A new angle stable nailing concept for the treatment of distal tibia fractures

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Abstract

Purpose Surgical treatment of distal tibial fractures demands a stable fracture fixation while minimizing the irritation to the soft tissues by approach and implant. Biomechanical studies have demonstrated superior performance for angular-stable locked nails over standard locked nails in distal tibial fractures. The experimental Retrograde Tibial Nail (RTN) is a minimally invasive local intramedullary osteosynthesis, which has been under design by our group. We conducted a biomechanical comparison in composite tibiae of the Retrograde Tibial Nail against the Expert Tibial Nail (Synthes®). Our hypothesis was that the RTN would provide equivalent biomechanical stability with respect to extra-axial compression, torsion and load to failure testing, in an extra-articular distal tibia fracture model.

Methods Biomechanical composite bone testing was conducted in 14 biomechanical composite tibiae in an AO 43 A3 fracture model. In both groups, triple angle stable interlocking was performed in the distal fragment.

Results Results show a statistically non-significant higher stability of the ETN during the axial loading tests. Torsional stability testing resulted in a statistically superior performance for the RTN ($p=0.018$).

Destructive extra-axial compression resulted in failure of six ETN constructs, while all RTN specimens survived the maximal load.

Conclusions The experimental Retrograde Tibial Nail provides the key features for the treatment of distal tibial fractures. It combines a minimally invasive local intramedullary

osteosynthesis with the ability to securely fix the fracture by multiple angle stable locking options.

Keywords Distal tibia · Metaphyseal fractures · Intramedullary nailing · Retrograde nailing · Angle Stable Locking System

Introduction

Prospective clinical trials and meta-analysis have shown that intramedullary nailing is a viable alternative to plate osteosynthesis in the treatment of distal tibial fractures [1–3]. It offers stable fracture fixation while preserving the integrity of the surrounding soft-tissue and vascular supply. However, the further the fracture extends distally, the mechanical fixation becomes less stable. In the distal metaphysis, the cross section of the tibia changes from a triangular to a round form. The diameter of the medullary canal increases distally, forming an hourglass shape. Additionally, the tibial cortex thins and is centrally replaced by metaphyseal secondary spongiosa and cancellous bone [4]. Whilst in young patients, this cancellous bone provides good screw purchase, in elderly patients, the microstructure of the bone changes. An increased distal canal diameter and a decreased cancellous bone density are present [4]. In clinical studies intramedullary nailing was associated with a higher incidence in malalignment and non-unions in comparison to plating [1–3].

In 2009 an Angular Stable Locking System (ASLS, Synthes®, Solothurn, Switzerland) was introduced for intramedullary nails [5]. The system consists of a resorbable 70:30 poly(L-lactide-co-D,L-lactide) sleeve assembled on a screw with three different outer diameters. When the sleeve-screw combination is inserted into the nail, the sleeve expands resulting in a tight fit that prevents toggling between nail and screw. This allows for the creation of a fixed-angle construct.

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The use of ASLS locked intramedullary nails have been described as a new osteosynthesis principle, namely, that of an “intramedullary fixator”. Biomechanical studies have demonstrated the advantages for the angular-stable locked nails with regard to a significantly higher axial and torsional stiffness, significantly less fracture gap movement and a significant reduction of the neutral zone in bending [6–9]. Biomechanically, two ASLS locking screws provide equal stability to three standard locking screws [10]. An animal trial in sheep with tibial osteotomies showed superior bone-healing in histomorphometric, radiographic and mechanical analysis in the angle stable locking group [11]. ASLS has mainly been promoted in cases requiring a high degree of stability such as metaphyseal fractures and in osteoporotic patients. A prospective-randomized clinical trial comparing standard to ASLS locking in tibial fractures has been conducted. However, the clinical results are still pending.

While in other long bones retrograde nailing is an alternative, until now no retrograde intramedullary tibial implant has been introduced into daily clinical practice. The experimental Retrograde Tibial Nail (RTN) is a small caliber intramedullary implant, which can be introduced through a 2-cm long incision at the tip of the medial malleolus [12]. The concept is that of a truly minimally invasive local intramedullary osteosynthesis. This includes sparing of the knee joint, leaving the medullary channel uninvolved and minimal surgical soft-tissue injury. In this study we investigate whether this prototype implant provides sufficient stability in comparison to an antegrade intramedullary nail (ETN®, Synthes), both with angle stable locking of the distal segment. The null hypothesis was that the RTN provides equivalent biomechanical stability with respect to extra-axial compression, torsion and load-to-failure testing in an extra-articular distal tibia fracture model (AO 43 A3).

Materials and methods

Implants

The RTN is an experimental intramedullary implant under design by our group. The geometry is based on CT morphometric studies and displays a straight proximal section with an angulated tip and a curved distal section. The implant has a length of 120 mm and a diameter of 8 mm. The implant features double proximal and triple distal locking options. The three distal locking holes are located at 9, 17, and 25 mm from the nail tip. The distal locking screws converge in the AP plane towards the tibial plateau at 45 mm and diverge in the lateral view by 25° to each other.

The nail is introduced through the medial cortex near the tip of the medial malleolus. A 9-mm opening and cavern through the medial malleolus is created by an awl. The nail,

assembled on the aiming device, is introduced by hand force with slight twisting movements. The angulated tip allows for easy introduction, while the nail slides along the lateral cortex of the distal tibia. All locking options can be addressed through the aiming device (Fig. 1). ASLS locking screws of 4.0-mm diameter are used distally. Proximal locking is performed by two standard 4.0-mm locking screws, each of which deviates by 15° from the midline. An end cap leads to an angle-stable distal screw to nail construct.

A standard Expert Tibial Nail (ETN) was used as a “state of the art” comparison. The 315-mm length nails were implanted according to the manufacturers instructions. Proximal locking is performed with two standard 4.0-mm locking screws. Distal locking was employed with 4.0-mm ASLS locking screws through the antero-posterior, medio-lateral and oblique locking option. They are located at 22 mm, 13 mm and 5 mm from the nail end.

Angle stable interlocking in both groups was performed at the three most distal options. After 3.2-mm drilling, the near cortex were reamed with the ASLS4 reamer. The 4-mm ASLS screws were introduced with the matching bioresorbable sleeve according to the manufacturers instructions.

Biomechanical testing

The investigation used 14 fourth-generation biomechanical composite bone tibiae (Sawbones Europe, Malmö, Sweden). There were seven bones in each group. An AO/OTA 43 A3 fracture model was created by a 10-mm wide transverse defect osteotomy after implant insertion into the intact bone (Fig. 2a–d). The osteotomy was from 40 to 50 mm from the plafond. To ensure a secure interface, the tibial ends were potted in poly-methyl methacrylate (PMMA) with two screws at each interface.

Fig. 1 Schematic CAD drawing of the Retrograde Tibial Nail assembled on the aiming device, which allows for X-ray free proximal and distal interlocking

All potted constructs underwent X-ray control in two planes to document the correct implant position and to exclude any damage. Biomechanical testing was performed by a pneumatic universal testing machine (SincoTec; Clausthal-Zellerfeld, Germany) with the setup based on Hansen et al. [13]. The testing machine was controlled by the native PneuSys software (SincoTec, Clausthal-Zellerfeld, Germany).

Non-destructive testing consisted of extra-axial compression with low (350 N) and high (600 N) force, as well as bi-directional torsion test with 8 Nm. Afterwards an axial “load to failure” test was performed for extra-axial compression of up to 900 N. All constructs underwent the same testing sequence. An overview is shown in Table 1.

For all extra-axial compression tests the load transmission point at the knee joint was in accordance with Horvitz et al. [14]. The force was introduced into the tibial plateau through a steel ball in a trough. The point of transmission was located with a 10 mm offset posteromedial from the tibial eminentia. A force-transmitting bar was positioned above the steel ball. Distally the PMMA potted tibiae were placed in a socket on a cardanic joint, since the kinematics of the upper and lower ankle joint are best simulated by this technique. Axial loading was started under a preload of 18 N and increased up to 350 N (low), respectively 600 N (high), and returned back to 18 N over a 20 second cycle. One pre-cycle and three measurement cycles were recorded. The testing machine measured the stiffness of the constructs resulting in load-to-deformation curves.

For torsional testing, the constructs were anchored proximally and distally. Bi-directional torque was applied under a constant preload of 10 N from 0 Nm to 8 Nm clockwise to 8 Nm counter-clockwise and back to 0 Nm over a 20 second timeframe. First one pre-cycle and then three measurement cycles were recorded. A rotational transducer connected to the actuator registered the rotational difference of the proximal to the distal segment. This resulted in a torsion to rotation curve.

An extra-axial “load to failure” test was performed as a final investigation. The force was increased to the maximal applicable load of 900 N. Failure of the constructs was defined as plastic deformation or actual implant breakage. Construct stiffness was measured by the load to deformation curve.

Table 1 Test sequence of the biomechanical evaluation. All RTN and ETN constructs underwent the same test sequence 1a-b, 2 and 3

Test sequence	7 RTN vs. 7 ETN (Synthes®)	
1. Non-destructive tests	a. 350 N	b. 600 N
Extra-axial compression		
2. Non-destructive tests	8 Nm	
Torsion		
3. Destructive tests	up to 900 N	
Extra-axial compression		

Data management and analysis

Statistical analysis was conducted with SPSS software (SPSS 21.0, IBM, Armonk, New York, USA). The load-displacement, force-rotation and force-failure values of the two implant types were analyzed by the two-tailed non-parametric Wilcoxon signed-rank test. Statistical significance was defined as an error level of less than 5 % (p-value, 0.05).

Results

Axial compression

Results show a higher stability in the ETN group during the low (ETN 888 ± 249 N/mm vs. RTN 609 ± 149 N/mm) and high (ETN 773 ± 229 N/mm vs. RTN 627 ± 113 N/mm) axial loading tests (Fig. 3a and b). The difference did not prove to be statistically significant for the low ($p=0.109$) and high ($p=0.063$) axial loading tests.

Torsion

Rotational stability testing resulted in a superior performance for the RTN. The average force-rotation value was 1.60 ± 0.11 Nm/° in the RTN vs. 0.66 ± 0.04 Nm/° in the ETN group during clockwise rotation (Fig. 4a), and respectively, 1.52 ± 0.10 Nm/° in the RTN vs. 0.68 ± 0.06 Nm/° in the ETN group during counter-clockwise rotation (Fig. 4b). Statistical analysis proved a significant difference (both p values 0.018) between the RTN and ETN groups for torsional stability.

Destructive extra-axial compression

Destructive extra-axial compression resulted in failure of six ETN constructs, five of which were due to plastic deformation and one was due to nail breakage at the most proximal locking option at the distal end of the nail. Failures occurred between 626 and 900 N. All RTN specimens survived the maximal load of 900 N. Plastic deformation did not occur in any RTN specimen. The Kaplan-Meier survival curve for destructive extra-axial compression is shown in Fig. 5.

Discussion

Intramedullary nailing offers relative stability but allows micro-motion, which induces callus formation. In our biomechanical testing, results show a slightly higher axial construct stability of the ETN during the low and high axial loading tests. Torsional stiffness tests resulted in far superior performance for the RTN with absolute movement reduced by the factor of approximately 2.5 in comparison to antegrade

Fig. 2 Fluoroscopy image in AP and lateral views of ETN (**a** and **b**) and RTN (**c** and **d**) implanted in a biomechanical composite tibia with an AO/OTA 43A3 fracture model

nailing. The applied osteosynthesis must keep the interfragmentary strain within optimal limits to avoid excessive movement and strain. Mainly torsional and shear stresses have proven to delay bone healing [15, 16]. The significant reduction in torsional movements could represent a relevant advantage in the treatment of distal tibia fractures. A primary anatomical alignment may develop into a secondary malalignment by displacement from relative instability of the bone to nail construct. Angular malunions have been widely reported after intramedullary nailing with older generation nails [17]. Modern nail designs and angular locking options are implant modifications which reduce this risk [18]. The “load to failure” test in our setup resulted in nail breakage in one ETN and in plastic deformation of five other

ETN specimens, while all RTNs withstood the maximum force. This demonstrates the higher stability of this experimental construct while being tested against the current “state of the art” implant.

The specific design of the RTN allows further addressing distal fractures in comparison with antegrade nails. When the nail is placed far distally so that the most distal locking option lays just proximal to the plafond, all three locking options can be placed within the most distal 25 mm of the tibia. While the most distal screw runs parallel to the plafond, the two others converge in the AP plane towards the tibial plateau. In contrast, the ETN requires an approximately 40-mm distal long fragment for triple distal locking. Therefore

Fig. 3 Axial construct stability for extra-axial force with 350 N (**a**) and 600 N (**b**) for the ETN (*dark*) and RTN (*light*). Results demonstrate a trend towards higher construct stability for the ETN group without statistical significance

Fig. 4 Torsional stability testing of the ETN (*dark*) and RTN (*light*). Results demonstrate a statistically significant superior performance of the RTN in comparison to the ETN. This is present in clockwise (**a**) and counter-clockwise torsion (**b**)

the RTN with angle stable locking can provide stable fixation of tibial fractures in the distal 6 cm. Likely indications for the Retrograde Tibial Nail are far distal tibial shaft fractures (AO 42 A-C) and distal extra-articular metaphyseal tibial fractures (AO 43 A1-3). Further investigations should explore the possibility of addressing pilon fractures with simple intra-articular involvement after primary lag screw fixation.

The RTN offers distinct conceptional design advantages over antegrade nails. The retrograde introduction through the medial malleolus spares the knee joint and patella tendon. Anterior knee pain after antegrade tibial nailing is by far the most common complaint of patients and frequently does not subside after implant removal [19–23]. Additionally, the retrograde approach with this short implant leaves most of the medullary canal uninvolved. Since the isthmus is never reached, it reduces the risk for fat emboli, which mainly occur during the first two reaming steps and during nail advancement through the isthmus. Another positive feature is the opportunity for radiation-free proximal and distal interlocking.

Fig. 5 Kaplan-Meier survival curve for destructive extra-axial compression of up to 900 N for the ETN (*dark*) and RTN (*light*). Six out of 7 ETNs failed while all RTN implants survived the maximal load of 900 N

Critical factors in retrograde tibial nailing are the selection of the correct entry point, low-pressure creation of the cavern through the medial malleolus and subsequent nail insertion while crossing the fracture line. As in other metaphyseal nailing procedures, fracture reduction has to be achieved prior to nail insertion, since the nail does not aid the reduction.

We would also like to address the limitations of this study. While artificial biomechanical composite bones have replicated mechanical properties well, they most likely resemble those of young adults. The bone geometry is based on a 183-cm, 90-kg male and the mechanical properties simulate those of healthy adult bones of less than 80 years of age [24]. However, it has been proven that the failure modes and typical fracture patterns are close to the ones published for human bones [24, 25]. Fixation in osteoporotic patients will most likely fail at lower values. We chose biomechanical composite bones due to their advantage since no biological variations exist, which influences the comparability between samples. Therefore, artificial biomechanical composite tibiae provide consistent geometric and structural properties, which are a valuable asset for implant testing. However, an additional biomechanical study in human osteoporotic bone could help to validate these findings.

An additional investigation, which might be of interest and has not been addressed in this study, is the use of ASLS screws for both proximal and distal interlocking. This option could provide additional stability, especially to the RTN, which is more dependent on the locking screws since no friction of the nail in tibial isthmus adds to the constructs stability.

Conclusions

The newly designed Retrograde Tibial Nail combines a minimally invasive local intramedullary osteosynthesis with the ability to securely fix the fracture by multiple angle stable locking options. Biomechanical testing resulted in superior stability for torsion and “load to failure” extra-axial loads. Therefore it provides the key

features for the treatment of distal tibial fractures and should be further investigated.

Conflict of interest The authors declare that they have no conflict of interest.

References

- Im GI, Tae SK (2005) Distal metaphyseal fractures of tibia: a prospective randomized trial of closed reduction and intramedullary nail versus open reduction and plate and screws fixation. *J Trauma* 59(5): 1219–1223, discussion 1223
- Vallier HA, Cureton BA, Patterson BM (2011) Randomized, prospective comparison of plate versus intramedullary nail fixation for distal tibia shaft fractures. *J Orthop Trauma* 25(12):736–741. doi:10.1097/BOT.0b013e318213f709
- Iqbal HJ, Pidikiti P (2013) Treatment of distal tibia metaphyseal fractures; plating versus intramedullary nailing: a systematic review of recent evidence. *Foot Ankle Surg: Off J Eur Soc Foot Ankle Surg* 19(3):143–147. doi:10.1016/j.fas.2013.04.007
- Ding M, Odgaard A, Linde F, Hvid I (2002) Age-related variations in the microstructure of human tibial cancellous bone. *J Orthop Res* 20(3):615–621
- Hontzsch D, Blauth M, Attal R (2011) Angle-stable fixation of intramedullary nails using the Angular Stable Locking System(R) (ASLS). *Oper Orthop Traumatol* 23(5):387–396. doi:10.1007/s00064-011-0048-4
- Gueorguiev B, Wahnert D, Albrecht D, Ockert B, Windolf M, Schwieger K (2010) Effect on dynamic mechanical stability and interfragmentary movement of angle-stable locking of intramedullary nails in unstable distal tibia fractures: a biomechanical study. *J Trauma* 70(2):358–365. doi:10.1097/TA.0b013e3181dbaaaf
- Horn J, Linke B, Hoentsch D, Gueorguiev B, Schwieger K (2009) Angle stable interlocking screws improve construct stability of intramedullary nailing of distal tibia fractures: a biomechanical study. *Injury* 40(7):767–771
- Wahnert D, Stolarczyk Y, Hoffmeier KL, Raschke MJ, Hofmann GO, Muckley T (2012) The primary stability of angle-stable versus conventional locked intramedullary nails. *Int Orthop* 36(5):1059–1064. doi:10.1007/s00264-011-1420-6
- Wahnert D, Stolarczyk Y, Hoffmeier KL, Raschke MJ, Hofmann GO, Muckley T (2013) Long-term stability of angle-stable versus conventional locked intramedullary nails in distal tibia fractures. *BMC Musculoskelet Disord* 14:66. doi:10.1186/1471-2474-14-66
- Gueorguiev B, Ockert B, Schwieger K, Wahnert D, Lawson-Smith M, Windolf M, Stoffel K (2011) Angular stability potentially permits fewer locking screws compared with conventional locking in intramedullary nailed distal tibia fractures: a biomechanical study. *J Orthop Trauma* 25(6):340–346. doi:10.1097/BOT.0b013e3182163345
- Kaspar K, Schell H, Seebeck P, Thompson MS, Schutz M, Haas NP, Duda GN (2005) Angle stable locking reduces interfragmentary movements and promotes healing after unreamed nailing. Study of a displaced osteotomy model in sheep tibiae. *J Bone Joint Surg Am* 87(9):2028–2037. doi:10.2106/JBJS.D.02268
- Kuhn S, Appellmann P, Pairon P, Mehler D, Rommens PM (2013) The Retrograde Tibial Nail: presentation and biomechanical evaluation of a new concept in the treatment of distal tibia fractures. *Injury*. doi:10.1016/j.injury.2013.10.025, in press
- Hansen M, Mehler D, Hessmann MH, Blum J, Rommens PM (2007) Intramedullary stabilization of extraarticular proximal tibial fractures: a biomechanical comparison of intramedullary and extramedullary implants including a new proximal tibia nail (PTN). *J Orthop Trauma* 21(10):701–709
- Horwitz DS, Bachus KN, Craig MA, Peters CL (1999) A biomechanical analysis of internal fixation of complex tibial plateau fractures. *J Orthop Trauma* 13(8):545–549
- Augat P, Burger J, Schorlemmer S, Henke T, Peraus M, Claes L (2003) Shear movement at the fracture site delays healing in a diaphyseal fracture model. *J Orthop Res* 21(6):1011–1017. doi:10.1016/S0736-0266(03)00098-6
- Epari DR, Kassi JP, Schell H, Duda GN (2007) Timely fracture-healing requires optimization of axial fixation stability. *J Bone Joint Surg Am* 89(7):1575–1585. doi:10.2106/JBJS.F.00247
- Robinson CM, McLauchlan GJ, McLean IP, Court-Brown CM (1995) Distal metaphyseal fractures of the tibia with minimal involvement of the ankle. Classification and treatment by locked intramedullary nailing. *J Bone Joint Surg Br* 77(5):781–787
- Kuhn S, Hansen M, Rommens PM (2008) Extending the indications of intramedullary nailing with the Expert Tibial Nail. *Acta Chir Orthop Traumatol Cech* 75(2):77–87
- Court-Brown CM, Gustilo T, Shaw AD (1997) Knee pain after intramedullary tibial nailing: its incidence, etiology, and outcome. *J Orthop Trauma* 11(2):103–105
- Katsoulis E, Court-Brown C, Giannoudis PV (2006) Incidence and aetiology of anterior knee pain after intramedullary nailing of the femur and tibia. *J Bone Joint Surg Br* 88(5):576–580
- Keating JF, Orfaly R, O'Brien PJ (1997) Knee pain after tibial nailing. *J Orthop Trauma* 11(1):10–13
- Toivanen JA, Vaisto O, Kannus P, Latvala K, Honkonen SE, Jarvinen MJ (2002) Anterior knee pain after intramedullary nailing of fractures of the tibial shaft. A prospective, randomized study comparing two different nail-insertion techniques. *J Bone Joint Surg Am* 84-A(4): 580–585
- Vallier HA, Cureton BA, Patterson BM (2012) Factors influencing functional outcomes after distal tibia shaft fractures. *J Orthop Trauma* 26(3):178–183. doi:10.1097/BOT.0b013e31823924df
- Gardner MP, Chong AC, Pollock AG, Wooley PH (2010) Mechanical evaluation of large-size fourth-generation composite femur and tibia models. *Ann Biomed Eng* 38(3):613–620. doi:10.1007/s10439-009-9887-7
- Heiner AD (2008) Structural properties of fourth-generation composite femurs and tibias. *J Biomech* 41(15):3282–3284. doi:10.1016/j.jbiomech.2008.08.013