Automated fit quantification of tibial nail designs during the insertion using computer 3D modelling

Jayani P Amarathunga[1], Michael A Schuetz [1, 2], Prasad KVD Yarlagadda[1, 3], Beat Schmutz[1]

Jayani P Amarathunga

Institute of Health and Biomedical Innovation, Queensland University of Technology, Australia

Michael A Schuetz

Institute of Health and Biomedical Innovation, Queensland University of Technology, Australia; Trauma Services and Orthopaedics, Princess Alexandra Hospital, Australia

Prasad KVD Yarlagadda

Institute of Health and Biomedical Innovation, Queensland University of Technology, Australia; School of Chemistry, Physics and Mechanical Engineering, Science and Engineering Faculty, Queensland University of Technology, Australia

Beat Schmutz

Institute of Health and Biomedical Innovation, Queensland University of Technology, Australia

Corresponding author

Beat Schmutz, Institute of Health and Biomedical Innovation, Queensland University of Technology, 60 Musk Avenue, Kelvin Grove, QLD 4059, Australia.

Email: b.schmutz@qut.edu.au

Abstract

Intramedullary nailing is the standard fixation method for displaced diaphyseal fractures of the tibia. An optimal nail design should both facilitate insertion and anatomically fit the bone geometry at its final position in order to reduce the risk of stress fractures and malalignments. Due to the nonexistence of suitable commercial software, we developed a software tool for the automated fit assessment of nail designs. Further, we demonstrated that an optimised nail, which fits better at the final position, is also easier to insert.

3D models of two nail designs and 20 tibiae were used. The fitting was quantified in terms of surface area, maximum distance, sum of surface areas and sum of maximum distances by which the nail was protruding into the cortex. The software was programmed to insert the nail into the bone model and to quantify the fit at defined increment levels.

On average, the misfit during the insertion in terms of the four fitting parameters was smaller for the ETN-Proximal-Bend (476.3mm^2, 1.5mm, 2029.8mm^2, 6.5mm) than the ETN (736.7mm^2, 2.2mm, 2491.4mm^2, 8.0mm). The differences were statistically significant ($p \leq 0.05$). The software could be used by nail implant manufacturers for the purpose of implant design validation.

Keywords

3D modelling, automation, tibia, intramedullary nail, nail fit, fracture fixation

Introduction

Intramedullary nailing is the standard fixation method for displaced diaphyseal fractures of long bones such as tibia and femur in adults.[1, 2] The anatomically shaped modified tibial nails allows an easier insertion, enhances the 'bone-nail construct' stability, and reduces axial mal-alignments of the bone fragments as well as the risk of stress fractures.[3-6]

The nail shape validation is equally important for both newly designed nail implants and modified nail designs. In the traditional approach, the nail implant validation was conducted using cadaver bone trials or clinical studies. As the nail insertion takes place on the bone, the geometric misfit of the nail to the bone cannot be visually assessed or quantified like in the case of pre-contoured plates.[7] It is to note that, for intramedullary nails, ease of nail insertion as well as anatomical fitting of the nail to the bone at the final position are equally important to reduce the risk of iatrogenic fractures in the intra-operative stage, stress fractures in the post-operative stage and to avoid malalignment of bone fragments. Either, ease of nail insertion or anatomical fitting of the nail to the bone at the final implanted position cannot be visually assessed.

Traditionally, the anatomical fitting of nail designs is assessed through cadaver trials. While they form an important and integral part of the validation process they suffer the following drawbacks. The insertion force associated with the insertion depth of the nail can be obtained by utilising an instrumented nail. Even though this load history profile can be used as an indicator for the anatomical fitting of the nail design to a particular bone, it does not provide any information about the locations where the mismatches occurred or the extent of mismatch of the nail implant to the bone..[8] In addition, this method cannot be used for obtaining the anatomical mismatch of the nail design to the bone when the nail is at its final implanted position.

The utilisation of x-ray images is an alternative for assessing the anatomical fit of the nail design to a particular bone. However, x-rays are in the form of 2D and it does not necessarily indicate the true fit between nail and the bone in 3D. Moreover, x-rays contain an unknown amount of magnification and distortion which adversely affect to the accuracy of the bone-nail fit quantification data.

The nail implant validation in the form of cadaver bone trials is also limited by the availability of number of cadaver specimens.

Furthermore, the available collection of the cadaver specimens might not truly represents the target patient population in terms of age, ethnicity as well as the stature.

In addition, cadaveric specimens are not suitable for assessing different nail designs with the same bone, as multiple insertions and removals can compromise the structural integrity of the bone.[8]

To address the limitations associated with traditional approach, the authors have previously developed a semi-automated method utilising computer 3D models of bone and nail implants for quantifying the anatomical misfit of nail designs in their final position inside 3D tibiae models.[9] The application of that method for twenty Japanese tibia models has demonstrated that the modified Expert Tibial Nail (ETN Proximal Bend) fits better than the original ETN at the final position. In the ideal case, after repositioning the main fragments, the bone geometry should be identical to the intact bone. Therefore, intact tibiae were used in that study for assessing the anatomical fit of the nail designs as this provides a more accurate indication of nail fit for a particular tibia.

While this covers one aspect of the design validation for an intramedullary nail, the question still remains whether the nail design that anatomically fits better at the final position is also easier to insert. It is important to note that, the path of the nail tip during the insertion is determined by both nail design and the bone geometry.

Wallenböck et al have conducted a quantitative study and demonstrated that the nail design influences both the implantability as well as the removal of the nail.[8] Therefore, the answer to this question is of great importance to both implant manufacturers and clinicians alike.

The previously developed virtual method, based on manual processing utilising commercial reverse-engineering software, is not suited for automating and quantifying the nail insertion process.

Therefore the first objective of this study was to develop a customised software tool for assessing the anatomical fit between bone and nail designs during the insertion process and at the final position. The second aim was to determine whether the optimised ETN design, which fits better at the final position, is also easier to insert. To the best of our knowledge, this is the first study which presents a quantitative 3D analysis of bone-nail anatomical fit during the insertion process.

Materials and methods

3D models of bones

3D models of the medullary canals/ inner cortex surfaces of twenty Japanese tibiae were available from the previous study.[9] The morphological bone data was obtained by means of CT scans and reconstructed using a commercial software (Amira, FEI, Hillsboro, OR) according to a standard protocol.

The donors (male-6 and females -14) mean age was 64 years (, range: 44-77, SD: 10.6) and the mean height was 155cm (, range: 142-178, SD: 8.4). We used right tibiae and all the bone models were in the normal appearance with no reported bone deceases. The 3D models were first saved in the STL-file format and then imported into Matlab (The Mathworks, Natick, MA) as matrices of vertices and faces.

3D models of nails

The 3D models of the two different nail designs (ETN (Expert Tibial Nail) and ETN-proximal Bend –Synthes, Bettlach, Switzerland) were used as in the previous study.[9] The ETN proximal bend is a modified version of the original ETN. In order to improve the anatomical fitting of the nail modified ETN (ETN Proximal bend) a new bend has been introduced to the original ETN at the distal tip. In addition, the existing proximal bend has been moved to a more proximal location.

The appropriate nail length for each bone model was chosen according to clinical conventions. The nail diameter was chosen such that the nail sufficiently fills the medullary cavity for achieving a stable bone-nail construct. The digital files were imported into the reverse engineering software package Rapidform2006 (Inus Technology Inc., Seoul, Korea) to extract the outer surfaces and to create polygonal meshes of the nail models as the screw hole or the thread details were not needed. All 3D polygon meshes of the nails' outer surfaces were then imported into Matlab as matrices of vertices and faces.

Nail entry point

The nail entry point on the inner cortex surface was available for each nail and bone model from the previous study. The nail entry point on the inner cortex surface has been established by the authors according to the implant manufactures' guidelines[10] using an anterior and a sagittal view.[9] The nail entry point was same for both nail designs (ETN and ETN Proximal bend) by referring to the manufacturer's technical guidelines.

Quantification of nail fit

In an ideal case, the anatomically shaped nail fits entirely inside the medullary cavity of the bone which means that the bone-nail construct stability is optimal and the axial anatomical alignment of the bone is preserved. If there is a geometrical mismatch of the nail to the bone, the nail model protrudes from the 3D model of the medullary canal of the intact and the extent of nail protrusion indicates the amount of mismatch. Therefore, the anatomical fitting of the nail model to a particular bone was quantified

in terms of the total surface area, and the maximum distance (in the axial plane) by which nail was protruding from the medullary cavity of the virtual model.[9] The sums of protrusions (surface area and maximum distance), calculated at each increment level, were used to assess/quantify the overall fitting of each design for a particular tibia model. The nail fitting was quantified for the unreamed bones. The two-sided paired t-test was used to test for statistical significance. The level of statistical significance was set to $p \leq 0.05$.

Development of automated fit quantification tool

The methods were developed to quantitatively assess the anatomical fit of the nail during the insertion and coded in Matlab software using computer programming techniques and related mathematics. Starting at the entry point, the fit analysis 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 the anatomical fitting was quantified at 15mm increments until full insertion. At each increment level, the optimal nail position (with the least area of protrusion) was obtained and quantified while keeping the proximal part of the nail centred at the nail's entry point on the bone model.

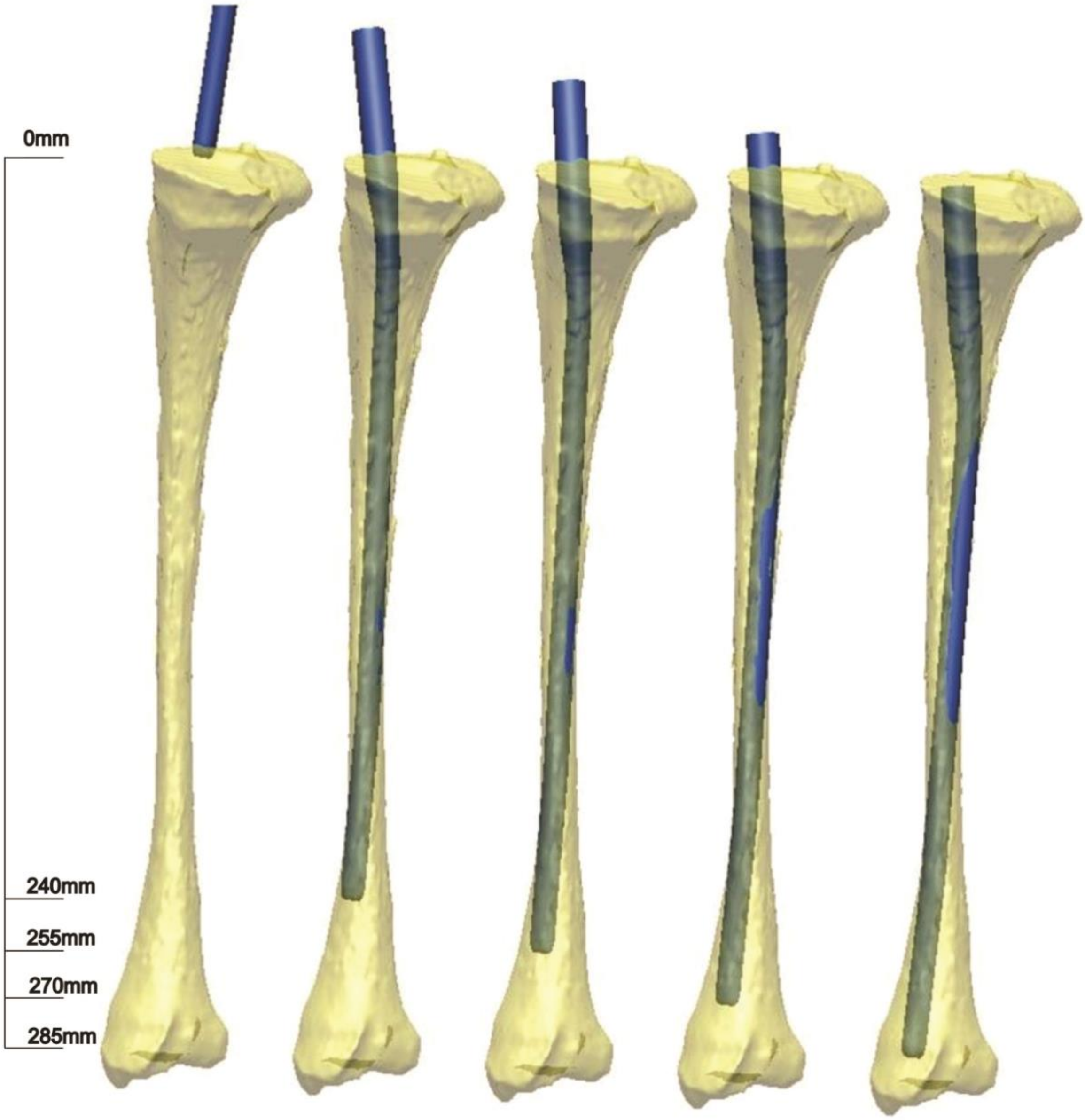


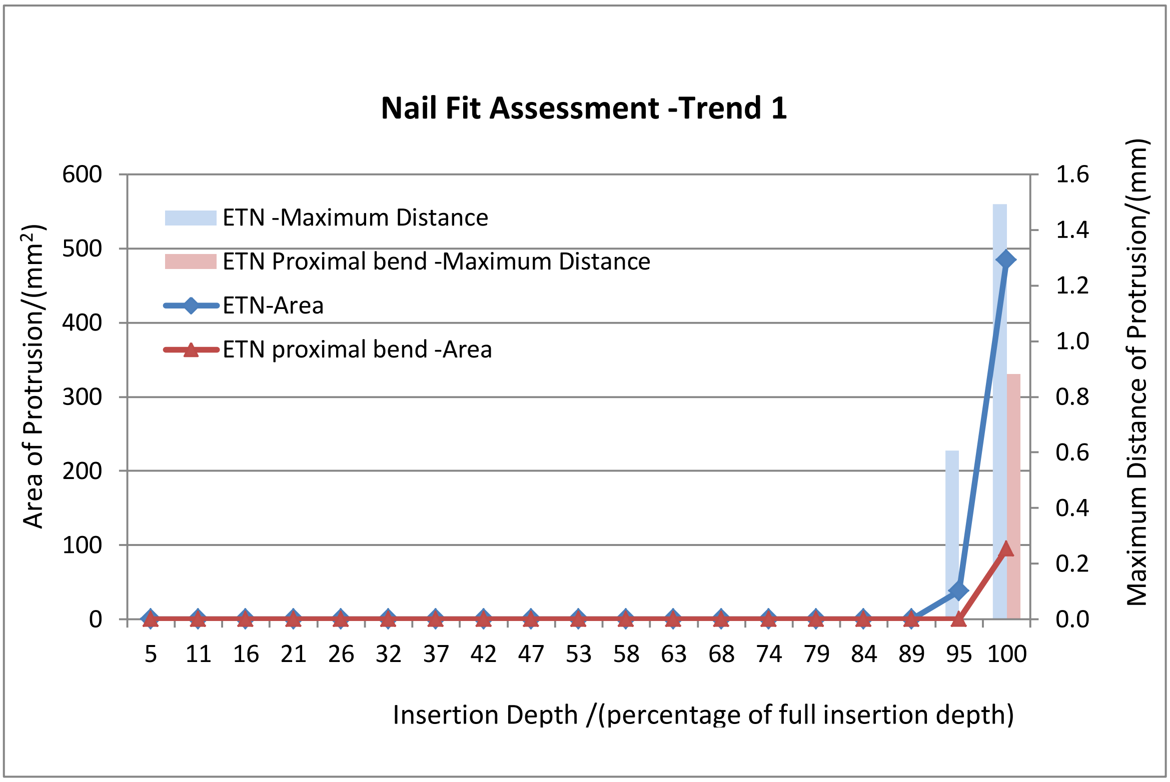
Figure 1: The illustration of the automated nail insertion into the inner cortex surface. The nail insertion levels are set at 15mm. Left to right: The first image shows the start of the insertion, with the tip of the nail at the entry point on the bone. The remaining images show the last 4 increment levels of the nail insertion. The nail protrusion from the medullary canal is clearly visible on the posterior side of the bone for the last 3 levels.

The overall misfit in terms of the sums of surface areas of nail protrusions from the medullary cavity was smaller for 18 out of 20 bone models (mean: 2029.8mm^2, SD: 4149.2mm^2, range: 3.1-18330.2mm^2) for the ETN-Proximal bend compared to the ETN (mean: 2491.4mm^2, SD: 4454.4mm^2, range: 197.5-20544.9mm^2). Similarly, the overall misfit in terms of the sum of maximum distances of nail protrusion for the ETN Proximal bend was smaller in 17 out of 20 bone models (mean: 6.5mm, SD: 7.5mm, range: 0.9 -34.0mm) than for the ETN (mean: 8.0mm, SD: 10.5mm, range: 1.1-50.7mm). The difference between the original ETN and ETN Proximal bend in terms of overall misfit based on total surface area was statistically significant (ρ <0.05). However the differences between ETN and ETN Proximal bend in terms of the overall misfit based on maximum distance of protrusion was not statistically significant.

Similarly, the greatest misfit during the insertion in terms of the maximum area of the nail protrusion for the ETN-Proximal bend was smaller for 18 out of 20 bone models (mean: 476.3mm^2, SD: 628.0mm^2, range: 2.0-2591.6mm^2) compared to the ETN (mean: 736.7mm^2¸SD: 637.0mm^2¸ range: 92.6-2822.5mm^2). Also the greatest misfit in terms of the maximum distance of protrusion for the ETN –Proximal bend was smaller for 18 out of 20 bone models (mean: 1.5mm, SD 1.0mm, range: 0.6-4.5mm) than that for the ETN (mean: 2.2mm, SD: 1.4mm, range: 0.6-6.7mm). The difference between the original ETN and the ETN Proximal bend in terms of the greatest misfit based on both surface area and the maximum distance of protrusion was also statistically significant (ρ<0.05). The results are summarised in Table 1.

By plotting the area and maximum distance of the nail protrusion against the percentage nail insertion depth, we were able to identify three trends of nail protrusion patterns

Trend 1: The area of protrusion rapidly increased at the last few levels for both nail designs. The overall misfit of the ETN Proximal bend is smaller than that of the ETN. Eight tibiae were in this category (Bone number: 2, 3, 7, 9, 13, 14, 19, and 20).



Please see Figure 2: The illustration of nail protrusion pattern for Trend 1. The insertion depth is presented as a % of the full nail length. The area of protrusion increased rapidly at last few levels for both nails. The overall misfit of ETN Proximal bend is smaller than that of ETN.

Trend 2: The surface area of nail protrusion increased for the ETN Proximal bend after inserting the first half of the full nail length and then decreased within the last few levels compared to the ETN. However, the overall misfit based on the sums and maximum values for the area of protrusion in the ETN Proximal bend was smaller than that of the ETN when considering the whole insertion Six tibiae were in this category (Bone number: 4, 5, 6, 8, 10 and 12).

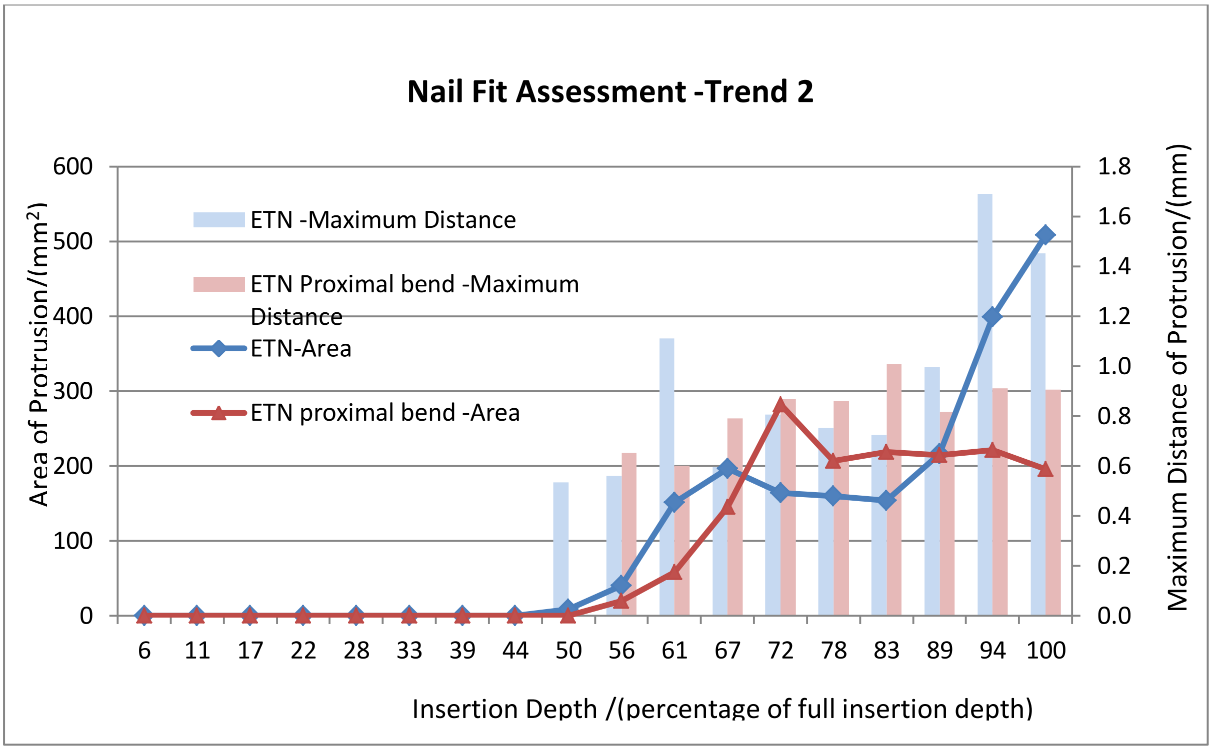
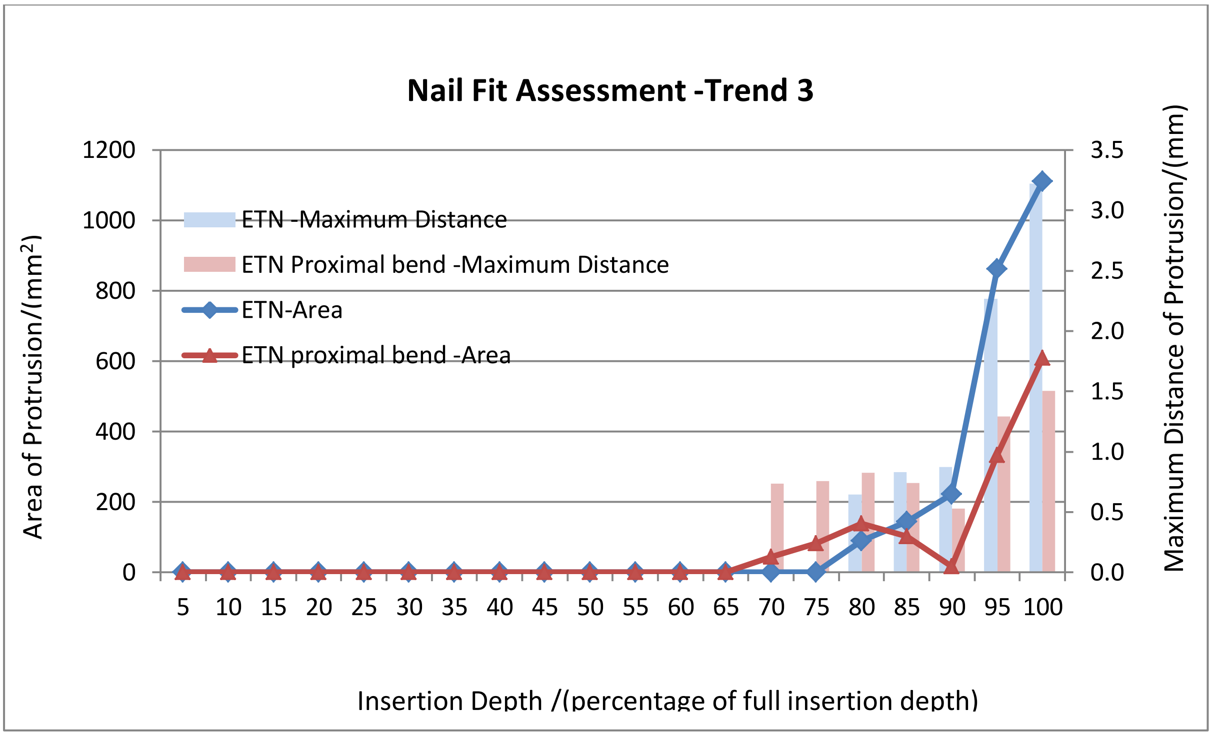


Figure 3: The illustration of nail protrusion pattern for Trend 2. The insertion depth is presented as a % of the full nail length. The area of protrusion increased for ETN proximal bend after inserting the 50% of the nail length and then deceased within the last few levels compared to ETN. The overall misfit of ETN proximal bend is smaller than that of ETN.

Trend 3: The surface area of nail protrusion increased for the ETN Proximal bend after inserting the first half of the nail and then it showed a sinuous pattern. However, the overall misfit of the ETN Proximal bend was smaller than that of the original ETN. Three tibiae were in this category (Bone number: 11, 15 and 18).



Please see Figure 4: The illustration of nail protrusion pattern for Trend 3. The insertion depth is presented as a % of the full nail length. The surface area of protrusion increased for ETN Proximal bend after inserting the first half of the nail length and then it showed a sinuous pattern. The overall misfit of ETN proximal bend is smaller than that of ETN.

It is to note that three tibiae did not fall into one of these categories (Bone number: 1, 16 and 17). In Tibia #1, although the plot of the surface area of the nail protrusion looked like trend 2, the overall fitting was better for the ETN compared to the ETN Proximal bend. Tibia #16 has a very narrow canal and even the smallest nails (8mm diameter) started to protrude when inserted 43% and 33% of the full nail length of the ETN and the ETN Proximal bend respectively. In Tibia #17, the plot of the surface area of the nail protrusion looked like trend 3, however the overall fitting of the original ETN was better when compared to the ETN Proximal bend.

When considering the nail fitting at the final position, the misfit of the ETN Proximal bend was smaller for 19 out of 20 bone models in terms of the surface area of the nail protrusion (mean: 409.0mm^2¸ SD: 603.2mm^2, range: 0-2591.6mm^2) compared to the ETN (mean: 714.8mm^2¸ SD: 640.1mm^2, range: 24.1-2822.5mm^2). Moreover, the misfit of the ETN Proximal bend in terms of the maximum distance of the nail protrusion was smaller for 18 out of 20 bone models (mean: 1.3mm, SD: 1.1mm, range: 0-4.46mm) compared to the ETN (mean: 2.1mm, SD: 1.4mm, range: 0.6-6.7).

For the bone models in this study, the ETN Proximal bend can be inserted 50% of the nail's full length for 19 bone models without any protrusion and by 70% on average. Similarly, the ETN can be inserted 50% of its full length without any protrusion for 18 bone models and by 66% on average.

Regardless of the nail design, the majority of the nails started to protrude at the posterior side of the bone (ETN: 10 out of 20 nail protrusions, ETN Proximal bend: 9 out of 18 nail protrusions) during the insertion. The second main protrusion site was at the medial side of the bone (ETN: 9 out of 20, ETN Proximal bend: 5 out of 20). When considering the nail fitting at the final position, the majority of the nails protruded at the posterior side in the middle third of the tibia (ETN: 15 out of 20 bone models, ETN Proximal bend: 11 out of 17 bone models) and the second main protrusion site was at the medial side of the tibia (ETN: 5 out of 20, ETN Proximal bend: 5 out of 20). For all the cases, during insertion, the protrusion appeared in the mid or distal shaft on the bone. At the final position, the majority of protrusion sites similarly appeared in the mid or distal shaft of the bone, but in two cases, the protrusion site appeared in the distal part of the bone. For trend 3, both nail designs started to protrude in the medial side and then it shifted to the posterior side of the bone at the final position. Other than these observations, we were not able to identify a clear relationship between protruding trends and the protruding side on the bone.

The average elapsed time for processing one pair of bone and nail models was 90 hours. For protrusion trend 1 and 3, the average time elapsed for processing one pair of bone-nail models was shorter (59 hours) compared to the protrusion trend 2 (106 hours), regardless of the nail design. All the fit assessment tasks were executed on QUT HPC (High Performance Computer Centre) group's SGI Altix XE Cluster which is composed of 1924x 64bit Intel Xeon Cores.

Discussion

The optimal design of anatomically shaped nail implants enables ease of insertion and better fitting at the final position. The implant shape validation is one of the most important aspect of designing a new or improving an existing nail design. In traditional approach, the implant shape validation is often conducted through cadaver bone trials and clinical studies based on planar x-ray images.

To address the limitations of the traditional approach, the authors have previously developed a virtual method for quantitatively assessing the anatomical fit of the nail designs in their final position inside 3D tibia models utilising a reverse engineering software.[9] Although the previous study covers one aspect of validation of nail designs, it does not provide any indication whether the nail design which fits better at the final position is also easier to insert. In addition, the previous method utilising commercial software is not capable for of assessing the anatomical fit between nail and bone during insertion.

Therefore, in this study, we addressed the main limitations of the previously developed virtual method. To the best of our knowledge this is the first customised software tool which quantifies the geometric misfit between the nail designs and tibiae during the insertion as well as at the final position. In an ideal case, after repositioning the main fragments, we expect to achieve the original anatomical shape of the bone. In other words, if the nail shape fits better to an intact bone, it is more likely to ensure/allow anatomical alignment of main fragments. Therefore we used intact tibiae to assess anatomical fitting of the two nail designs as they provide the most accurate indication of any geometric mismatch between bone and nail. Egol et al[11] argued that any mismatch in the curvature between the nail and bone can be accommodated by angulation at the fracture and overreaming. However, for proximal or distal shaft fractures, there are cases were a mismatch between bone and nail geometry cannot be eliminated through angulation of the main fragments. It is to note, if the fracture accommodates any large mismatch between bone and nail, then the resulting alignment of main fragments may not be within the clinically acceptable range. Further , a biomechanical study confirmed that overreaming will results in weakening of the bone which may cause iatrogenic fractures and/or post-operative stress-fractures.[12]

Based on the results obtained, the ETN Proximal bend shows a statistically significant better anatomical intramedullary fit with least nail protrusion than the original ETN during the insertion as well as at the final position. The overall misfit in terms of surface area of protrusion is smaller for ETN Proximal bend (average: 2029.8mm^2) when compared to the original ETN (average: 2491.4mm^2). Similarly, the overall misfit in terms of maximum distance of protrusion is also smaller for ETN Proximal bend (average: 6.5mm) when compared the original ETN (average: 8.0mm). The greatest misfit during the insertion in terms of both surface area and maximum distance of protrusion is also smaller for the ETN Proximal bend (average: 476.3mm^2 and 1.5mm respectively) than that of the original ETN (average: 736.7mm^{2,} 2.2mm respectively). The average length by which the nail can be inserted into the bone without any protrusion is 70% of the nails' full length for the ETN

Proximal bend while it is 66% for the original ETN. This suggests that, if at all, stress fractures are more likely to occur during the insertion of the second half of the nail.

The results for the nail fitting at the final position clearly shows that the ETN proximal bend fits better at the final position in terms of both surface area and the maximum distance of protrusion (average: 409.0mm^2, 1.3mm respectively) when compared to the original ETN (average: 714.8mm^2, 2.1mm).

To the best of our knowledge, this is the first study which demonstrates that an optimised tibial nail design which fits better at the final position is indeed also easier to insert. Furthermore, the software tool was developed to function independent of bone and nail geometry. Therefore it will be suitable for quantifying the anatomical fitting of other nails such as femoral nails and humeral nails with only minor modifications and/or extensions of the software code.

A further advantage of the developed software tool is that the different nail designs can be assessed by inserting into the same bone model without damaging the bone, or compromising its structural integrity through the multiple insertions and removals of a nail.. In addition, the customised software tool is designed for quantifying the nail fitting at user defined increment levels which enables detailed investigation in the proximity of the misfits.

Moreover, if morphological bone data is obtained by means of MRI instead of CT, the presented method will be no-radiation as well as non-invasive. Therefore, it is suitable acquiring the bone data from healthy donors to reconstruct the 3D bone models. Then, the developed software tool can be effectively used for the nail fit quantification during the insertion in a particular target population.

The long execution time (average: 90 hours) can be considered as the main limitation of the developed customised software tool and is subject of further research by our group. The current standard methods for reconstructing bone models form CT or MRI data also take a long time. The improved fit quantification software with reduced execution time would need to be also incorporated with a time saving method of bone 3D reconstruction in order to ensure the benefits of the presented method as a pre-operative planning tool in clinics. Furthermore, the developed software tool quantifies only the geometric misfit between bone and nail designs using the two fit quantification parameters (total surface area and the maximum distance of protrusion). As such, the measurements obtained do not yet provide any information regarding the deformation of nail and bone during the insertion process and whether a certain amount of misfit can be tolerated, or might result in fracture extension or even lead to a stress fracture in the bone. Therefore the extension of the present work will be the incorporation of finite element analysis (FEA) into the fit assessment, which will enable the quantification of forces exerted on the cortex through a specific nail design during insertion and/or removal of the nail. The authors are currently working on a project aiming to address this. Even though, the developed software tool mainly facilitates implant shape validation, it could potentially be useful in pre-operative planning assisting the surgeon to choose the most appropriate nail design for the bone geometry of a particular patient. The developed method will facilitate the achievement of full recovery and hence improvement in patients quality of life through the anatomic reduction.

Acknowledgements

David Warner (High Performance Computer centre (HPC), Queensland University of Technology) assisted with advanced software coding.

Funding Acknowledgement

None

Conflict of Interest

Dr. Beat Schmutz has received an industrial scholarship from Synthes GmbH

References

1. Lefaivre KA, Guy P, Chan H and Blachut P. Long-Term Follow-up of Tibial Shaft Fractures Treated With Intramedullary Nailing. *Journal of Orthopaedic Trauma* 2008; 22: 525-9.
2. Penzkofer R, Maier M, Nolte A, Oldenburg GV, Püschel K, Bühren V and Augat P. Influence of Intramedullary Nail Diameter and Locking Mode on the Stability of Tibial Shaft Fracture Fixation. *Archives of Orthopaedic and Trauma Surgery* 2009; 129: 525-31.
3. Henley MB, Meier M and Tencer AF. Influences of Some Design Parameters on the Biomechanics of the Unreamed Tibial Intramedullary Nail. *Journal of Orthopaedic Trauma* 1993; 7: 311-9.
4. Nork SE, Barei DP, Schildhauer TA, Agel J, Holt SK, Schrick JL and Sangeorzan BJ. Intramedullary Nailing of Proximal Quarter Tibial Fractures. *Journal of Orthopaedic Trauma* 2006; 20: 523-8.
5. Kuhn S, Hansen M and Rommens P. Extending the Indications of Intramedullary Nailing with the Expert Tibial Nail. *Acta Chirurgiae Orthopaedicae et Traumatologiae Cechoslovaca* 2008; 75: 77-87.
6. Kuhn S, Hansen M and Rommens PM. Extending the Indication of Intramedullary Nailing of Tibial Fractures. *European Journal of Trauma and Emergency Surgery* 2007; 33: 159-69.
7. Goyal KS, Skalak AS, Marcus RE, Vallier HA and Cooperman DR. Analysis of Anatomic Periarticular Tibial Plate Fit on Normal Adults. *Clinical Orthopaedics & Related Research* 2007; 461: 245-57.
8. Wallenbock E and Koch G. Knick oder Krummung beim unaufgebohrten Tibiamar-knagel: Experimentelle Studie. *Langenbecks Archiv fur Chirurgie* 1997; 382: 257-65.
9. Schmutz B, Rathnayaka K, Wullschleger ME, Meek J and Schuetz MA. Quantitative Fit Assessment of Tibial Nail Designs using 3D Computer Modelling. *Injury* 2010; 41: 216-9.
10. Synthes: Expert tibial Nail:Technique Guide Synthes GmbH. 2006.
11. Egol KA, Chang EY, Cvitkovic J, Kummer FJ and Koval KJ. Mismatch of Current Intramedullary Nails With the Anterior Bow of the Femur. *Journal of Orthopaedic Trauma* 2004; 18: 410-5.
12. Pratt DJ, Papagiannopoulos G, Rees PH and Quinnell R. The effects of medullary reaming on the torsional strength of the femur. *Injury* 1987 5//; 18: 177-9.