Competitive Fitting Study for Locking Distal Anterolateral Tibia Plates

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Abstract

Introduction: Stryker has developed a new plating system for tibia fractures, using 3D-models of more than 50 virtual bones in order to achieve optimal anatomical fit. This paper describes the anatomical plate-to-bone-fit of the new AxSOS 3 Titanium Distal Anterolateral Tibia plates as compared to five different competitor plates on a large range of different virtual patients. Material: AxSOS 3 Titanium Distal Anterolateral Tibia plates in 10-, and 14-hole lengths, Smith & Nephew Peri-Loc 3.5mm Anterolateral Distal Tibia 10-hole plate, Synthes LCP 3.5mm Anterolateral Distal Tibia 11-hole plate, and Synthes 2.7/3.5 mm VA-LCP Anterolateral Distal Tibia 14-hole plate. The comparison was carried out on 622 virtual tibiae from Stryker’s SOMA bone database. Method: Utilization of SOMA’s proprietary software solution SIFT (Stryker Implant Fitting Tool) allowed for reproducible comparison of different osteosynthesis plates. Results: The SOMA based analysis on 622 virtual tibiae revealed that the distal anterolateral tibia plates from Stryker feature a significantly better anatomical fit than the competitors. Conclusion: 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.

1 Introduction

Bone shape variability within a specific population has seldom been investigated and used to optimize implant design in trauma and orthopedic research. Implant fit is commonly performed by evaluating plate-to-bone fitting on a limited amount of bones.

Alternatively, tests on cadaver bones can be performed. However, extrapolating the findings reached by such tests to the whole target population can lead to implants that may fit some patients, but not others. The importance of determining a range of implants that fit most of the population is paramount, both from a clinical and an economic perspective [1]. The discrepancy between plate contour and individual anatomical bone shapes may lead to well-known clinical complications resulting from inadequate fixation [2].

In order to achieve an optimized fit on a high percentage of a certain target population, Stryker uses a proprietary technology called “SOMA” (Stryker Orthopedic Modeling and Analytics) to design and optimize implants. SOMA encapsulates the concept of a uniquely comprehensive bone database containing several thousand 3D-models of bones and dedicated software which supports design analysis and implant optimization. This large collection of bones reflects the anatomical variability of bone morphology.

Today’s implant design in fact benefits from SOMA and can be proven by the design of the Stryker AxSOS 3 Titanium Distal Anterolateral system.

The purpose of the analysis presented in this paper is to quantitatively determine anatomical fit and compare the results between commercialized distal anterolateral tibia osteosynthesis plates such as Smith & Nephew, Stryker and Synthes.
2 Material

For the analysis presented in this paper five different plates were used (see table 1). All plates are used for plating of the distal anterolateral tibia. The two Stryker plates are identical except for the length. The competitor plates (see figure 1) were scanned via 3D-scanning devices to get a 3D-model.

![Available plates used in the analysis. S&N 7182-0610, Synthes 441.447, Stryker 627460, Synthes 02.118.213, Stryker 627464 (from left to right, 3D-renderings only)](image)

Since the plates were available in different lengths, two groups were created: intermediate group with lengths between 148 and 180 mm, and long group with a length of 232 mm. The reason for this grouping is that the fitting quality decreases when the plate length increases, which can be seen with the different lengths of the Stryker plates in the results section. Therefore it was assured that the Stryker plate is equal or longer than the competitor plates of the same group.

<table>
<thead>
<tr>
<th>Group</th>
<th>Plate</th>
<th>System</th>
<th>Holes</th>
<th>Length</th>
<th>Impl. patch area</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intermediate</td>
<td>S&amp;N 7182-0610</td>
<td>Peri-Loc 3.5mm</td>
<td>10</td>
<td>148 mm</td>
<td>20.8 cm²</td>
</tr>
<tr>
<td></td>
<td>Synthes 441.447</td>
<td>3.5 mm LCP</td>
<td>11</td>
<td>158 mm</td>
<td>17.3 cm²</td>
</tr>
<tr>
<td></td>
<td>Stryker 627460</td>
<td>AxSOS 3 Titanium</td>
<td>10</td>
<td>180 mm</td>
<td>22.3 cm²</td>
</tr>
<tr>
<td>Long</td>
<td>Synthes 02.118.213</td>
<td>2.7/3.5 mm VA-LCP</td>
<td>14</td>
<td>232 mm</td>
<td>26.3 cm²</td>
</tr>
<tr>
<td></td>
<td>Stryker 627464</td>
<td>AxSOS 3 Titanium</td>
<td>14</td>
<td>232 mm</td>
<td>27.7 cm²</td>
</tr>
</tbody>
</table>

Table 1: Plates used in the analysis. Implant patch describes the bottom face of the plate (see fig. 4)

All plates were tested against two groups of 3D-models of the left tibia from the SOMA bone database:

1. Caucasian population (437 tibiae)
2. Asian population (185 tibiae)
A further break down of the Asian population into Japanese and “Other Asian” was discussed in white paper AXSOS-WP-2. Since there was no statistically significant difference, it was decided to create a single group for all Asian tibiae.

The distribution of genders for both groups is shown in figure 2.

![Figure 2: Distribution of genders for both Caucasian and Asian population](image)

### 3 Method

The test was done with help of Stryker’s proprietary software solution SIFT (Stryker Implant Fitting Tool) which is part of SOMA.

SIFT was developed to quantitatively and automatically check how well a given osteosynthesis plate fits to a large collection of different bones included in SOMA. Therefore the analyzed implant is placed on the surface of a template bone. Additionally an area of allowed movement on the bone is defined (called: “bone patch”) in which the origin of the plate is allowed to move (see figure 3).

![Figure 3: Left: Definition of bone patch (light blue) which defines the tolerated movement of the implant on a template tibia (red ball marks defined plate origin), right: Example of graphical output from SIFT](image)
With the help of a unique mapping algorithm which is able to map any point from the surface of the template bone to the corresponding point on every individual bone [3], SIFT is able to automatically transfer the user defined implant placement to all bones included in SOMA. In an additional processing step SIFT then uses this transferred placement as a starting point to minimize the distance between the bottom of the implant, the so-called “implant patch” (see figure 4) and the bone surface. As a result, SIFT finds an implant placement for every individual bone which closely resembles the placement a surgeon would choose in the majority of cases (see figure 3 right).

By means of the calculated implant placement, SIFT creates images and calculates the so called fitting error for the specific plate – patient combination. The fitting error is calculated by measuring the squared distance between equally spaced measurement points on the implant patch to the bone surface. For every square millimeter of implant patch area, one measurement point is generated and the squared distance to the bone is calculated. Finally the sum of distances is divided by the number of measurement points to normalize the measurement. The result of this is called the fitting error in mm². The lower this number is, the lower is the distance between implant and bone. If an implant would have a constant distance of 1 mm to a bone this would result in a fitting error of 1 mm², while a constant distance of 2 mm would result in a fitting error of 4 mm² (2 mm x 2 mm = 4 mm²) and a constant distance of 0.5 mm to the bone would result in a fitting error of 0.25 mm² (0.5 mm x 0.5 mm = 0.25 mm²).

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

For the selected eight plates, the “implant patch” of the plates was defined as shown in amber in figure 4. The initial placement and the tolerated movement of the plates were defined identically for all analyzed plates as shown in figure 3.
Results

The analysis reveals that all plates except the Synthes LCP 441.447 fit better to the Caucasian than to the Asian population (see table 2). The difference between the plates is similar in both groups (see figure 5, all boxplots as defined in IBM SPSS). In the group of the intermediate plates (length between 148 and 180 mm) the Synthes 441.447 shows the least suitable fit, the S&N 7182-0610 shows an intermediate fit and the Stryker 627460 shows the best fit (p<0.001). In the “Long” group the Stryker plate is significantly better than the Synthes VA-LCP 02.118.213 (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 5) and extremes (stars in figure 5) are considerably lower than with the competitor plates.

Figure 4: Implant patches (marked in amber) for all analyzed plates (same scale). The implant patch is the region of the implant which is considered for the fitting analysis.

4 Results

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## Discussion

Stryker’s AxSOS 3 Titanium Distal Anterolateral Tibia plates were designed by using 3D-models of more than 50 virtual bones. The SOMA based analysis presented in this paper shows that, when reviewing such a design against 622 virtual tibiae, this three-dimensional approach leads to a superior anatomical compliance and a reduced distance between tibia and plate for the whole considered population.
6 Conclusion

The SOMA based analysis on 622 virtual tibiae revealed that the distal anterolateral tibia plates from Stryker feature a significantly better anatomical fit than the comparable plates from 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.

7 References


Publisher: Stryker Trauma GmbH
Schönkirchen, Germany

Content ID: AXSOS-WP-3 Rev. 1

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