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 5mm and 10mm 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 5mm away from the SEP, which improved the overall fit by 40% on average. However, entry points 10mm away from the SEP doubled the misfit.

The optimised bone-nail fit can be achieved through the SEP and within the range of a 5mm 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. 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[4], 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.[5, 6] 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.[7] 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, 8] 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.[7] 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 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.[7]

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.[9]

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.[9] 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.[7] The pixel size was 0.39x0.39mm with 1mm image slice space for the 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 155cm (SD: 8.4cm, range: 142-178cm). 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.[7] 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 *(Figure 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.

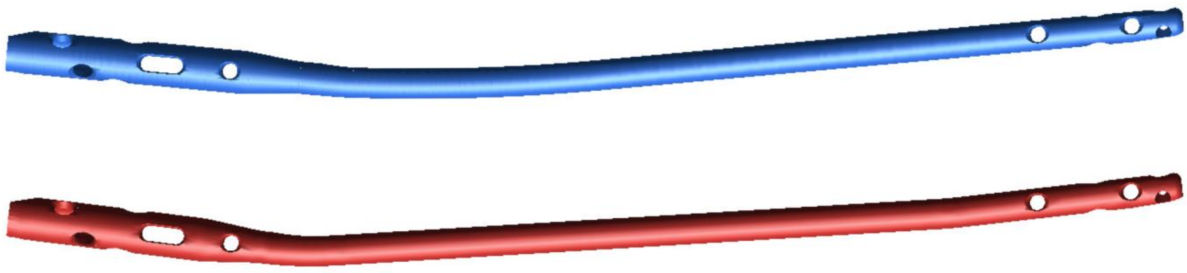

Figure 1: The two nail designs: ETN (blue) and ETN-Proximal Bend (red).

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.[9] 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 15mm 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 (Refer to section 2.5). 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.[5, 7] 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 5mm and 10mm laterally from the SEP and named L5 and L10 respectively. Similarly, another two nail entry points were defined at 5mm and 10mm medially from the SEP and named M5 and M10 respectively. Another entry point was defined at 5mm anterior from the SEP and named A5. No entry points on the posterior side were established as well as the entry point, which is 10mm away from the SEP in anterior side because of the clinical unacceptableness of these points due to the tibial geometry *(Figure 2)*. A distance of 5mm was considered to be within a surgically acceptable range, while 10mm would be a considerable deviation from the SEP for the normal bone anatomy.

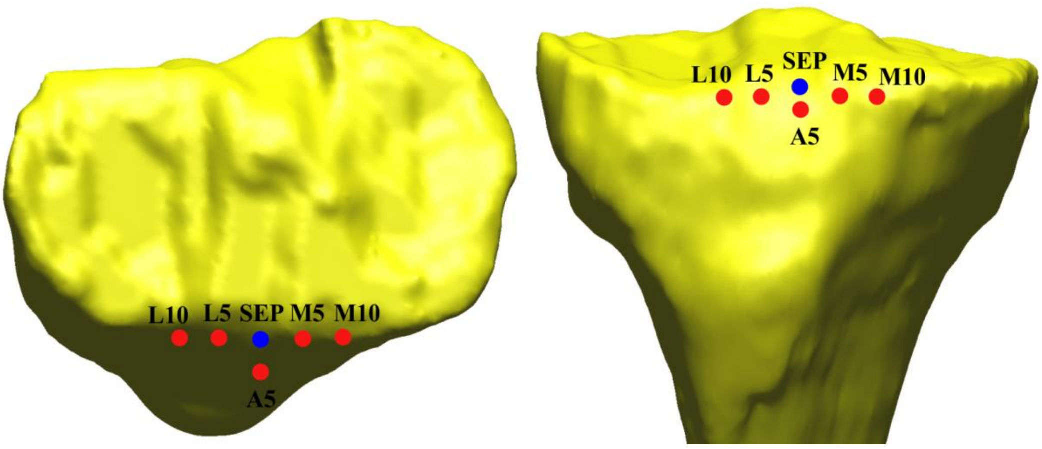

Figure 2: The first figure (left) illustrates the standard entry point (SEP) in blue colour and the other five candidate entry points in red colour in the superior view of the inner cortex surface of the tibia. The right figure illustrates the same entry points in the anterior view of the tibia.

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 construct stability is optimal and the axial anatomical alignment of the bone is preserved. Therefore, the anatomical fitting between nail and bone was assessed by the extent the nail model was protruding from the medullary cavity of a particular intact tibia model *(figure3)*. The fitting 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. [7, 9]

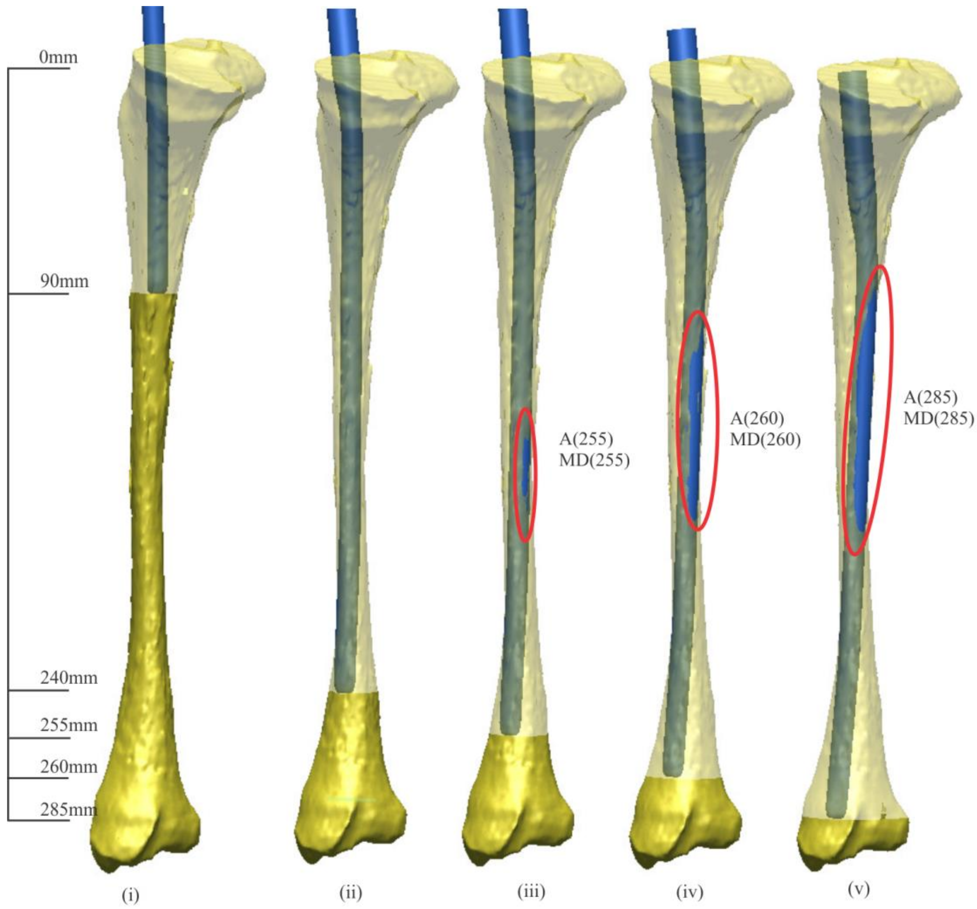

Figure 3: Illustration of the automated fit quantification of the tibial nails during the insertion and calculation of fitting parameters. The virtual levels have been established along the medullary canal with 15mm intervals. (i) The nail tip is 90mm below the insertion level. The nail has not been engaged with the cortical shell. (ii) When the nail tip is 240mm below the nail's entry point, the nail perfectly fits within the medullary canal with no nail protrusion form the medullary canal. (iii -v) The optimal nail positions at the last 3 insertion levels. 'A' is the total surface area and the 'MD' is the maximum distance of nail protrusion. The subscripts denote the insertion depth. The sum of area and the maximum distance were obtained by adding all the area and maximum distance values associated with each insertion level.

2.6 Measurements and determination of optimal entry points

For assessing fit between bone and nail, four different fitting measurements were taken. They are,

a) Sum of the total surface area of nail protrusion calculated at each incremental level,
b) Maximum area of nail protrusion during the insertion,
c) Sum of the maximum distance of nail protrusion calculated at each incremental level,
d) Maximum distance of nail protrusion during the insertion.

In order to simulate the nail insertion, the tip was translated to the different insertion levels which were established with 15mm intervals. The optimal point which gives the lease area of protrusion was searched for the each level. Then, the maximum distance of nail protrusion related to the each optimal point was calculated at each insertion level. The fitting parameter (a) describes the summation of the surface area of the nail protrusion calculated at each insertion level. Similarly, the fitting parameter (c) describes the summation of the related maximum distances calculated at each insertion level *(Figure 3).*

Three analyses were conducted and a candidate optimal nail entry point was determined from each analysis. Finally, the recommendations for selection of the optimal nail entry point for a given bone-nail pair were made by considering all three candidate optimal points resulting from each analyses. The three analyses were,

1) Global/overall fit during the insertion

A candidate optimal entry point called 'Global-Optimal Entry Point' (Global-OEP) was determined by considering the medians of all the fitting measurements (a, b, c and d) which were obtained for 20 bones with ETN and ETN-Proximal bend *(Refer to section: Analysis of results).*

2) Anatomical fitting of individual bone-nail pair during the insertion

A candidate optimal nail entry point called 'During Insertion-Optimal Entry Point' (DI-OEP) was determined for the individual bone-nail pairs by considering all the fitting measurements (a, b, c and d).

3) Anatomical fitting of individual bone-nail pair only at the final level/position.

A candidate optimal nail entry point called 'Final Position-Optimal Entry Point' (FP-OEP) was determined by considering the fitting measurements (a) and (c) obtained only at the final level/ Position.

The fitting was quantified for the unreamed bones.

2. 7 Analysis of results

For assessing the global/overall fit during the insertion and to determine Global OEP, median of all four fitting parameters were considered as the data sets were not normally distributed. 'Kruskal Wallis' test was conducted to investigate the statistically significant differences of fitting parameters between the SEP and candidate entry points.

For assessing the fit of individual bone-nail pairs during the insertion, all four fitting measurements (a, b, c and d) were used and equally weighted. Any fitting measurement which had been optimised by one of the candidate entry points, including the SEP, was listed under that entry point. An entry point which optimised the maximum number of fitting measurements (out of four) was selected as the DI-OEP.

For assessing the fit of an individual bone-nail pair related to the final position, the fitting measurements (a) and (c) were utilised. Entry points which optimised the fitting measurement

(a) and/or (c) were selected as the FP-OEP. Moreover, the plots of those fitting measurements obtained as related to FP-OEP during the insertion were considered in the analysis.

3. Results

3.1 Global/ overall misfit during the insertion and determination of the Global-OEP

The SEP generated the smallest median values for all the fitting parameters (a, b, c, and d) when compared to the five candidate entry points for 20 bones with both nail designs *(table 1)*. Therefore, SEP can be selected as the Global-OEP for both the nail designs: ETN and ETN-Proximal Bend. Moreover, the differences between SEP and 10mm entry points were statistically significant in terms of all four fitting parameters for both nail designs. Also, when considering the statistical differences between SEP and 5mm entry points in terms of four fitting parameters, the majority of ρ values are below 0.05.

able 1: The statistical analysis of overall mist fit for 20 bones in terms of four fitting measurement: (a) Sum of the total surface area of nail protrusion calculated at each incremental level, (b) Maximum area of protrusion during the insertion, (c) Sum of the maximum distance of nail protrusion calculated at each incremental level and (d) Maximum distance of protrusion during the insertion.

Parameter		ETN						ETN Proximal Bend					
		SEP	M5	L5	A5	M10	L10	SEP	M5	L5	A5	M10	L10
a	Median	1584.00	2847.95	2508.88	3246.63	8386.68	3957.29	724.00	2156.69	1983.10	2809.27	7872.90	3960.40
	ρ		0.016	0.465	0.062	0.000	0.009		0.021	0.117	0.016	0.000	0.001
b	Median	528.93	860.15	770.06	687.10	1375.20	1013.47	205.04	689.35	524.85	524.87	1338.55	953.20
	ρ		0.074	0.516	0.433	0.001	0.043		0.028	0.256	0.062	0.000	0.001
c	Median	6.56	12.87	8.70	18.94	32.09	16.63	4.73	10.43	8.88	16.33	30.66	20.79
	ρ		0.004	0.12	0.001	0.001	0.001		0.005	0.042	0.002	0.000	0.000
d	Median	1.74	2.79	2.50	3.29	4.75	3.59	1.06	2.10	1.71	3.27	4.26	3.48
	ρ		0.055	0.507	0.011	0.000	0.006		0.007	0.229	0.002	0.000	0.000

3.2 Misfit of individual bone-nail pairs during the insertion and determination of the DI-OEP

The SEP was not the optimal entry point for all the individual bone-nail pairs. This means, the SEP did not optimise the fit during insertion in terms of four fitting parameters for some of the bone-nail pairs when compared to the other five candidate nail insertion points. For ETN, the SEP was the best entry point (DI-OEP) for 9 out of 20 bones. The A5, L5 and M5 were the best entry points (DI-OEP) for 5, 4 and 2 bones respectively. For ETN-Proximal Bend, the SEP was the best entry point (DI-OEP) for 10 out of 20 bones. The L5, M5 and A5 were the best entry points (DI-OEP) for 5, 3 and 2 bones respectively. The 5mm shifted entry points improved the overall fit by 40% (area: 44%, maximum distance: 37%). Importantly, none of the nail entry points which were 10mm away from the SEP were selected as the optimal entry point for either nail design as they doubled the misfit. (*Table 2 and Figure 4).* The M10 increased the overall misfit of ETN and ETN-Proximal Bend by 205% and 285% respectively compared to the SEP, whereas the L10 increased the overall misfit by 124% on average for both nail designs compared to the SEP.

However, for some of the bones, the best nail entry point did not optimise all the four fitting parameters: a, b, c and d (*Table 2*). Only six tibiae optimised all four fitting parameters for the ETN while it was 14 for the ETN-Proximal Bend. Furthermore, 10 tibiae with ETN optimised three selection criteria out of four, while four tibiae with WTN-Proximal Bend satisfied the same condition. Lastly, four tibiae optimised only two selection criteria for the ETN while it was two for ETN-Proximal Bend *(Table 2).*

Table 2: The numbers of fit parameters satisfied by the each bone-nail pair at each entry point and the selection of DI-OEP.

Bone	Nail design	Number of criteria satisfied for each entry point						DI-OEP	Percentage fit (out of four parameters)
		SEP	A5	L5	M5	L10	M10		
1	ETN	bcd			a			SEP	75%
	ETN PB				abcd			M5	100%
2	ETN			abcd				L5	100%
	ETN PB			abcd				L5	100%
3	ETN	ac	b	d				SEP	50%
	ETN PB	abcd						SEP	100%
4	ETN	abd		c				SEP	75%
	ETN PB	b		acd				L5	75%
5	ETN	abcd						SEP	100%
	ETN PB	abcd						SEP	100%
6	ETN	acd	b					SEP	75%
	ETN PB	abcd						SEP	100%
7	ETN		abc		d			A5	75%
	ETN PB		abcd					A5	100%
8	ETN	abcd						SEP	100%
	ETN PB	abcd						SEP	100%
9	ETN	c	abd					A5	75%
	ETN PB	abcd						SEP	100%
10	ETN	acd	b					SEP	75%
	ETN PB	abcd						SEP	100%
11	ETN	a	bd		c			A5	50%
	ETN PB	ac	b		d			SEP	50%
12	ETN	b		acd				L5	75%
	ETN PB			abcd				L5	100%
13	ETN			abcd				L5	100%
	ETN PB			abcd				L5	100%
14	ETN	c			abd			M5	75%
	ETN PB	abcd						SEP	100%
15	ETN	ac		d		b		SEP	50%
	ETN PB		b		acd			M5	75%
16	ETN	b		ac	d			L5	50%
	ETN PB	bcd		a				SEP	75%
17	ETN	abcd						SEP	100%
	ETN PB	abcd						SEP	100%
18	ETN				abc		d	M5	75%
	ETN PB		c		bd		a	M5	50%
19	ETN		acd	b				A5	75%
	ETN PB		b	acd				L5	75%
20	ETN		abcd					A5	100%
	ETN PB		abcd					A5	100%

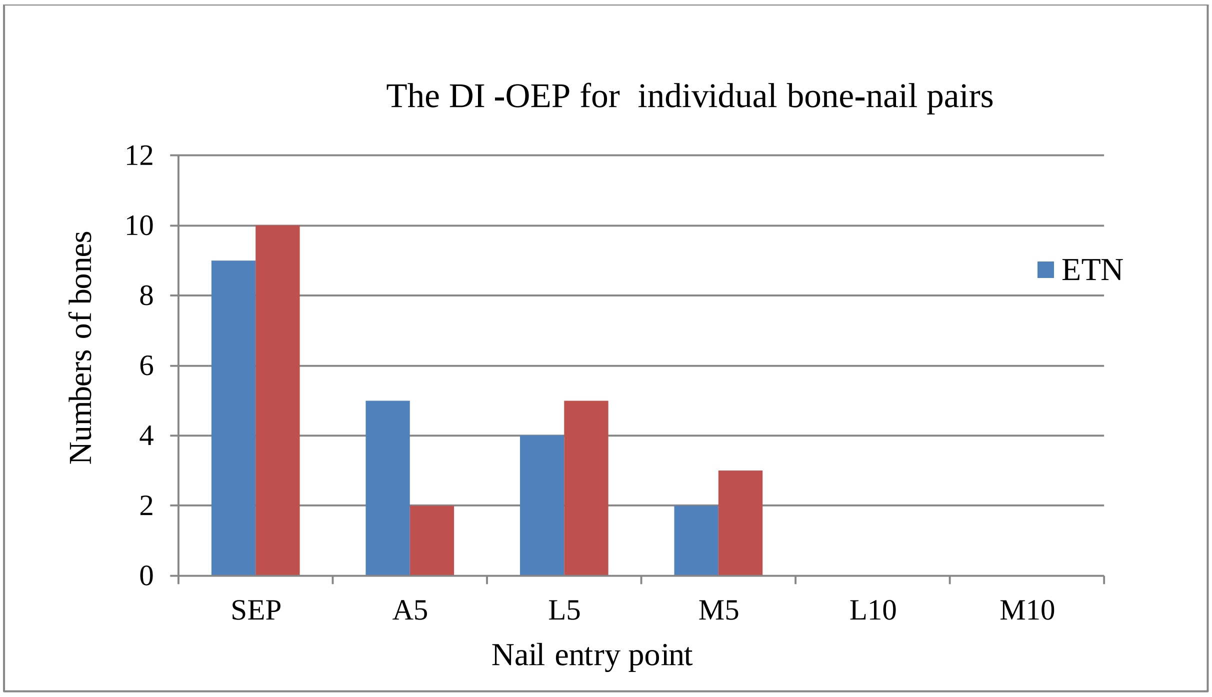

Figure 4: The optimal nail entry point (DI-OEP) for 20 bone-ETN pairs and 20 bone-ETN- Proximal Bend pairs.

3.3 Misfit at the final level and determination of the FP-OEP

The nail entry point which optimised the fit at the final level (FP-OEP) was obtained using the fitting measurements (a) and/or (c). It is important to note that, for a particular bone-nail pair, the entry point which optimised the fit at the final level (FP-OEP) did not optimised the fit during the insertion (DI-OEP) (*Table 3).*There were 13 such cases for each nail design. The plots of surface area and the maximum distance of protrusion during the insertion were created related to the DI-OEP and FP-OEP. Two groups were identified from the protrusion plots.

Table 3: The optimal insertion point which optimised the misfit during the overall insertion (DI-OEP) and the optimal insertion point which optimised the misfit only at the final level (FP-OEP) for both nail designs.

Bone number	ETN			ETN Proximal Bend		
	DI-OEP	FP-OEP		DI-OEP	FP-OEP	
		Area	MD		Area	MD
1	SEP	M10	M10	M5	M10	M5
2	L5	L5	L5	L5	L5	L5
3	SEP	A5	L10	SEP	SEP	SEP
4	SEP	M10	SEP	L5	SEP	SEP
5	SEP	SEP	SEP	SEP	SEP	SEP
6	SEP	L10	L10	SEP	SEP	SEP
7	A5	M10	M10	A5	A5	A5
8	SEP	SEP	SEP	SEP	SEP	SEP
9	A5	M10	M5	SEP	M5	M5
10	SEP	M5	A5	SEP	M5	M5
11	A5	L10	L10	SEP	L10	L10
12	L5	L5	L5	L5	L5	SEP
13	L5	L5	L5	L5	L10	L10
14	M5	M5	A5	SEP	SEP/A5	SEP/A5
15	SEP	L10	L10	M5	M10	SEP
16	L5	SEP	A5	SEP	SEP	A5
17	SEP	SEP	SEP	SEP	SEP	M5
18	M5	M5	M10	M5	M10	M10
19	A5	L5	A5	L5	L10	L5/L10
20	A5	A5	A5	A5	A5	A5

Group 1: The peak generated by the optimal entry point based on the insertion (DI-OEP) is lower than the peak generated by the optimal entry point/s related to the final level (FP-OEP) *(Figure 5)* for both surface area and maximum distance plots. There were six and ten bone-nail pairs in this group for ETN and ETN-Proximal Bend respectively.

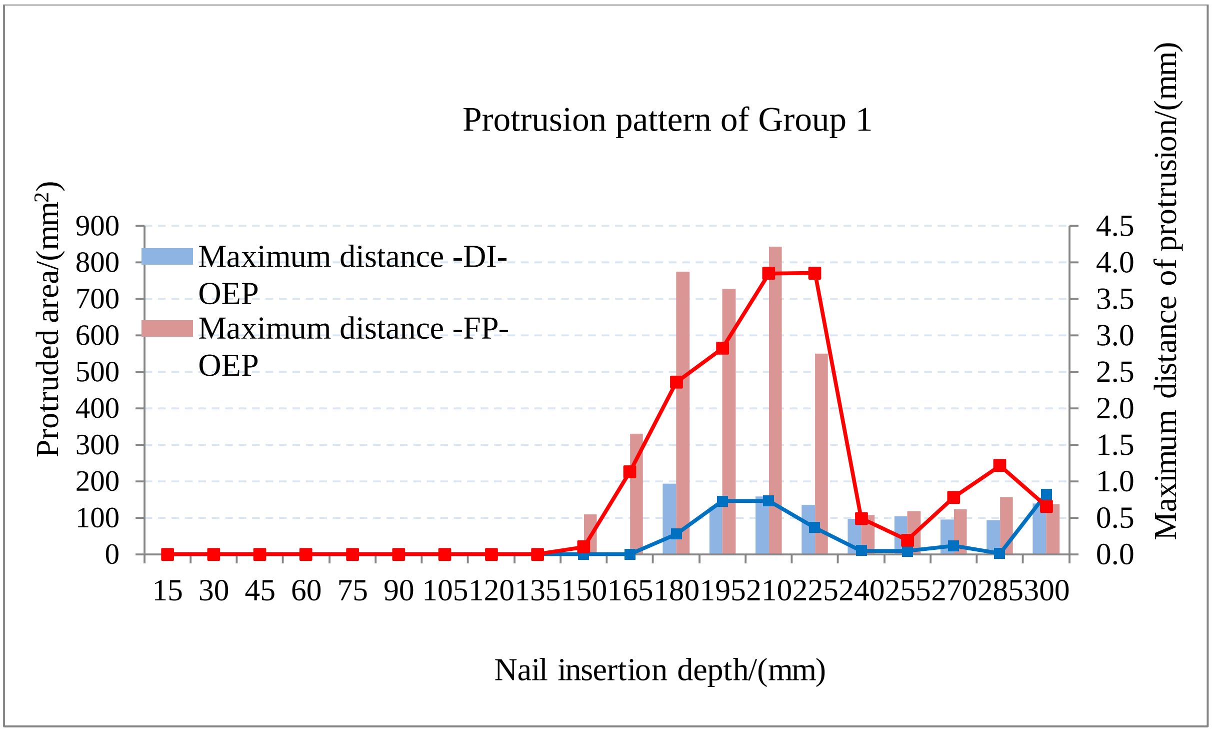

Figure 5: This illustrates the protrusion pattern of Group 1. The FP-OEP generates slightly lower misfit compared to the DI-OEP only at the final level. Although, during the insertion, FP-OEP generates significantly higher peak values for both surface area and the maximum distance of nail protrusion compared to the values generated by DI-OEP.

Group 2: The peak generated by DI-OEP is higher than the peak generated by FP-OEP in one of the plots (maximum protruded area or maximum distance) *(Figure 6)*. For the cases where the peak area generated by DI-OEP is higher than peak area generated by FP-OEP, the difference was 38.32mm^2 on average for the ETN. Also, the difference in the maximum distance was 0.16mm on average for such cases for the ETN. The average differences of protruded area and the maximum distance were 12.31mm^2 and 0.12mm respectively for ETN-Proximal Bend. There were six and two bone-nail pairs in this group from ETN and ETN-Proximal Bend respectively. However, one bone-nail pair with each design (ETN and ETN-Proximal Bend) did not fit in either group. The bone 16 has a very narrow canal and the nail with smallest diameter didn't fit for the canal. Therefore, when the nail was at 33% of full insertion depth, protrusion was generated and then gradually increased over the rest of the insertion levels. Therefore, the plots of protruded area and the maximum distance for this bone with ETN showed that both DI-OEP and FP-OEP generated the similar misfit during the insertion. For the bone 4, the nail size (diameter -8mm) was selected according to the clinical conventions. The selected nail was perfectly fitted until it reaches 80% of the full insertion depth. For the rest of the few levels, protrusion was gradually increased. Therefore, the plots of protruded area and the maximum distance for this bone with ETN-Proximal Bend showed that both DI-OEP and FP-OEP generated the similar misfit during the insertion.

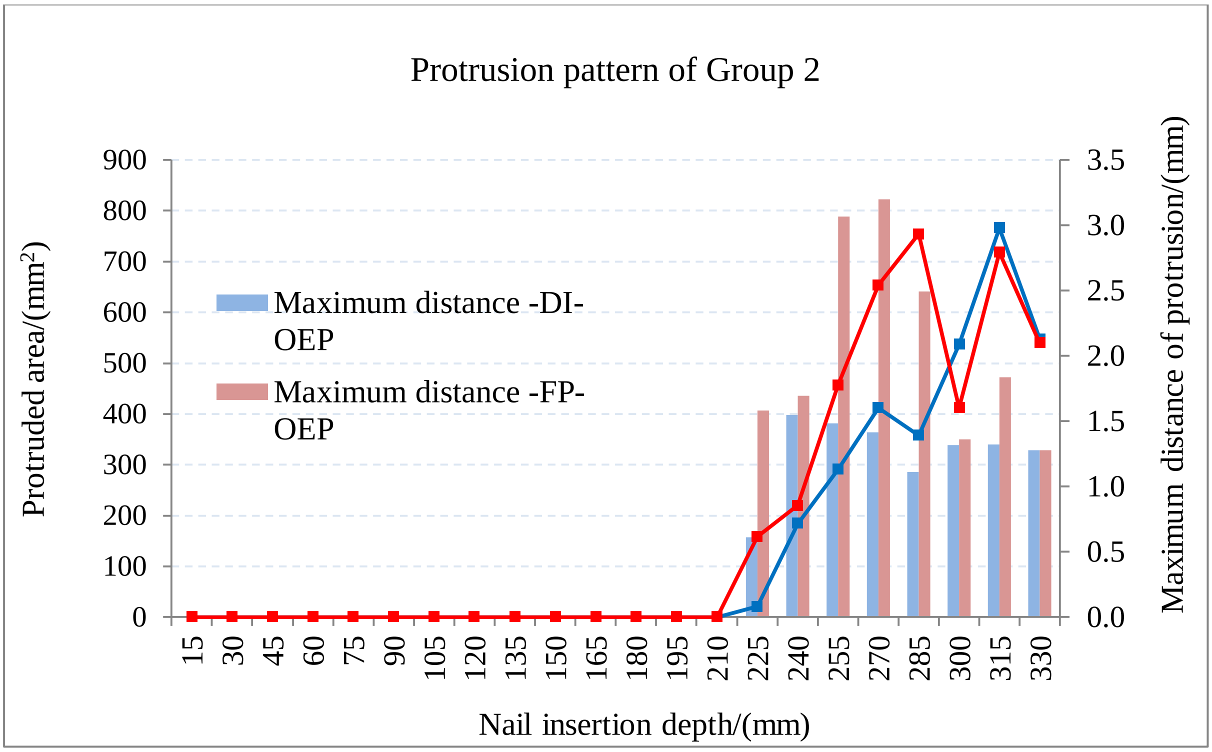

Figure 6: This illustrates the protrusion pattern of Group 2. For the area measurement, the FP-OEP generates a slightly lower peak value compared to the peak value generated by DI-OEP. For the maximum distance of protrusion, the FP-OEP generates a significantly higher peak value compared to the peak value generated by the DI-OEP.

4. Discussion

The nail insertion point is important for axial alignment of the main bone fragments and for avoiding iatrogenic fractures during the insertion. However, selecting the optimal entry for a particular bone and nail is quite a challenging task. The current use of cadaver bones for evaluating different nail entry points is often limited by various factors. Once the entry point has been opened with an awl or drill then it is no longer possible to select a new entry point that is close by as the nail will slip back into the existing hole. The other major limitation is the damaging effect to the bone after inserting the first nail which will affect the subsequent fit quantification data. Moreover, the cadaver bones are available in limited numbers and they are not always representative of the majority of the patient population in terms of age, gender and ethnicity, as well as morphological variations.

To overcome the main limitations with the use of cadaver bones, this study utilised computer 3D models of bones and nails for simulating the nail insertion at different nail entry points. Generally, morphological bone data is obtained by means of CT and MRI scans. As MRI is non-radiation, it can be used to acquire bone data from the healthy donors. In order to reconstruct the 3D bone models standard methods and dedicated commercial software are available. Moreover, this study was conducted using custom-designed software to quantify the anatomical fit in 3D during the nail insertion and at the final position to avoid the limitations accompanied with commercially available software for this type of specific task. According to the semi-automated method based commercial software[7], the area and maximum distances were 1045mm^2/540mm^2 and 2.7mm/1.2mm respectively for ETN and ETN-Proximal Bend at the final position. It was 672mm^2/508mm^2 and 2.0mm/1.7mm with the custom-designed software.

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 with particular nail insertion point, 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 with six different insertion points as they provide the most accurate indication of any geometric mismatch between bone and nail.[9]

For this study, in order to investigate the effect of the entry point on the fitting of the nail to the bone, five candidate points were established around the SEP except posteriorly. Clinically, the entry points at the posterior side are unacceptable. There is a high risk of harming the anterior and posterior cruciate ligaments (ACL and PCL) and neuro-vascular bundle by moving the tip of the nail toward the posterior direction.

In order to investigate the optimal nail insertion point in terms of ease of insertion as well as at better fitting at the final position, three analyses were performed. According to the first analysis, the SEP is the Global-OEP for the ETN and ETN-Proximal Bend.

When considering the fit during insertion for individual bone-nail pairs, the SEP optimised the fit of 9 and 10 bone-nail pairs for ETN and ETN-Proximal Bend respectively. The M5, A5 and L5 optimised fit of remaining bone-nail pairs regardless of the nail design. Interestingly, those points (M5, A5 and **L5**) improved the overall fit of individual pairs by 40% on average compared to SEP. The M10 and L10 doubled the misfit. This clearly demonstrates that the optimal nail entry point (DI-OEP) is within the range of 5mm from the SEP and the far lateral or medial entry points cannot be recommended. Interestingly, the all findings of this study based on anatomically shaped nails are in the line with the findings of previous studies based on both straight nails[2] and anatomically shaped nails.[3]

Lastly, the optimal entry point which optimised the fit only at the final position (FP-OEP) was investigated. There were 13 cases from each nail design, where the FP-OEP was not the same as DI-OEP. Two groups were found when analysing the protrusion patterns related to FP-OEP and DI-OEP. For group 1, even though the FP-OEP generated a slightly lower misfit at the final level, it generated a significantly higher misfit at the intermediate levels for both fitting measurements when compared to the DI-OEP. This may cause stress fractures in the bone before getting to the final level. Therefore, the DI-OEP can be considered as the optimal entry point for the bone-nail pairs in Group 1. The remaining cases fall into the Group 2 except two for both nail designs. For the bone-nail pairs in Group 2, the FP-OEP generated a slightly lower misfit at the final level and also it generated a slightly lower peak for one of the fitting measurements (b or d) during the insertion when compared to the DI-OEP. In contrast, the FP-OEP created a significantly higher peak for the remaining fitting measurement which may cause stress fractures in a bone before getting to the final level. Similar to Group 1, the DI-OEP can be selected as the optimal entry point for the bone-nail pairs in Group 2. Therefore, authors recommend that the optimal entry point should be selected by considering the overall insertion not by considering only the fit at the final level.

One of the main limitations related to this study is the relatively long execution time of the software tool. To assess a bone-nail pair, the software took 113 hours on average. However, with improved execution time, the proposed method can be potentially used as a pre-operative planning tool for selecting the optimal nail design as well as the optimal nail insertion point. In turn, it will potentially change the current surgical procedure and save the procedure time.

Also, this study quantifies only the geometrical misfit of the bone and nail. 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 presented work will be the incorporation of finite element analysis (FEA) into the fit assessment, which will enable quantifying the 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.

Furthermore, in this study, any difference due to the gender of the specimen was not investigated as the sample sizes are very small for making general recommendations. Although, the developed method can be applied for any bone data set, the findings of this study cannot be generalised for the entire patient population as we used ethnic specific specimens.

In summary, the results of this study clearly demonstrated that the optimal entry point, for both nail designs, is located within a 5mm range of the SEP. Also, by moving the entry point within that range, the fit can be improved by 40% on average. Further, the far lateral or far medial entry points are not recommended. Moreover, it is recommended that the optimal entry point should be selected by considering the fit during insertion and not only at the final position.

The expected clinical implications of an improved anatomical fitting by utilising a bone-nail specific entry point are a reduction in malalignments, a lower likelihood for fracture extension and/or new fracture creation during the nail insertion and potentially an easier nail insertion. In addition, the developed method and the fit quantification tool can potentially be used as a teaching tool for surgeons, as it would enable determination of the best entry point and visualization of the bone-nail misfit during insertion and at the final position caused by inappropriate entry points.

Conflict of Interest

The last author has received an industrial scholarship from Synthes GmbH.

Role of funding source

None

Ethical Approval

None

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(See below for Declaration form)

Journal: MEDICAL ENGINEERING & PHYSICS	**Title of Paper**: Is there a bone-nail specific entry point? Automated fit quantification of tibial nail designs during the insertion for six different nail entry points

Declarations

The following additional information is required for submission. Please note that failure to respond to these questions/statements will mean your submission will be returned to you. If you have nothing to declare in any of these categories then this should be stated.

Conflict of interest
All authors must disclose any financial and personal relationships with other people or organisations that could inappropriately influence (bias) their work. Examples of potential conflicts of interest include employment, consultancies, stock ownership, honoraria, paid expert testimony, patent applications/registrations, and grants or other funding.

Ethical Approval

Work on human beings that is submitted to *Medical Engineering & Physics* should comply with the principles laid down in the Declaration of Helsinki; Recommendations guiding physicians in biomedical research involving human subjects. Adopted by the 18th World Medical Assembly, Helsinki, Finland, June 1964, amended by the 29th World Medical Assembly, Tokyo, Japan, October 1975, the 35th World Medical Assembly, Venice, Italy, October 1983, and the 41st World Medical Assembly, Hong Kong, September 1989. You should include information as to whether the work has been approved by the appropriate ethical committees related to the institution(s) in which it was performed and that subjects gave informed consent to the work.

Competing Interests

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

Please state any sources of funding for your research

None.

DOES YOUR STUDY INVOLVE HUMAN SUBJECTS? Please cross out whichever is not applicable.

~~**Yes**~~

No

If your study involves human subjects you MUST have obtained ethical approval.
Please state whether Ethical Approval was given, by whom and the relevant Judgement's reference number

None

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