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Is there a bone-nail specific entry point? Automated fit quantification of tibial nail designs during the insertion for six different nail entry points

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ABSTRACT

Intramedullary nailing is the standard fixation method for displaced diaphyseal fractures of tibia. Selection of the correct nail insertion point is important for axial alignment of bone fragments and to avoid iatrogenic fractures. However, the standard entry point (SEP) may not always optimise the bone-nail fit due to geometric variations of bones. This study aimed to investigate the optimal entry for a given bone-nail pair using the fit quantification software tool previously developed by the authors.

The misfit was quantified for 20 bones with two nail designs (ETN and ETN-Proximal Bend) related to the SEP and 5 entry points which were 5 mm and 10 mm away from the SEP.

The SEP was the optimal entry point for 50% of the bones used. For the remaining bones, the optimal entry point was located 5 mm away from the SEP, which improved the overall fit by 40% on average. However, entry points 10 mm away from the SEP doubled the misfit.

The optimised bone-nail fit can be achieved through the SEP and within the range of a 5 mm radius, except posteriorly. The study results suggest that the optimal entry point should be selected by considering the fit during insertion and not only at the final position.

1. Introduction

Intramedullary nailing is the standard fixation method for displaced diaphyseal fractures of tibia in adults. Previous studies demonstrated that the location of the insertion point is important for axial alignment of the bone fragments [1–3]. Moreover, the medial insertion point caused a valgus deformity, together with the medial shift of distal fragment [1]. The lateral entry point resulted in varus deformity, together with a lateral shift of the distal fragment. Moreover, an improperly placed nail insertion point may cause iatrogenic fractures during the nail insertion. Selection of the most appropriate nail entry point is quite a challenging task [4]. Ideally, insertion point would allow the nail to travel down the centre of the intramedullary canal of both fracture fragments ending in the centre of the distal tibia. One of the previous studies recommends that the insertion point should be over the medial aspect of the tibial tubercle in the coronal plane. Moreover, that study recommends that insertion sites lateral to tibial tubercle should be avoided [2]. However, these recommendations were based on straight nails. As modern tibial nails contain an anterior proximal bend which moves the entry point anterior [5], there is still a need to investigate the effect of different entry points for these modern designs.

Generally, the nail entry point has been defined using an average bone in the implant manufacturers' technical guides [6,7]. The geometry of an individual bone may deviate from this average bone geometry due to age and ethnicity. In addition, nails are typically designed with the view to fit at least the 50th percentile of a patient population [8]. Therefore, the commonly defined nail entry point in an implant manufacturers' technical guide may not be the optimal nail entry point for a particular bone and nail.

The traditional approach for investigating the effect of the different nail insertion points was based on cadaver bone trials and post-operative X-ray images [1–3, 9]. The validation through cadaver bones is limited by the generally small number of available specimens. Furthermore, age and ethnicity of the specimens might not be representative of the target population. Unlike for the fit assessment of plates, bones from collections or museums cannot be used for nail entry point validation studies due to the damaging effect which the insertion would have on the specimen [8]. Furthermore, the same bone can usually not be used for investigating the effects of different entry points especially if they are close together, as the nail tends to slip into the hole that has been generated for the first insertion. The planar X-ray images do not necessarily reflect the true fit of nail to the bone in 3D. Because of these limitations, X-ray images cannot

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be utilised effectively for quantifying the bone-nail misfit associated with different nail insertion points. In addition, planner X-rays contain an unknown amount of magnification and distortion which have a potential impact on subsequent nail fit quantification [8].

Therefore, to address these limitations, computer 3D models of bones and nails were used for this study. Commercially available software has very limited capability for assessing the nail fit during the insertion. Therefore, the 'Fit Quantification Software Tool' which was previously developed by the authors was utilised to quantify the nail fit during insertion [10].

The first objective of this study was to investigate whether there is a nail and bone specific entry point. A nail insertion point which optimises the fit during insertion may not always optimise the fit at the final level [10]. Therefore, the second objective was to determine whether the optimal fit during insertion or the optimal fit at the final level should be considered for selecting the optimal nail insertion point for a given bone-nail pair.

To the best of our knowledge, this is the first study that quantitatively investigates the effects of entry point location on nail fit during insertion and at the final position.

2. Materials and methods

2.1. 3D morphological bone data

Twenty 3D models of the inner cortex surfaces of tibiae which were reconstructed according to a standard protocol from lower extremity CT scans of Japanese cadaver specimens were available from the previous study [8]. The pixel size was 0.39 mm × 0.39 mm with 1 mm image slice space for all the CT scans. Only the right tibiae were used from 6 male and 14 female donors and all the models were considered to be of normal appearance. The mean age of the specimens was 64 years (SD: 10.6 years, range: 44–77 years) with a mean height of 155 cm (SD: 8.4 cm, range: 142–178 cm). The 3D models were saved in the STL-file format and then imported into Matlab (The Mathworks, Natick, MA) as matrices of vertices and faces.

2.2. 3D models of nails

Two nail designs (ETN (Expert Tibial Nail) and ETN-Proximal Bend – Synthes, Bettlach, Switzerland) in the form of digital models were used as in the previous study [8]. The ETN-Proximal Bend is a modified version of ETN. For the modified design, the proximal bend of the nails has been moved to a more proximal location. In addition, the distal part of the nail contains another bend towards the anterior cortex (Fig. 1). According to clinical conventions, the appropriate nail length for each bone model was determined and the nail diameter was chosen such that the nail sufficiently fills the medullary cavity for achieving a stable bone-nail construct using the radiographic ruler and diameter gauge available in manufacturer's technical guide. The digital files were imported into the reverse engineering software package Rapidform2006 (Inus Technology Inc., Seoul, Korea) where the outer surfaces were extracted and converted into polygon meshes. All 3D polygon meshes of the nails' outer surfaces were imported into Matlab (The Mathworks, Natick, MA) as matrices of vertices and faces.

2.3. Automated fit quantification tool

The automated fit quantification tool for assessing the bone-nail misfit during the insertion as well as at the final position was developed by the authors in a previous study [10]. Firstly, the fit quantification methods were developed and then coded in Matlab (The Mathworks, Natick, MA) software using computer programming techniques and related mathematics. The tool was programmed to automatically insert the nail model at user defined increments into the 3D model of the inner cortex surface until the nail was fully inserted. For this study, starting at the entry point, the anatomical fitting was quantified at 15 mm increments until full insertion. The nail tip was positioned at the centroid of the bone cross section to initiate the searching for the optimal point at any given level. This avoids the risk of posterior proximal iatrogenic fractures due to a flat insertion angle at the first few levels before the nail engages with the cortical shell (Fig. 3). During the searching and fit quantification process, the proximal part of nail was always centred at the nail entry point on the bone model.

2.4. Nail entry points

Five candidate entry points were established around the standard entry point (SEP) for the Expert Tibial Nails. The SEP on the inner cortex surface was defined according to the implant manufactures' guidelines such that the entry point is in line with the axis of the intramedullary canal and with the lateral tubercle of the inner-condylar eminence in AP view and at the ventral edge of the tibial plateau in lateral view [6,8]. The candidate nail entry points were defined around the SEP by considering the anatomy of the proximal tibia and knee joint. Two nail entry points were established 5 mm and 10 mm laterally from the SEP and named L5 and L10 respectively. Similarly, another two nail entry points were defined at 5 mm and 10 mm medially from the SEP and named M5 and M10 respectively. Another entry point was defined at 5 mm anterior from the SEP and named A5. No entry points on the posterior side were established as well as the entry point, which is 10 mm away from the SEP in anterior side because of the clinical unacceptableness of these points due to the tibial geometry (Fig. 2). A distance of 5 mm was considered to be within a surgically acceptable range, while 10 mm would be a considerable deviation from the SEP for the normal bone anatomy.

2.5. Quantification of nail fit

Ideally, the anatomically shaped nail fits entirely inside the medullary cavity of the bone which means that the bone-nail

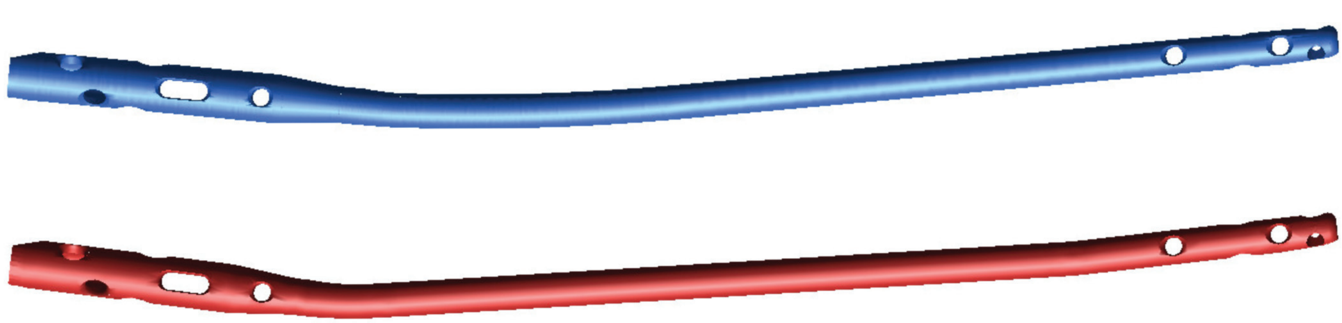

Fig. 1. The two nail designs: ETN (blue/top) and ETN-Proximal Bend (red/bottom). (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)