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OBJECTIVES

A good anatomical fit of pre-contoured plates is ideal to decrease malalignment of fracture fragments, reduce OR-time, and avoid unnecessary soft tissue prominence. This last point is of great importance when plating the distal medial tibia, since the soft tissue coverage is very thin. This study quantitatively compares the plate fit of eight different anatomic distal medial tibia plates from four different manufacturers on a large collection of 3D tibia models created from high resolution clinical CT scans.

MATERIAL & METHODS

We generated 573 3D-models of the tibiae from CT scans of healthy subjects. 403 models were created from scans of Caucasian patients, 170 models were created from the Asian population. There were female models (51%) and male models (49%). All models were created by using standard segmentation software (Mimics, Materialise BV, Leuven, Belgium and MeVisLab, MeVis Medical Solutions AG, Bremen, Germany). Automatic fitting software was developed, which quantitatively determines how well a given implant fits to a large collection of varying 3D-tibia models. With help of a least squares approach, the software finds an implant

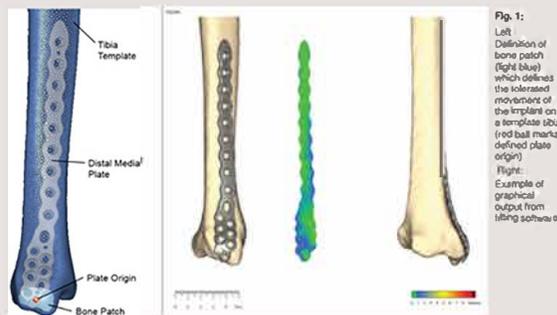


Fig. 1: Left: Definition of bone patch (right blue) which defines the tolerated movement of the implant on a template tibia (rod ball marks defined plate origin) Right: Example of graphical output from fitting software

placement for every individual tibia which closely resembles a surgical placement (see Figure 1).

The software then calculates the so called fitting error (*I_e*) in mm² for every plate – tibia combination. The lower this number is, the lower is the remaining distance between implant and bone. If an implant had a consistent distance of 1 mm to a bone this would result in a fitting error of 1 mm², while a consistent distance of 2 mm would result in a fitting error of 4 mm² (= 2 mm x 2 mm).

The lower the number for the fitting error, the better the anatomical compliance of the implant, and the larger number of patients that may be treated without the need to bend the implant.

For this study eight different distal medial tibia plates were optically scanned and imported to the computer software (see Figure 2): DePuy ALPS 9-hole (8162-11-009), Synthes LCP 3.5 mm 8-hole (238.705), Stryker AxSOS 10-hole (627410), Smith & Nephew Peri-Loc 3.5 mm 10-hole (7182-1110), Synthes 2.7/3.5 mm LCP 10-hole (439.913), Synthes 2.7/3.5 mm VA-LCP 12-hole (02.118.011), Stryker AxSOS 16-hole (627416).



Fig. 2: Plates used in the analysis: DePuy ALPS, Synthes 3.5 mm LCP, Stryker AxSOS 3 Ti, S&N Peri-Loc 3.5 mm LCP, Synthes 2.7/3.5 mm LCP, Stryker AxSOS 3 Ti, Synthes 2.7/3.5 mm VA-LCP, Stryker AxSOS 3 Ti

RESULTS

The analysis revealed that all plates fit better to the Asian than to the Caucasian population (see Table 1, Figure 3). The difference between the plates is similar in all three groups (see Figure 3, all boxplots as defined in IBM SPSS). In the group of the shorter plates (length between 168 and 176 mm) the Synthes 3.5 mm LCP shows the least suitable fit, the DePuy ALPS shows an intermediate fit and the Stryker AxSOS shows the best fit (*p*<0.001). In the "Intermediate" group both S&N Peri-Loc 3.5 mm and Synthes 2.7/3.5 mm LCP show a significantly less suitable fit than the Stryker AxSOS plate (*p*<0.001, Figure 3). In the "Long" group the Stryker plate is again significantly better than the Synthes 2.7/3.5 mm VA-LCP (*p*<0.001). Additionally it can be seen that not only the median is lower for all Stryker plates, also all outliers (circles in Figure 3) and extremes (stars in Figure 3) are considerably lower than with the competitor plates.

Group	Plate	System	Holes	Median Fitting Error Cauc./Asian
Short	DePuy 8162-11-009	ALPS	9	2.14 mm ² / 1.82 mm ²
	Synthes 238.705	3.5mm LCP	8	3.05 mm ² / 2.81 mm ²
	Stryker 627410	AxSOS 3 Titanium	10	1.51 mm ² / 1.22 mm ²
Intermediate	S&N 7182-1010	Peri-Loc 3.5mm	10	5.24 mm ² / 3.92 mm ²
	Synthes 439.913	2.7/3.5mm LCP	10	5.48 mm ² / 3.99 mm ²
Long	Stryker 627412	AxSOS 3 Titanium	12	1.76 mm ² / 1.25 mm ²
	Synthes 02.118.011	2.7/3.5 mm VA-LCP	12	5.33 mm ² / 3.70 mm ²
	Stryker 627416	AxSOS 3 Titanium	16	1.96 mm ² / 1.61 mm ²

Table 1: Plates used in the analysis. Implant patch describes the bottom face of the plate which was considered to calculate the fitting error.

CONCLUSION

The SOMA based analysis on 573 virtual tibiae revealed that the Stryker Distal Medial Tibia plates feature a significantly better anatomical fit than the comparable plates from DePuy, Smith & Nephew and Synthes. The SOMA analysis also revealed that the Stryker plates show better results both for the median tibia geometry and for extreme tibia geometries.

The superior plate-to-bone fitting results as generated by means of SOMA suggest an improved anatomical compliance with a reduced need for plate bending when using these plates on real patients.

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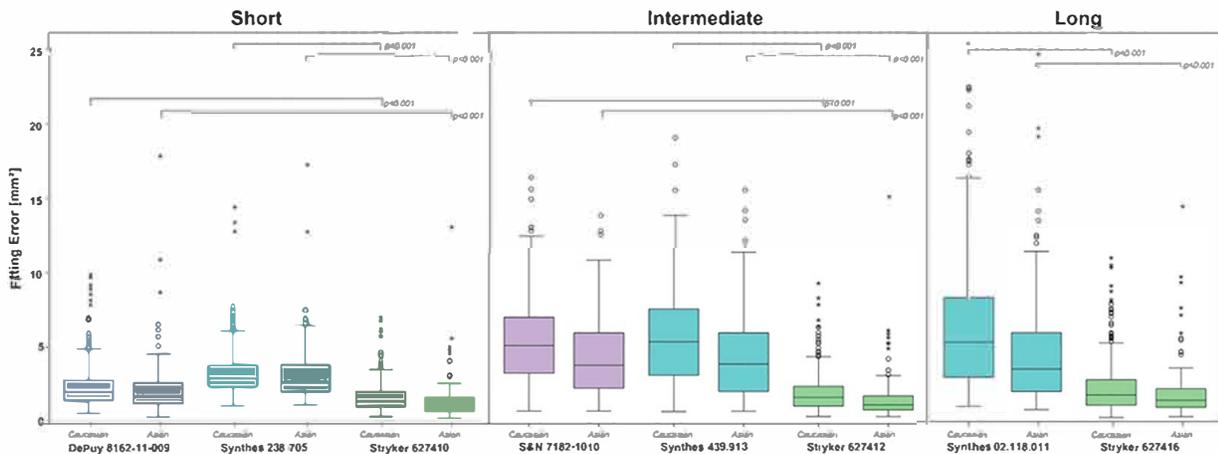


Fig. 3: Box plots showing the fitting error for the different plates and the different populations. The median fitting error of all Stryker plates shows a significant difference to all competitor plates.

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