Injury, Int. J. Care Injured 45S (2014) S66–S70

Contents lists available at ScienceDirect

Injury

journal homepage: www.elsevier.com/locate/injury

Fracture near press-on interlocking enhances callus mineralisation in a sheep midshaft tibia osteotomy model

G. Gradl [a,*], P. Herlyn [a], J. Emmerich [a], U. Friebe [b], H. Martin [c], T. Mittlmeier [a]

[a] *Department for Trauma and Reconstructive Surgery, University of Rostock, Germany*
[b] *MediClin Müritz-Klinikum, Clinic for Anaestesiology and Intensive Care Medicine, Waren, Germany*
[c] *Institute of Biomedical Engineering, University of Rostock, Germany*

ARTICLE INFO

Keywords:
Press-on interlocking
Midshaft tibia osteotomy
Intramedullary nailing
Callus mineralisation
Micro-CT
Vascularisation

ABSTRACT

Introduction: Factors which impair fracture healing after intramedullary (IM) nailing of long bone fractures range from surgical and biological factors to mechanical parameters. Mechanical parameters known to prolong bony consolidation are share forces at the site of the fracture. Fracture near press-on interlocking reduces share forces directly at the fracture site and is hypothesised to enhance callus mineralisation. A sheep model of midshaft tibia osteotomies evaluates the technique.
Materials and methods: Fracture near interlocking was achieved by surfacing a custom made nail with special hutches that enable firm screw seating on top of the nail ("golf ball" structure). Virtual (fine element analysis (FEA)) and biomechanical pilot tests were completed before in vivo application in 12 adult female German black sheep. Midshaft tibia osteotomy was performed creating a subcritical 7 mm gap for delay in union. One group ($n = 6$) was treated with reamed IM nailing employing the custom made nail and in addition to proximal and distal standard interlocking a fracture near press on interlocking was employed. A second group of six sheep without additional press on interlocking served as control. 10 weeks after operation the quality of fracture healing was determined by micro-CT.
Results: The FEA showed that axial loading up to 4000 N did not lead to implant fatigue. Fracture near press on interlocking led to significantly more callus mineralisation compared to the conventional interlocking procedure (0.567 g/cm^3 $\pm$ 0.106 g/cm^3 versus 0.434 g/cm^3 $\pm$ 0.0836 g/cm^3, $p = 0.043$).
Conclusions: Fracture near press on interlocking increases callus mineralisation in a subcritical osteotomy model in sheep. The results indicate that the reduction of share forces at the fracture site after nailing procedures may be effective in reducing the time until bony consolidation.

Introduction

Intramedullary nailing (IM) continues to be the gold standard of treatment of long bone diaphyseal fractures [1–6]. The healing time of midshaft tibia fractures averages four months after intramedullary nailing, although non operative fracture care may last considerably shorter. The healing process can be influenced not only by the quality of fracture reduction and biological factors but also by mechanical parameters.

Enhancement of mechanical stability in IM nailing can be achieved by two major techniques. One is interlocking of the nail and the other one of press-fit of the nail in the IM canal using excessive reaming. Excessive reaming bares the risk of heat-induced bone necrosis, which has to be avoided [7]. However, minimal reaming with less mechanical effect offers the advantage of slightly improved press-fit together with less deterioration of cortical blood supply [8].

Biological effects of reaming can be classified into systemic and local. The former has been associated with intravasation of fat into the venous system, whereas the latter affects the diaphyseal bone blood flow, which changes from centrifugal to centripetal. Intramedullary nails – particularly tightly fitted reamed nails – may interfere with the subsequent revascularisation process of the bone and might lead to a higher risk of non-union and infection [7,9,10]. Nails inserted with the unreamed technique, possessing a smaller diameter, appear to lessen these effects on the bone vascular kinetics but their use has been complicated with early fatigue of locking screws and the nail itself [11,12]. The controversy about the advantages and disadvantages of reamed vs. unreamed nailing is ongoing, although recent literature suggests a beneficial effect of reaming in closed tibia shaft fractures [13].

* Corresponding author at: Department for Trauma and Reconstructive Surgery, University of Rostock, Schillingallee 35, 18055 Rostock, Germany.
Tel.: +49 381 4946050; fax: +49 381 4946052.
E-mail address: georg.gradl@med.uni-rostock.de (G. Gradl).

0020–1383/$ – see front matter © 2013 Elsevier Ltd. All rights reserved.
http://dx.doi.org/10.1016/j.injury.2013.10.028

The mechanical environment of a fracture (type of stabilisation) plays an important role in the development of a successful fracture healing response. Even well-vascularised fracture healing zones could develop non-union if mechanical stability is insufficient favouring a more fibrocartilaginous callus formation [14,15]. Proximal and distal locking retains the intramedullary nail in the precise position relative to the proximal and distal fracture fragment. Besides the problem of fatigue breakage of the locking screws, this procedure does not eliminate the fracture-near movement. Although it is widely accepted that moderate axial movement accelerates healing it still remains unclear in which range these movements provide an effective stimulus for periosteal callus formation [16]. The effect of shear movement is unclear but excessive shear appears to decelerate the healing process [17]. For an external stabilised sheep model Augat et al. ascertained that axial movement defined of 1.5 mm resulted after 8 weeks in a threefold increase in bone formation. A possible cause for this finding might be the disadvantageous effects of shear movements on the vascularisation of the healing zone [18].

The aim of the present study is to draw consequences out of the little evidence that we have about IM nailing and bony healing. The study tries to combine the special biological advantages of minimal reamed nailing with the mechanical advantages of improved stiffness and nail press fit in the IM canal. By using a new technique of press on interlocking close to the fracture site without penetrating the nail this surgical procedure strongly reduces share forces directly at the fracture site, without the need of a firm nail-cortical press fit. The hypothesis is that this technique will add stability and at the same time does not negatively affect vascularisation that will in turn lead to a better callus mineralisation.

Materials and methods

Intramedullary nail

The study used a custom made intramedullary nail, especially designed for the sheep tibia model and engineered by MORE Medical Solutions (Rostock, Germany). In order to create a firm fix, seating cavities were placed on the nail surface matching exactly to the screw tip leading to a "golf ball" structure (Fig. 1). The dimensions of the nail were 8 × 200 mm, 11 mm in top diameter, 8 mm in lower diameter. Screws were designed to not cross the intramedullary nail, but press on top of the nail fixing the nail in the medullary canal (press on interlocking).

FEA

In a mid-shaft fracture model of a 30 mm fracture gap a 9 mm canulated nail was tested virtually (FEA) and biomechanically (4 in 1 testing machine) in either artificial bone (Remshape BM5166) or fresh frozen human cataveric femur. Interlocking nailing consisted of 3 screws inserted at each side of the fracture being anchored with a torque of 0.93–3.13 N (Fig. 2). The model of the screw was loaded by an axial force, which was calculated from the maximum screw fastening torque. The nail was loaded by the maximum possible screw force in each deepening. The material law was assumed to be linear elastic with Young's modulus of 210 GPa for screw and 160 GPa for nail. A non-linear finite element analysis was performed.

Fig. 1. Intramedullary nail in total view (A) and in detail showing the "golf ball" structure of the surface (B).

Surgery

In the present animal study (LALLF M-V/TSD/7221.3-1.2-046/08), 12 adult female German black sheep (average weight: 69 kg) were treated with reamed IM nailing with minimal reaming. One group ($n = 6$) was treated with a reamed tibia nailing and conventional proximal and distal two fold interlocking. In the second group six sheep were treated by reamed tibia nailing and additional fracture near press on interlocking.

The operative procedure was performed under general anaesthesia. The anaesthetised sheep was placed in supine position and the right leg was shaved and disinfected. A longitudinal skin incision was made in the distal part of the patellar tendon between the tip of the patella and the tibial tuberosity. The patellar tendon was split longitudinally. The entry zone of the nail was located on the anterior aspect of the tibial plateau. The bone was penetrated with an awl. Subsequently, a straight awl (∅ 9 mm) was positioned in the direction of the diaphyseal medullary canal and the fracture zone was marked under fluoroscopy monitoring. After introducing the guide wire into the medullary cavity, it was drilled with the reamer (diameter of reamer heads 7.0 mm, 7.5 mm and 8.0 mm, respectively). To produce the fracture zone the first osteotomy was performed at the marked place with the gigli saw. The locking nail was inserted with the targeting instrument. For proximal interlocking the tissue protecting sleeve was inserted into the hole of the targeting instrument. A skin incision was made and the inner drill sleeve was inserted into the tissue protecting sleeve and pushed forward to the bone. The interlocking hole was drilled. Two proximal interlocking screws were inserted. Distal locking was carried out

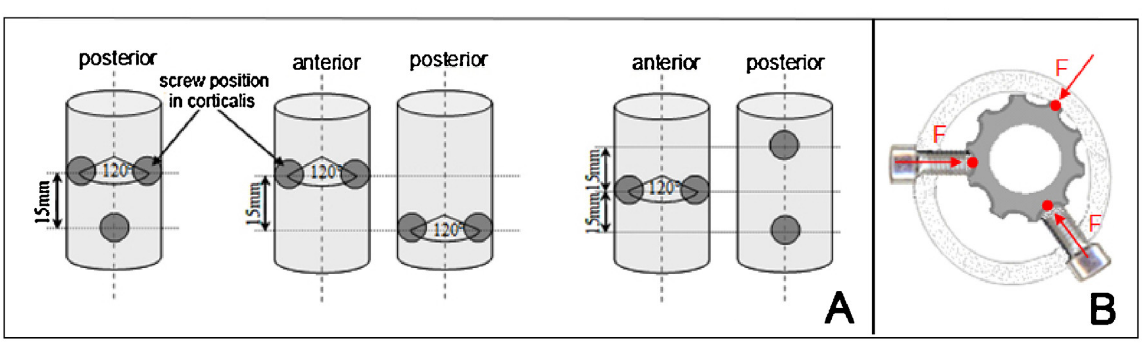

Fig. 2. Experimental set-up for FEA. (A) Alternative screw positions. (B) Schematic demonstration of the cross-section showing the effective forces which result in the fixation of the intramedullary nail inside of the cortical bone.