Lessons learned from a clinical study of the expert tibial nail.

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Clinical experience with the expert tibial nail

Introduction  Based on the success of closed, locked, reamed nailing of the tibial diaphyseal fractures, surgeons have extended the indications for tibial nailing into the metaphyseal area of the proximal and distal tibia [1, 2]. The advantage of a central, weight-bearing and minimally invasive technique was weakened by high rates of primary and secondary malalignment with a need for reoperation. To solve these problems the expert tibial nail (ETN) was designed. Particular attention was paid to the entry point, nail bending, and stable locking options.

Expert tibial nail  The basic idea behind the ETN was to design one implant for all extraarticular tibial fractures. The expanded indications are proximal end segment extraarticular tibial (A1-A2/A3) and distal end segment extraarticular (A3-A1/A2/ A3) fractures. Borderline indications are proximal tibial end segment simple articular (A1-C1/C2) and distal tibial end segment simple articular (A3-C1/C2) fractures. These are fractures with extension into the knee and ankle joint without displacement or impaction.

The proximal segment of the nail, which contains the five interlocking holes, is straight. The next segment is bent 10° (a bow, which accounts for 8° and a curve of 2°). The distal part is straight. The straight part is half the length of the whole nail. As a consequence, the length of the bow is different for each nail length. The new defined entry point in the AP view is in line with the axis of the intramedullary canal and with the lateral intercondylar tubercle. In the lateral view the entry point is at the ventral edge of the tibial plateau.

To improve stability, there are five proximal locking options in four planes. Three of them are cancellous bone locking screws to achieve maximal bone purchase. The most proximal one can be locked with an end cap. At the distal end of the nail there are four locking options with one far distal locking hole at the tip of the implant in a 30° oblique direction. As one is able to place three locking screws in three planes in an area 25 mm proximal to the ankle joint, it is possible to address very distal tibial fractures.

Multicenter study

Aim  The study aim was documentation of intraoperative and postoperative data as well as 12-week and one-year follow-ups to evaluate the safety and clinical outcome of the expert tibial nail. Ten different trauma centers from Europe participated.

Material and methods  A one-year prospective multicenter case-series was conducted and included patients with AO type 41, 42, and 43 tibial fractures of all degrees of severity, which were amenable to surgical fixation with an ETN. Treatment with the ETN was performed by surgeons from ten European trauma units. Study monitoring, database management (including data entry) and statistics were performed by ACOID. During hospitalization, patient demographics and baseline characteristics were documented. Fractures and soft-tissue injuries were classified according to the Müller AO and Gustilo/Tscherne classification by the treating surgeons. Intraoperative complications were reported concerning the instruments, implant, insertion, and iatrogenic fracture.

Patients were examined after 12 weeks and one year. At both follow-ups, patients were x-rayed in two planes (ie, AP and lateral) to survey joint alignment. Anticipated postoperative complications included loss of reduction, delay in healing, screw loosening, and/or breakage, nail protrusion and/or breakage, as well as surgical and other local or general complications. All ten clinics participated in this prospective case-series and recruited 181 patients with 186 fractures between July 2004 and May 2005. At the 12-week and 1-year follow-up examinations, 156 (86%), and 146 (81%) of the 181 patients were examined, respectively. 35 patients were lost at the 1-year follow-up: three died of unrelated causes and the other 32 could not be contacted or refused further examinations. The mean age of all patients was 44 years (range: 14–83 years) and included 69 (38%) women (mean age: 50 years) and 111 men (62%) (mean age: 41 years); the women were on average 9 years older than the males in the patient population.
Results 57 (30.8%) open fractures were treated and included: 15 grade I, 32 grade II and 10 grade III open fractures. 31 patients were polytraumatized (17.1%). Fractures were located in the proximal third in 22 cases (11.8%), the midshaft in 67 cases (36.0%) and 92 (49.5%) were distal third fractures; for the remaining five fractures, x-rays were not available. Reaming was performed in only about one third (64; 34.4%) of the fractures. Around 50–60% of all proximal third (13/22; 59.1%) and mid shaft (33/67; 49.3%) fractures were sustained after traffic accidents, whereas approximately a third of the distal fractures resulted from each of traffic (29.3%), home (29.3%) and sport accidents (26.1%).

After one year, the prevalence of nonunion was 12.2% (18/148) and was higher for open fractures (18.2%; 8/44) compared to closed fractures (9.7%; 10/103). Reamed fractures resulted in a lower proportion of nonunion compared to the unreamed group (8.2% vs 14.1%). According to fracture height, the percentage of nonunion was 5.9% (1/17) in proximal third, 16.7% (9/54) in midshaft and 10.5% (8/76) in distal third cases.

The risk of unplanned reoperation (including all dynamization procedures) was 18.8% (35/186). Bone grafting was achieved in five cases, in two other patients the nail was exchanged either with another nail or substituted with a plate and in another case, additional fibular plating was used. 21% of the patients reported pain in the operative region at the 1-year follow-up (30/145).

The risk of reporting a malignment > 5° in any plane one year after surgery was 4.3% (8/186). Proximal third fractures were at a higher risk of malalignment (13.6%; 3/22), whereas the risk was lower for mid shaft (4.3%; 4/92) and distal third fractures (1.5%; 1/67). Various complications within the first year after the operation included loss of reduction (risk: 1.1%; 2/186) and deep infection (risk: 1.6%; 3/186), as well as screw/bolt breakage (risk: 3.2%; 6/186).

Discussion The prevalence of nonunion (12%) is comparable to published data [3, 4, 5] and is surprisingly low at 6% for proximal fractures, whilst being quite high (17%) for middle third fractures. This is an adequate outcome yet requires further improvement. In my opinion, this current data represents the reality of our daily work, since 93 surgeons with skills at every level operated on the patients. This study is therefore not biased towards intramedullary nailing experts.

The need for reoperation (19%) was much lower than what has been reported in the literature [6, 7, 8]. It should be pointed out that dynamization was not routinely performed after six weeks, but was dependent on the status of bony healing as seen on the x-ray controls.

The ETN has important advantages in the treatment of proximal and distal tibia fractures. The risk of malalignment was much lower (4%) than that reported for the nailing of proximal tibia fractures; the working groups of Ahlers [9], Freedman [10] and Lang [11] observed between 58–84% malalignment. It is crucial to achieve adequate reduction while inserting the nail. This can be challenging and in some cases, one requires pointed reduction clamps, a distractor or external fixator, or has to try percutaneous reduction with Steinman pins and blocking screws. However once the fracture is reduced, the risk for secondary malalignment is low. The overall risk of loss of reduction was only 1% compared to 10% in a recent publication by Egol and co-workers [12]. The improved outcome of
reamed nailing regarding healing underlines the tendency in the literature of recent years [13].

**Conclusion** The ETN proved to be a very useful tool in treating proximal, midshaft and distal tibia fractures. Still it is challenging to reduce proximal and distal tibia fractures. One has to know all the tricks, but once the fracture is reduced, the risk of secondary malalignment is low due to improved locking options and higher stability of the nail. It is now safely possible to extend the indication for intramedullary nailing to the proximal and distal metaphyseal area of the tibia.

**Bibliography**


**The AO Foundation Charter defines the mission of the AO:** to foster progress in the field of trauma and diseases and trauma of the musculoskeletal system [1].

This mission has initially been achieved by the incredible success of the cooperation model between AO and industries producing implants and instruments for internal fixation (Mathys, Synthes USA, Stratec, and finally Synthes Inc.). However, to assure that the AO Foundation continues to foster progress in providing improved patient care it must seek other areas that will enhance its relationship with its implant production partners and provide its surgeons with current and future technologies and options in musculoskeletal care.

To further these concepts, the AO should complete its spectrum of alliances for all technical tools essential in the treatment of injuries and diseases of the musculoskeletal system. This should be done without creating competition problems with our original partner, Synthes. The realization that “imaging” has been essential to progress in orthopedic surgery over the last decades has finally led to a teaching agreement between the AO Foundation and Siemens, signed in Zürich on August 31, 2007. From now on “imaging” will be an integral part of all AO teaching events. This means that the AO Foundation is no longer limited to instruments and implants for internal fixation but has added another dimension. The logical next step is osteoporosis.

The AO Foundation has identified osteoporosis as one of the clinical priority projects (CPP). If we consider the large number of osteoporotic patients seen and symptomatically treated by every orthopedic surgeon involved in trauma, it becomes clear that every orthopedic surgeon must have a sound knowledge of the problem of osteoporosis. Is it acceptable that 40% of the patients admitted to an orthopedic unit for a fragility fracture have had a previous fracture due to osteoporosis without adequate diagnosis and treatment of the underlying disease? If the underlying osteoporosis is not taken care of, an optimal internal fixation of a fragility fracture remains a symptomatic therapy. Do we want to forget about being doctors and be only high level “fracture technicians”??