Plate Fitting Study for Superior Midshaft Clavicle Plates

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Abstract

Introduction: Stryker has developed a new plating system for clavicular fractures. This paper compares the plate-to-bone fitting of two different VariAx Clavicle plates to a competitor plate on a large range of different virtual patients. **Material:** Two superior midshaft 10-hole plates from the Stryker portfolio were compared to a competitor plate from Acumed (Locking Midshaft Clavicle Plate). The comparison was done with 83 virtual clavicles from Stryker's SOMA Bone Database. **Method:** The comparison was done with Stryker's proprietary software solution SIFT (Stryker Implant Fitting Tool) which allows for objective, reproducible comparison of different osteosynthesis plates. **Results:** The analysis shows that both 10-hole superior midshaft plates from Stryker show a better anatomical fit to the virtual bones than the 10-hole plate from Acumed. **Conclusion:** These superior plate-to-bone fitting results suggest an improved anatomical fit when using the Stryker plates on 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 mismatch leads 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 and dedicated software which supports design analysis and implant optimization. This large collection of bones reflects the natural variety of bone morphology better than ever before.

To which extent today's implant design in fact benefits from SOMA, can be shown on the development of the Stryker VariAx Clavicle system.

The purpose of the analysis presented in this paper is to determine the quantitative anatomical fit of the different osteosynthesis plates and to compare the results to those that have been derived utilizing the same method on a competitor plate from Acumed.

2 Material

For the analysis three different plates were used (Table 1). All plates are used for superior midshaft plating of the clavicle. The two Stryker plates are identical except for a different S-curvature (see figure 1). During surgery the surgeon would decide whether the decreased or the increased plate fits better to the individual clavicle. The Acumed portfolio offers only one 10-hole plate curvature. All plates have the same length of 121mm.

Plate	Description	S-curvature / implant patch in cm^2
Stryker 628010	Superior Midshaft plate 10-hole	Decreased / 10.08
Stryker 628110		Increased / 10.09
Acumed 70-0294		n/a / 7.26

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

Since such long plates will not fit some of the shorter clavicles, it was defined that the length of the clavicle used for this analysis must be at least 153mm. Given that the plate will be placed centered between the medial and lateral end of the clavicles, 16mm of bone will be uncovered by the plate in average on both ends. There are 83 clavicles available in SOMA which fulfill this criterion.

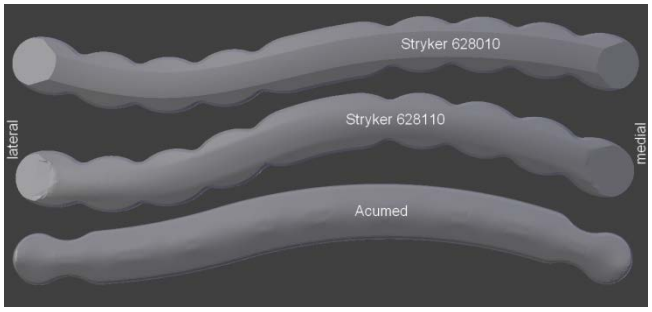

Figure 1: Superior midshaft 10-hole plates used for the fitting analysis (holes were virtually removed to accelerate distance calculations)

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 has to be placed on the surface of a template bone. Additionally an area of allowed movement on the bone must be defined by the user (called: "bone patch") in which the origin of the plate is allowed to move (see figure 2).

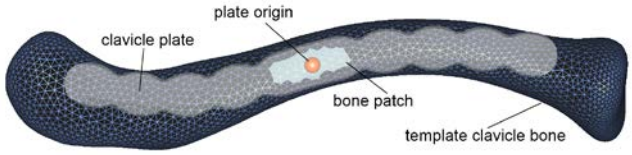

Figure 2: Definition of bone patch (light blue) which defines the tolerated movement of the implant on a template clavicle (red ball marks defined plate origin)

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 a 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 result, SIFT finds an implant placement for every bone which closely resembles the placement a surgeon would choose in the majority of cases.

By means of the calculated implant placement, SIFT creates images and calculates quantitative numbers for every single bone to which the implant is fitted. In figure 3 a sample of a color coded distance map is shown. It visualizes the distance between plate and bone. A comparable image was calculated for any of the three implants placed on all 83 clavicles.

The quantitative numbers collected for all 83 clavicles are condensed to a single number per implant, the so called "90%-fit". The 90%-fit defines for how much percentage of the analyzed bones 90% or more of the "implant patch" (plate's bottom) has a smaller distance than a certain limit to the bone surface. To determine a proper limit, a bending study was carried out, where 3 surgeons were asked to bend straight plates to 8 different clavicles [5]. With help of optical

scanning and the same SIFT approach, it was figured out, that 2.5mm distance is a proper limit for the maximum deviation between a superior midshaft plate and the clavicle.

With this defined limit, the 90%-fit can be used as a reproducible measurement to compare the fitting quality of different plates with each other. The higher the number for the 90%-fit, the better the anatomical fit of the implant is, and the larger number of patients can be treated without bending the implant.

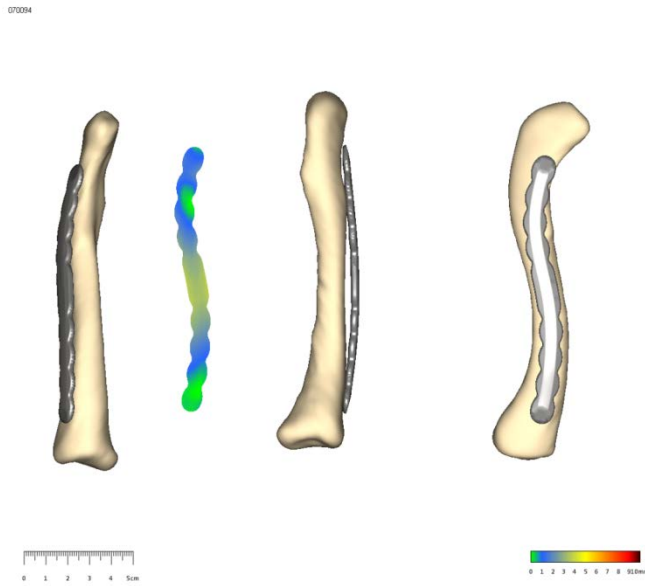

Figure 3: Example of graphical output from SIFT

For the selected three plates, the "implant patch" of the plates was defined as shown in red in figure 4. The initial placement and the tolerated movement of the plates were defined as shown in figure 2. From all three analyzed implants the holes were virtually removed to accelerate the calculations (see figure 2 and 4).

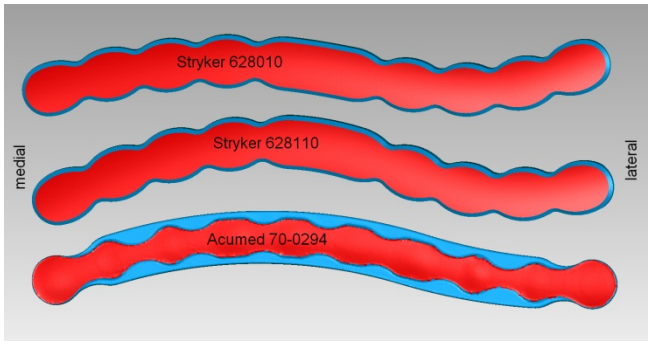

Figure 4: Implant patch (marked red) which is considered for the fitting analysis

4 Results

The analysis shows that the 90%-fit is fulfilled for 67% of the 83 clavicles for the Stryker 628010 plate and for 63% for the 628110 plate. The Acumed shows lower numbers, only for 59% of the clavicles the 90%-fit is achieved. When combining both Stryker plates (illustrating the actual choice surgeons have to use the curvature that fits better), the 90%-fit would be improved to 75% (see figure 5).

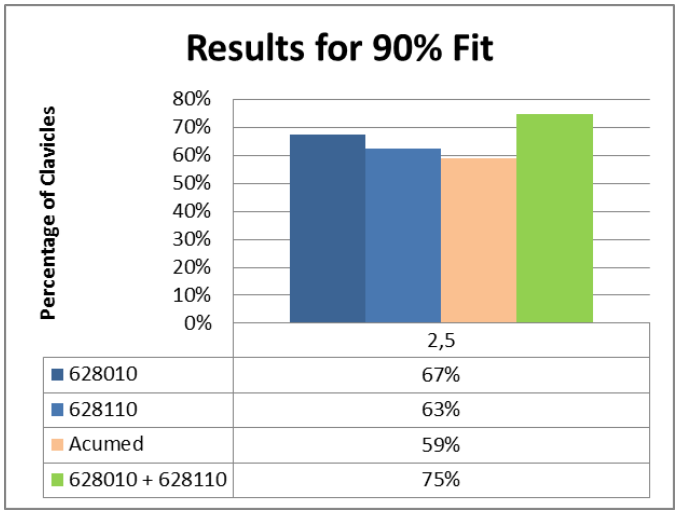

Figure 5: Bar chart showing the results of the 90%-fit for all plates with a limit of 2.5mm.

5 Discussion

Stryker's VariAx Clavicle portfolio was designed by using 3D-models of more than 50 virtual bones. In contrast to several other investigations which reduce the problem to two-dimensions [4], SIFT provides the opportunity to evaluate and optimize the real three-dimensional plate shape, which is curved in more than one direction. The analysis presented in this paper shows that, when reviewing such a design against 83 virtual clavicles, this three-dimensional approach leads to a superior anatomical shape and a reduced distance between clavicle and plate for the whole considered population.

6 Conclusion

The analysis shows that both Stryker plates show a better anatomical fit to the 83 virtual bones than the comparable plate from the Acumed portfolio. These superior plate-to-bone fitting results suggest an

improved anatomical fit with a reduced need for plate bending when using these plates on real patients.

7 References

[1] Miguel A. González Ballester, Philippe Büchler, Nils Reimers: Combined Statistical Model of Bone Shape – ERCIM 69 April 2007

[2] N. Reimers, F. Fischer, M. Vallotton, F. Wipf, A. P. Schulz: A New Methodology To Optimize The Shape Of Periarticular Plates Based On A Large Anatomical Database – 7th SICOT September 2010, Gothenburg, Sweden

[3] H. Gottschling, M. Schröder, N. Reimers, F. Fischer, A. Homeier und R. Burgkart. A System for Performing Automated Measurements on Large Bone Databases. World Congress on Medical Physics and Biomedical Engineering, September 7 - 12, 2009, Munich, Germany IFMBE Proceedings, 2010, Volume 25/4, 910-913

[4] Jerry I. Huang, Paul Toogood, Michael R. Chen, John H. Wilber and Daniel R. Cooperman. Clavicular Anatomy and the Applicability of Precontoured Plates. J Bone Joint Surg Am., 2007. Vol. 89: pp. 2260-2265

[5] Determination of proper 90%-Fit criteria for use in SIFT clavicle fitting studies. Stryker Internal Report 12-09-2012.

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