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Retrograde Tibial Nail: Anatomical Implantation and Surgical Feasibility Study

Retrográdní hřebování tibie: anatomická studie chirurgické proveditelnosti implantace

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ABSTRACT

PURPOSE OF THE STUDY

The treatment of distal tibial fractures requires a stable fixation while minimizing the secondary trauma to the soft tissues by the surgical approach and implant. The experimental Retrograde Tibial Nail is currently investigated as a minimally invasive alternative to plating and antegrade nailing. The purpose of this study was to evaluate the surgical feasibility in a cadaver model for all distal tibial fracture types generally considered treatable by nailing.

MATERIAL AND METHODS

Five different fracture types (AO/OTA 43-A1/A2/A3 and 43-C1/C2) were created on separate cadaveric limbs. In simple fractures (AO/OTA 43-A1/A2/A3) primary nailing was performed. In intraarticular fractures (AO/OTA 43-C1/2) reduction of the articular block and lag screw fixation was performed before nailing. Intraoperative complications, quality of reduction, fluoroscopy duration and operative time were evaluated.

RESULTS

Retrograde intramedullary nailing is feasible in simple fracture types by closed manual reduction and percutaneous reduction forceps. Retrograde nailing is possible in fractures with simple intraarticular involvement after primary lag screw fixation. The duration of surgery averaged 51.8 minutes (range 40–62 min). No major complications occurred during nailing.

CONCLUSIONS

The minimally invasive retrograde nail combines a minimally invasive local osteosynthesis with the ability to adequately fix extraarticular and simple intraarticular distal tibial fractures. The results suggests that retrograde tibia nailing is a promising new concept for the treatment of distal tibia fractures.

Key words: minimally invasive surgery, tibia, metaphyseal fractures, intramedullary nailing, retrograde nailing.

INTRODUCTION

Intramedullary nailing and plate osteosynthesis are both viable options to treat distal metaphyseal tibial fractures with or without simple intraarticular involvement. In prospective randomized clinical trials and meta-analyses, both techniques have demonstrated success in maintaining fracture reduction and achieving bony union (8, 10, 11, 22, 24). Still, operative treatment of distal tibial fractures remains debatable since both techniques hold distinct advantages and disadvantages, which need to be considered during surgical decision making. The two main factors to be taken into account are soft tissue integrity and construct stability. Intramedullary nailing allows for stable fracture fixation while conserving the soft-tissues and periosteal vascular supply. Per contra, in far distal fractures, the fixation becomes mechanically less stable due to the wide medullary canal. Clinical data show a higher incidence of malalignment and commonly reported anterior knee pain in comparison to plating (5, 8, 22). Plating on the other hand, has a higher incidence of soft-tissue complications due to implant irritation and deep infections (2, 9, 10, 22).

The Retrograde Tibial Nail is an innovative experimental implant. It is the first device specifically designed for retrograde nailing of distal tibial fractures. It introduces a new concept, namely that of a minimal invasive local intramedullary osteosynthesis. The goals are to offer a stable fracture fixation with minimal additional soft-tissue injury to the distal lower leg and to avoid the knee joint. Several biomechanical studies have demonstrated favorable results in comparison to antegrade nailing and angle-stable plate osteosynthesis (13–15). RTN shows superior torsional stability over antegrade nailing with both standard and angle-stable interlocking of the distal segment (14, 15). In comparison to angle-stable plate osteosynthesis, statistically significant differences were observed for axial and torsional stability (13–15).

In this cadaveric study we investigate whether this experimental implant can be safely used in simple extraarticular (AO/OTA 43-A1/A2), comminuted extraarticular (AO/OTA 43 A3) and simple intraarticular distal tibial fractures (AO/OTA 43-C1/C2). Our hypothesis was that retrograde intramedullary nailing with the newly developed RTN is feasible and safe.

MATERIAL AND METHODS

Implant

The RTN is an experimental retrograde intramedullary implant. Its design is based on a computed tomography morphometric analysis of the distal tibia. It features a banana-shaped design with a curved distal section, a straight proximal section and an angulated tip. The nail is 120 mm long and has a small caliber diameter of 8 mm. It offers double proximal and triple distal interlocking. All locking options can be addressed though the aiming device. The distal locking holes are located between 9 and 25 mm from the nail end. The locking screws show a unique locking concept. On AP view the locking screws converge towards the tibial plafond, while on the lateral view they diverge. Distally, the 4.0 mm locking screws feature a dual core design, which leads to an optimized purchase in the cancellous bone. Proximally standard 4.0 mm cortical screws are used and the two locking options deviate by 15° from true lateral in the anterior and posterior direction.

Anatomical specimen and fracture types

Fresh frozen cadaveric lower legs including all soft tissues were obtained from the Anatomical Institute of our University. The use of human cadaveric specimen has been approved by the local ethics committee (reference number 837.088.07). The implantations were carried out in five fresh cadavers. In order to exclude underlying pathologies the limbs were primarily evaluated by clinical examination and X-ray views in two planes. The different extraarticular and intraarticular distal tibial fracture types (AO/OTA 43-A1/A2/A3 and 43-C1/C2) were created through a posterolateral approach. Osteotomies were started with an oscillating saw and completed with a chisel. A fibula fracture was created at the same level of the tibia fracture. The approach was closed by skin suture prior to the start of the implantation study.

Implantation

In intraarticular fractures (AO/OTA 43 C1-2) reduction of the articular block and 3.5 mm lag screw fixation (Synthes®, Zuchwil, Switzerland) was performed prior to nailing. Afterwards retrograde tibial nailing was performed. In simple fractures (AO/OTA 43 A1/A2) reduction forceps were used. In this experimental study the fibula fracture was not treated.

The 2 to 3 cm long incision started at the tip of the medial malleolus and extends distally. The entry point at the medio-distal point of the medial malleolus was marked with a Kirschner wire and confirmed by fluoroscopy (Ziehm Vista, Ziehm Imaging GmbH, Nuremberg, Germany). Imaging properties were set at "Extremity" and 1/2 dose. It is crucial that the wire is drilled parallel and near to the medial cortex. Subsequently a 9 mm cannulated awl was used with low force and twisting motions to create the path until the medullary canal was reached. The awl and wire were removed. The nail was assembled on the aiming device. Then the nail was introduced with low force and small twisting movements until its end sat flush with the cortex of medial malleolus. The correct nail position was confirmed by AP and lateral fluoroscopy. Through stab incisions, a trocar combination enables drilling, depth measurement and screw introduction. Drilling was carried out with a 3.2 mm drill. The second most distal locking position was aimed at the distal tibiofibular joint. Therefore drilling was stopped at the trans cortex. In all other positions bicortical drilling was performed. Distally, triple 4.0 mm dual core screws were used, while 4.0 mm standard double screws were utilized proximally. The end cap leads to an angle-stable distal screw to nail construct. The resulting implantation was documented in both planes by fluoroscopy. Afterwards the incisions were closed by layered suture. The implantations were performed by the same orthopedic trauma surgeon. Figures 1a–d offer an overview of the surgical technique.

Evaluation of implantation

The evaluation of implantations was performed to evaluate the feasibility of this new technique. It included the recording of all intraoperative problems. Major complications were defined as: intraoperative secondary fracture, intraarticular screw positioning and primary malalignment greater 5° in any plane or greater 10° of rotation and intraarticular screw position. Alignment was radiologically evaluated by comparison of the pre-osteotomy vs. post-implantation AP and lateral view. Additionally the distance to achieve triple distal interlocking was measured on a scaled image. The duration for implantation (skin incision to closure) was recorded for the reduction and nailing procedure, and in case of intraarticular fractures involvement, additional percutaneous lag screw fixation. Additionally, the fluoroscopy time was recorded.

RESULTS

Retrograde intramedullary nailing with the newly developed RTN was feasible in the five investigated fracture types. No major intraoperative complication occurred during this study. Postoperative evaluation of alignment by fluoroscopy showed an excellent reconstruction of the normal anatomy. In the two intraarticular fracture types primary lag screw fixation resulted in an anatomical joint line reconstruction. During the subsequent retrograde nailing procedure no displacement occurred. The range of varus-valgus axis deviation was between 0° to 4° varus. No intraarticular malpositioning of screws occurred during the implantations. The distance from the joint line to achieve triple distal interlocking was between 26 and 29 mm (average 27.4 mm). The average operation time was 51.8 minutes. The shortest operative time was recorded for the AO 43-A1 fracture at 40 minutes; the longest was in the AO/OTA 43-C2 fracture taking 62 minutes. The average fluoroscopy duration was 0.38 min (range 0.26–0.58 min). Figures 2a–d and 3 a–d show exemplary retrograde tibial nailing on an extraarticular (AO 43-A1) and intraarticular fracture (AO 43-C1).

Figs 1a-d. Surgical implantation of the Retrograde Tibial Nail. Retrograde intramedullary nailing with the newly developed RTN in a lab setting. After a 2–3 cm long skin incision, the entry point at the tip of the medial malleolus is marked with a Kirschner wire (Fig. 1a). After creating a canal the nail can be introduced with low force and small twisting movements (Fig. 1b). All locking options can be addressed though the aiming device requiring only small stab incisions (Fig. 1c). The retrograde nailing procedure causes very limited additional soft tissue trauma by the approach and implant (Fig. 1d).

DISCUSSION

In the past decade, modern antegrade nails have expanded the indications for intramedullary nailing far beyond shaft fractures (16, 17). The implants are suitable for distal metaphyseal fractures as well as simple intraarticular fractures extending into the pilon. In the presented study we showed that retrograde intramedullary nailing with the newly developed RTN can fulfill the same spectrum as the extended indications for modern antegrade nails in a lab setting and even exceed them. As always in intramedullary nailing of metaphyseal or simple intraarticular fractures, certain technical aspects have to be respected in order to achieve an optimal result. Fracture reduction must be performed first, since metaphyseal fractures will not be corrected by nail insertion, whether ante- nor retrograde. Any malalignment will be fixed in a non-anatomical position and result in primary malalignment. In complex metaphyseal fractures retrograde nailing can be simplified if a temporary spanning external fixator is applied as a primary stabilization. In a clinical setting, this could be done intraoperatively and followed by retrograde nailing, or it could be used as a temporary stabilization with retrograde nailing being carried out as a secondary surgery at a later point. This staged protocol has proven clinical success in distal tibial fractures, especially if higher soft-tissue injuries are present (18, 20).

Choosing the correct nail entry point is also an essential requirement for all intramedullary nailing procedures, but with greatest relevance in metaphyseal fractures. The correct entry portal for retrograde nailing with the RTN is at the medial surface of tip of the medial malleolus and just posterior to the tip on true lateral. Using low pressure with the opening devices, a metaphyseal path parallel to the medial cortex is created. There is a potential risk of fracturing the medial malleolus at this stage or during the following nail insertion. This caution is important because a large population of patients have an osteopenic/-porotic bone structure. AO/OTA 43-A2/3 fractures, which we consider ideal indications for retrograde nailing, are considered to be fragility fractures (4). However if the entry portal is created with care and nail introduction equally carefully, this complication can be avoided. During our implantations, no fracture of the medial maleollus occurred. If the medial malleolus breaks, it should be reduced and fixed with lag screws. Depending of the resulting accessibility of the entry portal, retrograde nailing can be finished or a change of procedure to plate osteosynthesis has to be carried out.

Figs 2a–d. Retrograde tibial nailing in an AO/OTA 43A1 fracture. Fluoroscopy image of an AO/OTA 43A1 fracture in AP (Fig. 2a) and lateral (Fig. 2b) view treated by retrograde tibial nailing (Figs 2c and d).

Our results show that simple extraarticular fractures can be safely reduced by closed means with the help of a percutaneously inserted reduction forceps. Interlocking is carried out very quickly since all locking options can be addressed through the aiming devices. Fluoroscopy can be kept to a minimum. Complex extraarticular fractures may benefit from primary stabilization with an external fixator, or alternatively the temporary intraoperative use of a large distractor. Otherwise axis length and rotation may not be controlled adequately in highly comminuted metaphyseal fractures.

Antegrade intramedullary nailing augmented with primary screw fixation of the articular block has been published as a safe alternative to plating of intraarticular distal tibial fractures (12, 19). The treatment principles for retrograde nailing are the same. The articular fracture component has to be addressed by lag screw fixation prior to nailing. This mandatory step eliminates the risk of articular displacement during nail insertion. The creation of a metaphyseal path for the nail has to be done with minimal forces and nail insertion has to be performed equally carefully. In our study, anatomic reduction of the articular fracture was achieved in all cases.

Cases of angular malunion by secondary loss of reduction have been published by several authors in the past (10, 19). Modern antegrade nails with interlocking holes in close proximity to the tip of the nail enable the placement of up to four screws in the distal fragment. In some instances of far distal fractures, not all locking options are available. For example, the Expert Tibial Nail (Synthes®, Zuchwil, Switzerland) requires a 40 mm long distal fragment for triple and an approximately 50 mm long fragment for quadruple distal locking (17). The unique RTN design allows to addressing far distal tibial fractures, which go beyond the capabilities of modern antegrade nails. When the nail is placed ideally, with the most distal locking option just proximal to the plafond, all distal locking options are within 25–30 mm to the joint line. Even with optimally placed antegrade nails, triple distal interlocking will require at least a 40 mm long fragment.

Differences also exist when comparing the anatomy of the distal tibial segment with how the two nail concepts achieve their stability. The diameter of the tibial medullary canal increases in the distal segment, forming an hourglass shape. The tibial cortex thins and is centrally replaced by metaphyseal spongiosa. In elderly patients, the structure of the bone changes, resulting in a further increased distal canal diameter and a decreased bone density (6). Due to the nail diameter to medullary

Figs 3a–d. Retrograde tibial nailing in an AO/OTA 43C1 fracture. Fluoroscopy image of an AO/OTA 43C1 fracture in AP (Fig. 3a) and lateral (Fig. 3b) view treated by retrograde tibial nailing after primary lag screw fixation (Figs 3c and d).

diameter mismatch, the stability created by antegrade nails is almost solely dependent on the purchase of the distal locking screws in the cortex. In comparison, retrograde tibial nailing with the RTN achieves a certain degree of stability from the nail within the metaphysis. This is the likely reason why biomechanical investigations of ante- versus retrograde tibial nailing showed superior biomechanical performance for the RTN in an AO/OTA 43-A3 fracture model (14, 15). The studies showed comparable axial stability for the two implant types however a statistically higher rotational stability for the RTN. Absolute movements were reduced by a factor 2.5 to 3.0. Since mainly torsional and sheer stresses have proven to delay bone healing, this might influence secondary malalignment and delayed/non-union rates (1, 7).

As a small caliber, local implant, the RTN is minimally invasive and displays maximum soft tissue protection. Another positive aspect is the capability of radiation-free proximal and distal interlocking. The nail allows intramedullary nailing of fractures within the problematic to treat metaphyseal segment. Indications to be considered are all far distal tibia shaft fractures within 7 cm to the joint line (AO/OTA 42-A-C), distal extraarticular metaphyseal tibia fractures (AO/OTA 43-A1/A2/A3) and distal tibial fractures with simple intraarticular involvement (AO/OTA 43-C1/C2). The RTN offers additional conceptual advantages over antegrade nails, which were not addressed in detail in this study. Using a short retrograde nail spares the knee joint and patella tendon avoiding any possibility for anterior knee pain, which is the most common complaint after antegrade tibial nailing (5, 2, 23). Additionally the short implant leaves most of the medullary canal uninvolved, reducing the risk for fat emboli, which occur during reaming and nail insertion through the isthmus (3, 21).

There are certain limitations to this study we would like to address. Cadaveric implantation studies cannot fully recreate a surgery on an actual patient. Osteotomies created by saw and chisel only partially reflect a true fracture. Also this technique does not lead to soft tissue swelling. Additionally, due to differences between a lab and operating room settings, duration of surgery might be influenced. However we consider it to be a good preclinical evaluation technique on the way to a later surgical application.

CONCLUSIONS

In this study the RTN has demonstrated the general ability to be used in distal extraarticular metaphyseal tibial fractures (AO 43-A1/A2/A3) and distal tibial fractures with simple intraarticular involvement (AO 43-C1 and 43-C2). In our opinion this new minimally invasive concept provides biological and mechanical advantages over antegrade nails and plates and can further extend the indications for intramedullary nailing in distal tibial fractures.

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