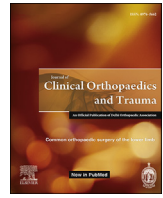




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Anatomical fitting of a plate shape directly derived from a 3D statistical bone model of the tibia

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ABSTRACT

Introduction: Intra- and inter-population variations of bone morphology have made the process of designing an anatomically well-fitting fracture fixation plate challenging. Although statistical bone models have recently been used for analysing morphological variabilities, it is not known to what extent they would also provide the basis for the design of a new plate shape. This would be particularly valuable in the case where no existing plate shape is available to start the process of fit optimisation. Therefore, this study investigated the anatomical fitting of a plate shape (statistical plate) derived from the mean shape of a statistical 3D tibia bone model in comparison to results available from two other plate shapes. **Methods:** Forty-five 3D bone models of tibiae from Japanese cadaver specimens, as well as 3D models of the plate undersurface of both a commercial and shape optimised Medial Distal Tibia Plate, were utilised from earlier studies. The mean shape of the 3D statistical bone model was generated from the tibia models utilising the Stalismo framework. With reverse engineering software, the plate undersurface of the statistical plate shape was derived directly from the mean surface of the statistical 3D bone model. Through an iterative process, the statistical plate model was placed at the correct surgical position on each bone model for fit assessment.

Results: The statistical plate was fitting for 20% of the tibiae compared to 13% for the commercial and 67% for the optimised plate, respectively.

Conclusions: The plate shape derived directly from a statistical bone model was fitting better than the commercial plate, but considerably inferior to that of an optimised plate. However, the results do clearly indicate that this approach provides an appropriate and solid basis for commencing shape optimisation of the statistical plate. Studies of other anatomical regions are required to confirm whether these findings can be generalised.

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1. Introduction

Anatomically pre-contoured plates are now the standard of care for the internal fixation of periarticular fractures. Often, they require minimal or no intraoperative contouring. For complex cases, such plates also assist the surgeon as anatomical template during fracture reduction.^{1,2} Additionally, an anatomically fitting plate reduces the chances of implant prominence, which is particularly important in areas where there is thin soft tissue coverage such as the medial malleolus, since this decreases the

likelihood of patient discomfort and soft tissue irritation.³

From a biomechanical standpoint, with the current locking screw technology it is not necessary to achieve a perfect fit between the plate undersurface and the bone.⁴ However, the efficacy of the fixation construct can be compromised if the distance between the plate and bone keeps increasing, as this results in an increase of bending moment and loading on the screws.⁵ This might be compensated by inserting additional locking screws.

Consequently, there needs to be a balance between a plate's design that exploits clinically acceptable plate to bone gaps in order to maximise plate fit for the intended patient population, while at the same time achieving a stable construct. These two in concert, contribute to a favourable environment for optimal fracture healing and a good long-term functional outcome for the patient. However,

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intra- and inter-population variations of bone morphology, which depend on factors such as age, gender and ethnic origin⁶, have made the process of designing an anatomically well-fitting fracture fixation plate challenging and time consuming.

Despite the generally good results, some of the current commercial pre-contoured plates have been shown not to fit the anatomy of bones well, particularly for patients of Asian origin, as they have been designed aiming to fit the 50th percentile of the Western population.^{2,3,7} Hence, there still exists a need for designing anatomically better fitting plates for the intended target patient populations. The typical approach for achieving this is iterative shape optimisation of an existing plate design for a chosen set of 3D bone models.^{1,8–10}

Regardless of the method chosen for performing iterative shape optimisation, an initial plate shape is required as input to start the process. Usually, this is the shape of an already existing plate designed for the anatomical region of interest. However, this does not work for anatomical regions where no such plate is available, or if a clinical need arises for designing a new plate with a footprint significantly different from existing designs.

One area of interest that is gaining popularity is the use of statistical bone models for the design of fracture fixation plates. They have often been used in anatomical studies for developing statistical shape models for the analysis of bone morphological variability,^{11–20} or for the segmentation of bones from image data.^{21–23} However, only a few studies have reported on their specific use for the design and fit optimisation of anatomical plates,^{8–10} and it is still unknown what level of resulting plate fit could be attained if a plate shape were derived directly from the mean 3D surface of a statistical bone model. There exist differing views on this subject amongst the clinical and implant manufacturer communities. At one end of the spectrum, there is the view that a plate shape of the statistical mean would fit poorly to the individual bones, because the surface of the mean of all morphological bone shape variabilities creates a new bone instance, which might not be representative of any of the bones in the dataset. While at the other end, there is the view that a statistical mean shape would result in optimal fitting, as the mean shape is the middle ground of the existing morphological variabilities. It is likely that the truth lies somewhere in between, considering that clinically no perfect plate fit is required and knowing that a single plate shape is not going to fit for all bones.

Therefore, this study aimed to determine what level of anatomical fitting could be achieved by a plate shape directly derived from the mean shape of a statistical 3D tibia model. Firstly, the study developed a statistical plate shape from the mean surface of a bone model dataset. Secondly, the anatomical fit between the statistical plate and bone models was quantified and compared to the known fitting of two different plate shapes.

2. Materials and methods

2.1. 3D bone and plate models

3D models of the external bone surface of tibiae, originating from post-mortem CT scans of 45 intact Japanese cadaver specimens, were available from earlier studies.^{1,3} Reconstruction of the 3D bone models were done using a standardised protocol.²⁴ The specimens had a mean age and height of 67 years (range 44–93) and 156 cm (range 142–178), respectively. There were 26 male and 42 right tibiae. All bones appeared normal when inspected visually.

A 3D model of a commercial 3.5 mm LCP (Locking Compression Plate) Medial Distal Tibia Plate (Synthes, Bettlach, Switzerland) and one optimised plate (numbered #2 in a previous study),¹ as well as their undersurfaces, were available from the same studies.^{1,3} In

these previous studies, the anatomical fitting of the commercial Medial Distal Tibia Plate was quantified against a set of clinically derived criteria and subsequently, based on the resulting recommendations for fit improvements, an optimal fitting plate shape was created. The optimised plate shape was generated through an iterative process of computer graphically modifying the distal and shaft regions of the commercial plate's 3D undersurface.^{1,3}

All 3D models were processed with a reverse engineering software (RapidForm2006, Inus Technology, Inc., Seoul, Korea), for plate fitting and fit quantification.

2.2. Statistical bone model

The framework for generating the statistical bone model is based on Gaussian Process Morphable Models (GPMMs), which are a generalised form of point distribution models (PDMs). As the processing steps along with their mathematical background have been described in detail by Lüthi et al.,^{15,25} the following summarises only the main steps. All tibia models were first rigidly aligned to a randomly selected reference tibia (Fig. 1a–b). This was achieved with an Iterative Closest Point (ICP) algorithm in combination with Procrustes analysis and distributed sample points on the model to be registered. Subsequently, the reference model is non-rigidly registered (Fig. 1c–e) to each of the tibia bones.^{26,27} In the first step (Fig. 1c–d), corresponding landmarks were used to non-rigidly deform the reference to closer match the tibia model. In the second step (Fig. 1d–e), an ICP algorithm in combination with Gaussian process regression and distributed sample points on the reference, were used to warp the reference mesh to fit the tibia model. This registration brings all of the shapes into correspondence, i.e. for each point on the reference, the corresponding point on each tibia model is identified. This allows a pointwise computation of the mean and variance for the statistical shape model (SSM) by way of Principal Component Analysis (PCA). The mean shape of the model is a fully 3D morphological mean bone. To reduce the bias introduced by choosing a specific reference bone, the reference bone was chosen as the sample that is closest to the mean bone. This was achieved through halfway to groupwise registration where two models were built, i.e. the processes illustrated in Fig. 1 were performed twice. In the first iteration, a throwaway arbitrary reference tibia was chosen for generating the statistical mean model, which was used only for identifying a suitable reference bone. The suitable reference tibia was then used in the second iteration for generating the final statistical mean 3D model.

Three of the 45 available Japanese tibiae models were excluded from the source pool as their proximal epiphysis (tibial plateau) was missing. The mean shape of the statistical tibia 3D bone model was generated utilising the Statismo framework.¹⁵

2.3. Generating plate shape from statistical bone model

In RapidForm2006, the undersurface of the optimised plate was placed at the correct surgical position on the mean statistical bone model based on a method developed previously (Fig. 2).³ In brief, the method involved positioning the plate on the bone using a trackball function to optimally align the two according to four clinical criteria and by using colour-coded deviation maps (please refer to the next section for details).

At this position, the boundary contour of the plate undersurface was utilised to generate a “cut-out” plate shape from the mean surface of the statistical bone model to generate the new plate shape (statistical plate). This was achieved by projecting the undersurface boundary curve onto an inferior offset plane, tangent to the distal third of the undersurface, and that created a second curve. A surface loft was then performed using the two curves to

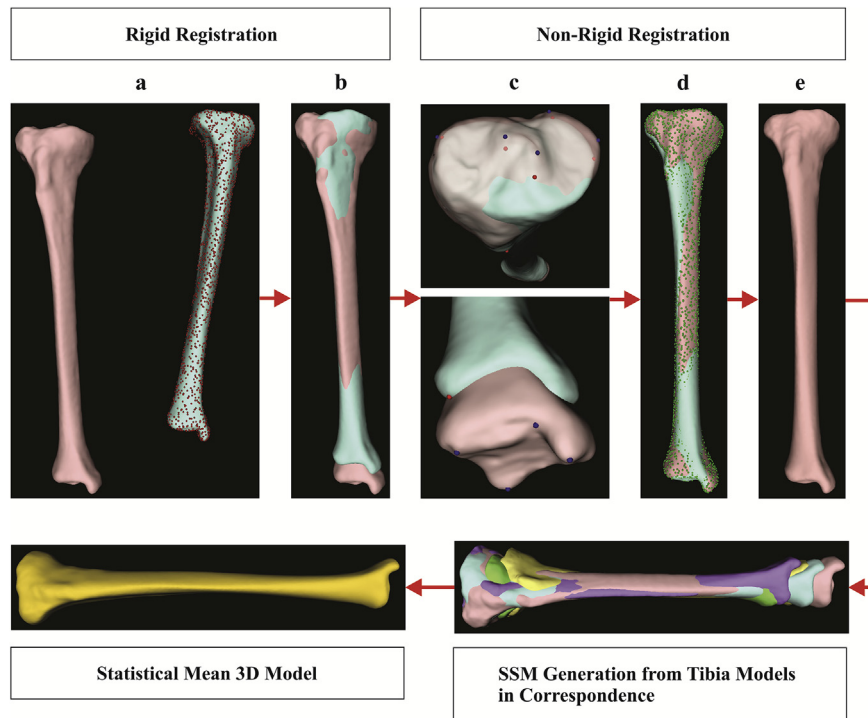


Fig. 1. Process steps for generating a statistical mean 3D bone model. (a): Reference model and tibia to be registered with sample points. (b): Rigid aligned models. (c): Corresponding landmarks on reference and target tibia. (d): Landmark based non-rigid registered reference showing the distributed sample points used for the subsequent non-rigid registration to the target tibia. (e): Reference non-rigidly registered/warped to target tibia.

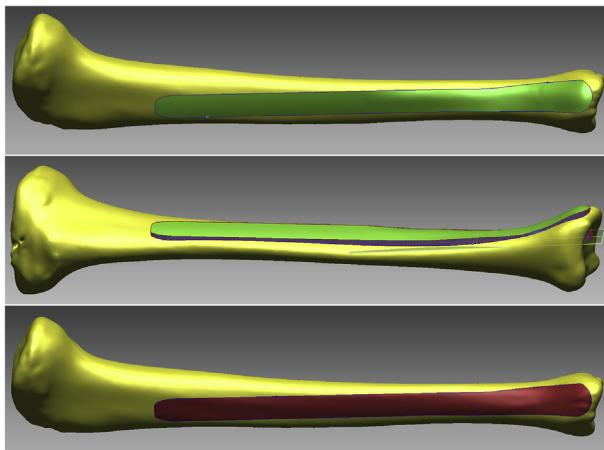


Fig. 2. Generating the statistical plate shape. Top: Mean statistical tibia model with positioned optimised plate shape from a previous study. Middle: Showing offset projection plane and cutting surface. Bottom: “Cut-out” plate shape from statistical tibia model.

generate the surface for cutting the plate shape out of the statistical bone model, as shown in Fig. 2. Thus, generating the statistical plate's undersurface which consists of the cut-out surface from the statistical mean bone model. No adjustments were made to the statistical plate's undersurface, as our aim was to quantify the anatomical fitting of this mean shape and to compare the results with those available from the commercial and optimised plate.

2.4. Fit quantification of plate to bone model

After creating the new plate shape from the mean statistical bone model, it was fitted in the correct surgical position to each

bone model (Fig. 3), aiming to satisfy the following four criteria previously defined based on clinical requirements³:

- (1) Proximal end: While a close fit at the proximal end is not required, the likelihood of plate prominence increases with the plate to bone distance. Hence, within 20 mm from the proximal tip of the plate, the distance between the bone and plate should be ≤ 4 mm;
- (2) Torsion angle: At 80 mm from the proximal tip of the plate, the angle of torsion between the bone and plate should not exceed 10° of clinically acceptable rotational malreduction^{28–30};
- (3) Middle distance: As the fracture is often located within the middle third of the plate, a close fit in this area is not required as this might restrict callus growth and/or the reduction of small bone fragments. Therefore, a maximum distance of 6 mm between bone and plate can be considered as acceptable. As distal and proximal main bone fragments are brought into contact with the plate, it is not expected that a local maximum distance of 6 mm would significantly compromise fixation stability;
- (4) Distal fit: A close anatomical fit in this area is critical, as this limits plate protrusion and facilitates anatomical reduction of the distal main fragment(s). Therefore, at the transition of meta- to diaphysis, three points at the distal boundary, and two points at the proximal boundary should not exceed 2 mm.

For all three plate shapes, an anatomical plate fit was defined as one that satisfies all four criteria.

2.5. Statistical data analysis

To test for statistical significance between the fit measurements

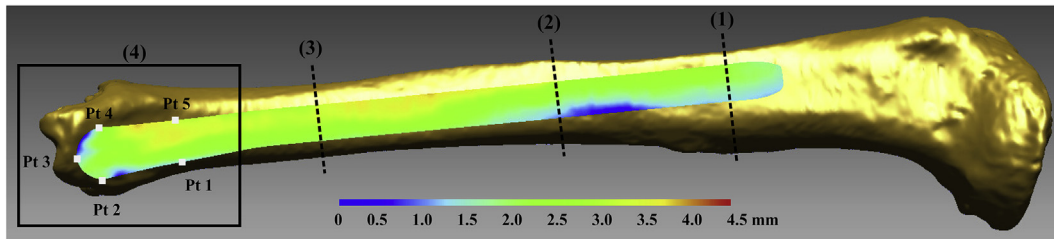


Fig. 3. The four plate fit criteria (adapted from Fig. 3 of¹). Numbers (1) to (4) represent the position of each clinical criteria required to achieve anatomical fitting between the plate undersurface and bone. At (4), five points were chosen to achieve a distal fit of the tibia. The plate is represented by the colour map of the plate-bone deviations.

of the statistical plate and the other two plates, the Wilcoxon Signed Rank test was used due to non-normal data distribution. The level of statistical significance was set to $p < 0.05$ for all tests. Statistical analysis was conducted with the SPSS software package (IBM SPSS Statistics 25; Chicago, IL, USA).

3. Results

The statistical plate achieved an anatomical fit on 20% ($n = 9$) of the bone models, as compared to 13% ($n = 6$) and 67% ($n = 30$), with the commercial and optimised plate, respectively (Table 1).

For the first three fitting criteria, the statistical plate was fitting significantly ($p < 0.05$) better on average compared to the commercial plate (Table 2). While there was no difference between the two plates on average in the number of distal points fitting, for the commercial plate there were double as many bones meeting that criteria. In the middle third, the statistical plate was fitting significantly better in terms of average distance compared to the optimised plate, still this resulted in equal numbers of bones satisfying this criteria. However, for the other three criteria, the optimised plate was fitting significantly better.

It was noted that while the torsion angle opened anterior for the commercial plate on all bone models, for the optimised plate it opened anterior on 26 bones and for the statistical plate the opening was anterior on 35 bones, respectively. For 12 bones, the statistical plate exceeded the 10° tolerance for torsional alignment.

An emerging trend was found for the fitting of the five distal points (Criteria 4) of the statistical plate, where Point 5 was the least fitting (53%) followed by Points 3 (71%) and 2 (73%), whereas Points 1 (80%) and 4 (82%) were fitting considerably better. The non-fit at Point 5 was the only single criteria that prevented seven of the bones from achieving a global fit (Fig. 4).

4. Discussion

This study determined the anatomical fitting of a plate shape, directly derived from the mean shape of a statistical 3D tibia bone model, for a set of 45 Japanese tibiae and four clinical based fit criteria. To the best of our knowledge, this study is the first to quantify and analyse the fitting of a plate shape generated in this way.

Somewhat surprisingly, the results showed that the statistical plate achieved an anatomical fit on markedly less than half of the

Table 1
Number of bone models that fit to plate shapes.

Anatomical region	No. of bones fitting		
	Statistical plate	Commercial plate	Optimised plate
Global fit	9	6	30
Proximal (criteria 1)	38	28	42
Torsion (criteria 2)	33	20	44
Middle (criteria 3)	43	26	43
Distal (criteria 4)	9	18	31

Table 2

Mean values and standard deviations (SD) of the plate shapes for the fitting criteria.

Fitting criteria	Mean values (SD)		
	Statistical plate	Commercial plate	Optimised plate
1. Proximal (mm)	2.6 (± 1.1) ^{a,b}	3.8 (± 1.4)	2.2 (± 1.2)
2. Torsion ($^\circ$)	6.1 (± 4.7) ^{a,b}	11.1 (± 5.1)	4.2 (± 2.9)
3. Middle (mm)	3.2 (± 1.4) ^{a,b}	6.1 (± 1.2)	3.6 (± 1.2)
4. Distal (points)	3.6 (± 1.0) ^b	3.5 (± 1.4)	4.4 (± 0.9)

^a $p < 0.05$ based on Wilcoxon Signed Rank test with statistical plate and commercial plate data.

^b $p < 0.05$ based on Wilcoxon Signed Rank test with statistical plate and optimised plate data.

specimens. However, this result is considerably better than the one achieved by the tested commercial plate. As could be expected, the fit of the statistical plate is substantially inferior to that achieved by the plate shape previously optimised to fit the bones in this dataset.

In terms of the individual fit criteria, the statistical plate achieved a significantly better fit on average for criteria 1–3 (diaphyseal region) compared to the commercial plate, which is also reflected by the higher number of bones satisfying these criteria. Although, on average the fitting of the statistical plate for criteria 2 and 3 was comparable to that of the optimised plate, it was the inferior distal fitting (criteria 4) which prevented the statistical plate from achieving higher numbers of global fit.

Consequently, in the first instance, fit optimisation of our statistical plate would need to be performed in the distal region, and particularly at Point 5, since nearly half ($n = 21$) of the bones were not fitting in this area. A second area that could be optimised is the torsion of the statistical plate, where it was observed that the angle opening on 35 bones was anterior, with 12 bones exceeding the 10° clinical threshold, as compared to 10 bones that had a posterior angle opening, for which none of them exceeded 6° .

In summary, the statistical plate was fitting reasonably well to the bones diaphyseal anatomy, but far from optimal in the distal region. The poor distal fitting can be attributed to the wide range of morphological variations in size and shape of the medial malleolus as illustrated in Fig. 4. This is supported by previous studies which have shown that a single plate shape, even when optimised, will not achieve anatomical fitting for all bones even in this relatively small and ethnically homogeneous dataset.^{1,31} The results demonstrate that a plate shape derived from the mean of a statistical bone model generates a reasonably fitting first prototype plate design that provides a solid basis for subsequent shape optimisation. This is of particular importance for situations where no existing plate shape is available to start the optimisation process. While some authors,^{19,20} of statistical bone shape modelling studies, rightfully suggest that information on mean bone shape and variability of the population of interest could be used for implant design, our findings indicate the need to be mindful that the statistical mean shape does not automatically represent the best fitting plate shape. The findings of our study are important as they provide quantitative

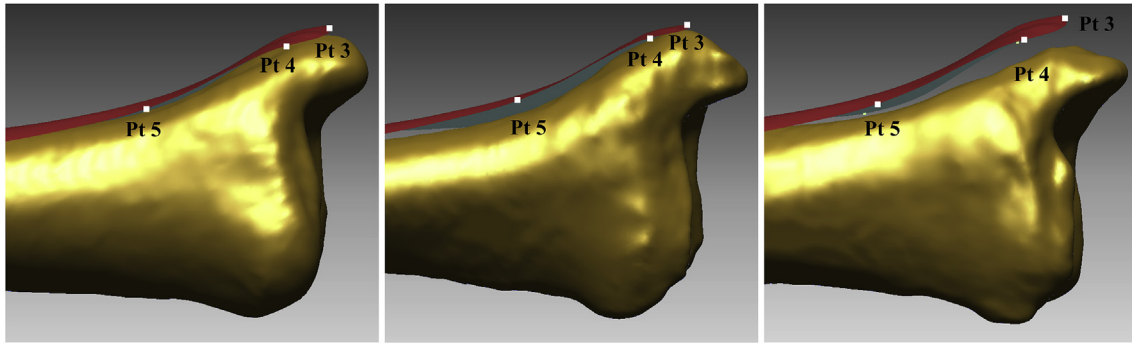


Fig. 4. Anterior view of the distal tibia showing the fitting of the statistical plate undersurface. Left: tibia with all five distal points fitting. Middle: tibia with distal fit except for Point 5. Right: tibia with fit only at Point 5.

data on the use of a statistical bone shape model for plate design and fit. This knowledge is crucial for the dialogue between manufacturing, surgical and scientific communities when designing anatomically better fitting plates.

In other similar studies, plate fit was quantified by calculating the mean distance between bone and plate (MBP).^{8,10,32} While the MBP is an appealing metric due to the ease of automating its calculation and its independence of bone and plate shape, it does not guarantee anatomical fit in the areas that are important clinically, as shown by Schmutz et al.³ Hence, the four fit criteria presented in our study can be considered more stringent compared to simply calculating the MBP. Due to this difference, the results of our study cannot be directly compared to similar other studies where fit was assessed based on MBP. Further, as these studies focused on methods of fit optimisation, it is to be expected that the improvements in fit of 40% presented by Kozic et al.⁸ and 36% by Petersik et al.¹⁰ are superior to the 7% fit increase of our study. However, in all of these studies, the fit optimisation processes are reliant on an existing plate shape as input, which necessitates the availability of the latter.

The main limitation of our study was the relatively small dataset used. Further limitations are that our dataset contains older specimens from a single ethnicity. Since age and ethnicity are known factors contributing to bone morphology, they might have influenced the results. Thus, further studies will be required to determine whether a statistical bone model generated from a larger dataset would improve on the findings presented, and to what degree age and ethnicity impact on tibial plate fit. Although we utilised validated virtual bone models, in this study, as in other state of the art plate fit studies,^{8,10,32} soft tissue structure were not simulated in the plate fit assessment which might have a bearing on the presented findings. In addition, in this study we quantified and analysed the fitting of a plate shape derived from the mean 3D surface of the statistical bone model. Hence, future studies ought to investigate the fitting of plate shapes derived from the 3D surfaces of the first few principal components of shape variation generated by the statistical bone model. This would elucidate whether a plate shape derived from one of those surfaces would lead to better anatomical fitting compared to the statistical mean used in this study. As the current work focussed on the distal medial tibia, future studies of other anatomical regions are required to determine whether the presented findings can be generalised.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.jcot.2019.04.019>.

Compliance with ethical standards

Ethical approval

The 3D bone models utilised were available from a study previously published.¹

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Conflicts of interest

B. Schmutz has received an industrial scholarship from DePuy Synthes Australia. The remaining authors have no conflicts of interest to declare.

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