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A numeric approach for anatomic plate design

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ABSTRACT

Osteosynthesis plate designs with high levels of anatomical compliance have been demonstrated to have numerous clinical benefits. The purpose of this paper is to introduce a systematic numeric approach for anatomic plate design on the example of the distal medial tibia. The advantage of using numeric approaches for plate design is to gain objective and complete anatomical input as opposed to cadaveric investigations with limited sample sizes. A recent development in this area is a proprietary technology called SOMA which is based on a large database of 3D bone models generated from thin-slice computer tomographic scans plus associated software tools. In this paper, one of these associated software tools is described which automatically assesses the anatomic fit of osteosynthesis plates based on a large database of bone models. As an example, this tool was applied to assess the mean plate to bone distance of distal medial tibia plates, when fitted onto 444 Caucasian and 310 Asian 3D bone models respectively. The analyses revealed differences in the anatomical compliance of plates from different generations and manufacturers. The anatomical compliance of SOMA designed plates was statistically significantly better compared to all other plates in all groups “Short”, “Intermediate” and “Long” and for both ethnicities “Caucasian” and “Asian” ($P<0.001$). The study has shown that using an underlying database with accompanying computational tools such as SOMA can be a powerful and efficient approach towards the development and advancement of osteosynthesis plates in trauma surgery, ultimately resulting in plates with high levels of anatomical compliance and potential clinical benefits.

Introduction

Osteosynthesis plate designs with high levels of anatomical compliance (i.e. plates which have a close anatomic fit to the respective bone surface) have been demonstrated to have numerous clinical benefits. For instance, opportunities for less invasive operative techniques have been shown to increase with the availability of optimized plate designs [1,2]. Furthermore, such plates require little to no intra-operative bending which is advantageous as bending has the potential to affect the locking mechanism and interfere with the mechanical stability of the plate resulting in an increased risk of implant failure [1,2]. Additionally, a well-shaped plate can be used as a template to realign fracture parts prior to surgical fixation which may support anatomical alignment and physiological load transfer [2–4]. Lastly, from an economic perspective, a reduced need for intra-operative plate bending results in shorter operation times, thus contributing towards more cost-effective surgeries [3,5].

From a post-surgical perspective, several benefits might be associated with the use of anatomic osteosynthesis plates. Through use of such enhanced plates, there is a higher likelihood for a reduced impingement of the soft tissue situated over and surrounding the plate due to the plate’s lower prominence and thus also the impact on the blood supply of the periosteum might be reduced. Significantly lower plate prominence may also decrease the risk of skin irritations and skin necrosis, a reported complication associated with plating in regions of thin soft tissue coverage [3,6,7]. Although subjective, numerous well-rated post-surgical outcomes from the perspective of the patient have been reported when low plate prominence has been observed [6,8].

Consequently, there are numerous benefits of designing osteosynthesis plates with a high degree of anatomical compliance. In the design process however, there are many factors that may mitigate the extent of anatomical compliance that can be achieved. Although product development within the field of orthopedic implant design is naturally considered a computer-based process, design and shape testing of products continues to be primarily performed on relatively small sample sizes of cadaveric specimens [1,9,10]. Implant designs are driven by industry engineers collaborating with trauma surgeons; taking knowledge and learning from past implant designs and applying them to new devices. Furthermore, design of

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implant shape and size is often dictated by cadaveric measurements. Physical prototypes are then typically tested in a small number of cadavers. This method allows modification of component shapes within the limits of mechanical constraints (for example, strength and manufacturability).

However, extrapolating findings reached through single cadaveric investigations to a wider target population can lead to implants that may fit some patients, but not others. Subsequently, discrepancy between plate contour and individual anatomical bone shapes may lead to well-known clinical complications resulting from inadequate fixation [1,2]. Furthermore, the number of tests performed on cadaveric specimens during the development process is rarely large enough to derive statistically meaningful conclusions with respect to the degree of anatomical compliance of a plate design. In practice then, the design of anatomically compliant implants using solely subjective input derived from cadaveric studies is not feasible. Additionally, cadaver tests are typically costly, and the availability of bodies of different age, gender, height, weight and ethnic origin is not always given [11]. As a result, the importance of developing a range of implants that fit the majority of the population well is paramount from both a clinical and an economic perspective [12].

To address these aforementioned clinical and economic implications, implant manufacturers need to develop and utilize new ways of collecting objective design input which is based on large test samples representative of wider target population as per the respective indications for use. Utilization of databases of three-dimensional (3D) bone models can have substantial informative value and provide the development team with additional virtual analysis and testing capabilities [13,14]. In contrast to a cadaveric analytic approach, a computational approach enables implant manufacturers to have access to much larger test groups, ultimately resulting in more statistically meaningful conclusions. Additionally, such databases typically have detailed patient metadata which allows manufacturers to analyze population-wide bone characteristics, e.g. characteristics related to gender, age or ethnic origin.

In summary, the benefit of using numeric approaches for plate design is to gain valid, objective and complete anatomical input. The purpose of this paper is to introduce a new systematic numeric approach for anatomic plate design using the example of an enhanced plate designed to treat fractures of the distal tibia. The new plate design was then compared to alternative plate designs in order to test its level of anatomical compliance.

Material and methods

A proprietary technology platform named SOMA (Stryker Orthopaedics Modeling and Analytics, named after the Greek word for body) represents a recent development in the area of implant design. SOMA is built upon a large database of bone models derived from thin-slice computer tomographic (CT) scans. A number of analytical software tools are contained within this platform and include: a database management tool, an anatomy analysis tool [13,15], and an implant fitting tool [12,16]. These computational tools allow for rapid analysis of all datasets within the database and then instantaneous simulation of any design proposal derived from the analysis. The software inherent in all these tools was developed as a collaboration between an academic institution (The Technical University of Munich, Germany) and an orthopedic device manufacturer.

SOMA architecture and computational tools

A prerequisite to using technology such as SOMA is the creation of a skeletal database library from CT scans acquired exclusively for medical indications, typically polytrauma, CT angiography, as well as others. CT scans are imported into computer software for standardized semi-automated segmentation to subsequently generate 3D models of the osseous structures. This standard segmentation process provides accurate outer and inner cortical geometry data which may then be stored for further use. As of early 2017 the database included more than 16,500 3D bone models of bones from a wide range of anatomical regions. Additionally, the CT scans were acquired from many different countries and therefore reflect the anatomical variability of bone morphology on a worldwide scale.

Within the SOMA portfolio, the so-called bone database management tool can be used as a first step to select the target population. It includes a search mask which automatically updates the available datasets based on the specific entries made by the user (e.g. entries related to the anatomical region of interest, gender, ethnic origin and/or patient age).

The anatomy analysis tool can be used to perform initial morphometric analyses during the development process in order to identify critical dimensions for basic implant design, such as implant length and overall curvature. This tool enables the user to select points on the bone surface of a "template" bone which are then automatically transferred, through use of an associated mapping algorithm [15], to any individual bone model in the database. This automated process allows the user to accurately measure distances and angles on individual bone models and furthermore, can be repeated over the entire database to study the variation in these parameters [15,17].

SOMA technology also includes an implant fitting tool which allows for iterative/final 3D shape enhancement. The tool automatically assesses the anatomical compliance on a selected target population. With the implant fitting tool, 3D models of various implants can be virtually placed on the bone models. An automated algorithm is subsequently used to minimize the gap between the implant and the bone specimen to obtain the best possible fit of the implant on that 3D bone model. This iterative process is repeated over the entire dataset to obtain an implant shape that is designed to provide an enhanced level of fit to large numbers of 3D bones. This digital process avoids the manual handling of individual bones to determine the fitting accuracy of different implant shapes. Furthermore, population demographics are automatically included in all computational analyses. In addition, the 3D computer-aided design modeling continuously provides virtual feedback and prevents testing of non-conforming prototypes thereby enabling a more time efficient product development process [17].

For the fitting analysis presented in this paper, nine different plates from four different manufacturers were selected (see Table 1 and Fig. 1). All plates are designed to be used for fracture treatment of the distal medial tibia. The three SOMA-designed plates from Manufacturer A are identical in overall shape, except for length of the plate and the number of holes. The other short plate from Manufacturer A represents an older generation of plate and was designed prior to utilization of a comprehensive database of 3D bone models and associated computational tools during the design process. All plates, other than those from Manufacturer A, were scanned via a 3D-scanning device to obtain a corresponding 3D model. Some plates were available as right sided versions only and thus were mirrored with 3D modeling software to the left side.

Since the nine plates available for analysis were in a range of different lengths, a decision was made to analyze the plates in three independent size groups: a "Short" group with lengths between 159 and 176 mm, an "Intermediate" group with lengths between 185 and 202 mm and a "Long" group with lengths between 232 and 254 mm. The reason for this classification was that the degree of anatomical compliance was observed to decrease, independent of overall plate shape, with increasing plate length (as can be observed with the different lengths of the plates from Manufacturer A presented in the results section). One goal of the study was to compare the level of