1). The effect of tightly fit unreamed nails on blood flow resulted in an overall tibial blood flow reduction of 72% compared with a 58% reduction when loosely fitting nails were used in an experimentally induced canine segmental fracture model. This damage was even more pronounced with reaming. Klein et al showed that reaming of the canine tibia resulted in damage to the blood supply of 70% of the cortex, compared with 31% of the cortex with an unreamed nail.

Interlocking intramedullary nailing is associated with neurologic and vascular damage secondary to drilling of holes for the interlocking screw fixation. This occurs in 2% to 30% of patients. The most serious vascular complication is damage to the popliteal artery in the area of the arterial trifurcation, followed by the medial inferior genicular artery, and to the posterior tibial and peroneal arteries. Three of our patients experienced neurologic deficits associated with the use of conventional interlocking IM nails (two required reoperations). In contrast, patients treated with an expandable nail had no interlocking screws and thus no interlocking screw complications.

A limitation for the use of the expandable nail includes shortening during the healing process of Type C AO/OTA fractures because of lack of longitudinal continuous cortical contact across the fracture site. We only included AO/OTA Types A and B fractures because with these fracture types there is at least one cortex in contact with both sides of the fracture. Careful judgment should be used when there is a short comminution area in Type C fractures. If both sides of the fracture are long enough to permit good canal interference with the nail and the patient’s condition allows it, the surgeon may use the expandable nail and risk some shortening. Longer unstable fractures should not be fixed with this system. Other limitations include fractures of the proximal 1/3 and the distal supramalleolar area of the tibia. Fractures in these locations should not be fixed with an expandable nail, as the requirements for a reliable canal-interference fit cannot be achieved.

Crack-fracture propagation is a problem with any IM nail insertion including the expandable nail. Unrecognized crack fractures may complicate fracture fixation when using any type of IM nail. The stress and pressure created by insertion of large tight-fitted conventional IM nails has been measured and is significantly greater compared with the pressures of expandable nail insertion and expansion.

An expandable nail’s biologic and technical advantages have important clinical implications for long-bone fracture fixation. Complications, rehospitalizations, and reoperations were reduced. They also resulted in shorter time to union, earlier ambulation, and reduced incidence of medical and technical complications. Hospital costs and overall expenses were substantially lower with expandable nails. Based on all these advantages, and its simplicity in use and short surgical technique, we recommend an expandable nail for treatment of tibial (AO Types A and B) shaft fractures.

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References


