Title:
Estimation of Clavicle Plate Bending Angles before Surgery

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Abstract:
Fractures of clavicle are very common. Surgical treatments on open Reduction Internal Fixation (ORIF) are the most common way to fix the bone fracture and facilitate rapid postoperative recovery. However, the current practice requires surgeons to bend the implant to fit with patients' skeleton during surgery. This not only increases risk of the patients, but also increase operation time and cost. Therefore we propose to develop a methodology to determine the bending angles before surgery. Experimental results show that the bent implant can fit with the template model satisfactorily.

Introduction:
Fractures of clavicle are very common which accounts up to 4% of all fractures [1], with a reported annual incident of clavicle fractures varying between 29 - 64 cases per 100,000 persons [2]. Surgical treatments on open Reduction Internal Fixation (ORIF) are the most common way to fix the bone fracture and facilitate rapid postoperative recovery. Although intramedullary nailing [3, 4] can be beneficial on less operative trauma for the patient, but there is a serious risk of pin migration. Plate fixation is more commonly applied in clavicular fracture fixation. To fit the plate with patients' skeleton, the plates are designed to provide flexibility for surgeons to bend the implant so that it can provide a more accurate and reliable bone fixture. However, the current practice of bending the implant is performed during surgery. It is because there is no precise perceiving profile of the clavicle bone. Surgeons need to modify the implant in the "bend and try" process during surgery. This process has several major problems. First of all, the process is very inefficient and increase the surgical time. According to Burghart et al. [5], the average time required for an experienced surgeon to bend an implant is 20 minutes in order to counter the profile of bone. This not only increases the infection risks during surgery, but also increase the operation cost. Moreover, the "bend and try" process may also weaken the strength of the implant because reverse bending may cause fatigue of the plate. In addition, due to diversity of bone profiles, low repeatability and accuracy of the method, the surgical outcome cannot be guaranteed.

Nowadays, numerous ways have been investigated to estimate bending angles of the implant before surgery. One practice is to reconstruct a 3D bone template model. Bending device is used to contour the implant in order to fit with the template model. The template model is usually constructed by CT scanning of real skeleton to build an epoxy model. This kind of template model is compared by measuring the distance between references points of the two models [6] and obtained quite accurate result. Although this method allows surgeons to bend the clavicle plate before surgery, the bending angle of the implant has not been estimated. The surgical outcome still relies on the skills of the

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surgeons. The method also spends a lot of time in pre-surgical processes including scanning and reconstruction of the human model and bending of the implant.

Burghart et al. [5] proposes to use a computer aided planning device for preoperative bending of osteosynthesis plates. They use Finite Element Method (FEM) to build a 3D bone model and segmented implants. The algorithm generates all possible options under volume and distance criteria. Then eliminate the options if the bending edges of the plate penetrate the bone. Despite the method has good accuracy in estimating the bending angle of the implant, skilled operators is required to perform threshold calculation, free edges reduction and volume meshing before analysis. Besides, powerful processers are required to perform computation and meshing processes. Another approach to estimate the implant bending angle is to use a virtual implant database [6]. The method simply make use of the database which store modification history of the implants, and then input the parametric like patient's gender, age and classification of fracture etc. The implant is modified according to the input parameters before surgery. However due to the variety of the human anatomical structure, the bended implant model may not fit with the anatomical structure of each patient.

Therefore in this research, we propose to develop a methodology to determine bending angles of clavicle. Based on the determined bending angles, surgeons can modify an implant that can best fit with the specific patient before surgery.

Methodology:

This project aims to determine bending angles of the clavicle implant. The method has three major steps. Frist of all, the 3D anatomical clavicle bone is reconstructed from MR images. The model is converted into a set of point cloud data. Then, the coordinates of the data point within the input constraints are extracted for calculation. Finally, the bending angles of the implant model are calculated based on the selected data point.

1. 3D Reconstruction

In this project, MR images are used to reconstruct the 3D clavicle model. The MR images data of clavicle bone is obtained from the Laboratory of Human Anatomy and Embryology [8]. To convert the MR images data in DICOM file format to 3D computer model, Materialize MIMICS software is used. The software convert the image data to the point crowd data which is then exported and further proceed by another computer aided design (CAD) software Maya in order to represent the 3D clavicle model.

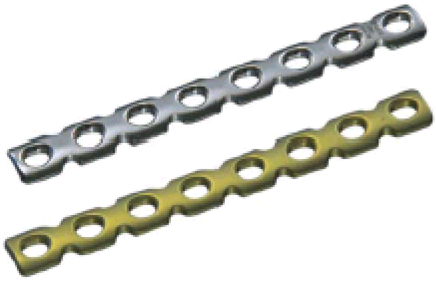

Fig. 1: Clavicle implant.

2. Data point extraction

   The designs of clavicle implants require surgeons to contour the implant manually during intra-operation in order to fix different fractured bone segments together and to fit different anatomy. Figure 1 shows the general clavicle implant. Since each of the screw holes allows the screws to switch in 0.1mm, and the point to point distance is 6mm, the distance allowance is 5.9mm to

6.1mm (Figure 2). Denote *i* to be the index of screw hole and bending spot, the distance constraint is given as:

$$5.9\text{mm} < \sqrt{(x_{i+1}-x_i)^2+(y_{i+1}-y_i)^2+(z_{i+1}-z_i)^2} < 6.1\text{mm} \quad (1)$$

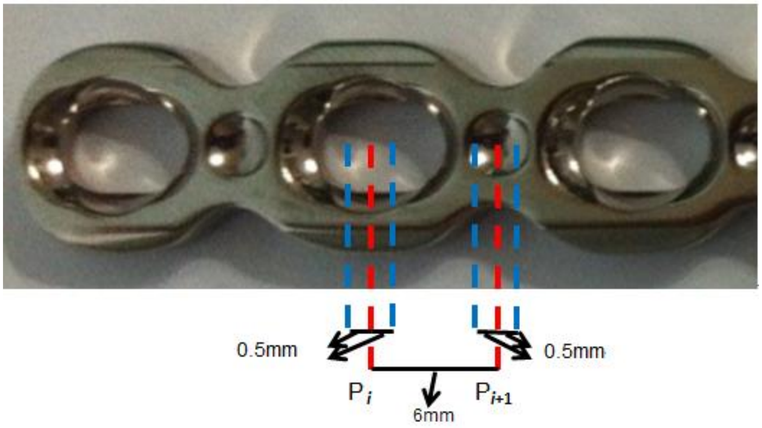

Fig. 2: Distance allowance obtained from implant design.

Figure 3 shows the criteria that used to define the effective point region. Based on these criteria, the point cloud in the effective point region will be checked. Then the points that satisfy the distance and maximum bending angles allowance will be selected. The selected points will be checked to see if penetration to the bone is happened and used for determining the implant bending angle.

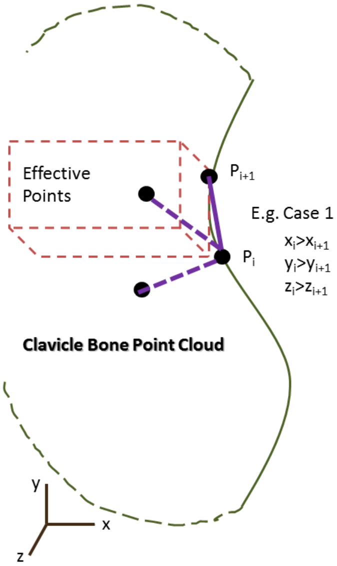

Fig. 3: Criteria that used to define the effective point region.

3. Calculation of bending angles

Since the implant needs to be modified to the suitable curvature of the clavicle bone, the maximum bending angles of the implant has to be considered to prevent possible failure of the material. The maximum bending angles is defined when line AB bent to AC, so the relative angle of ∠BAC is the maximum allowable bending angles which is equal to 60°. Figure 4 shows the maximum allowable bending angles.

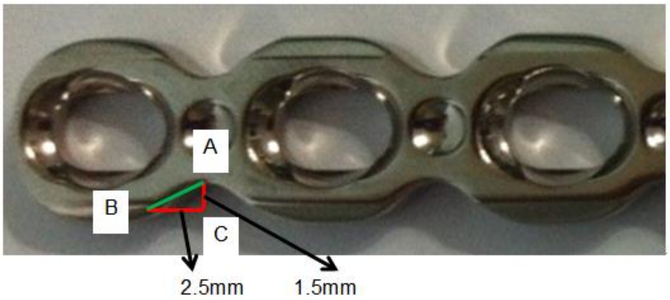

Fig. 4: Maximum bending angles allowance of implant.

The selected points in step 2 are used to calculate the bending angles using simple triangles. However if the bending angles exist maximum allowable angles, the selected point will be deleted and choose again. The process iterates until it satisfy both criteria.

Results:

In the project, we make use of 3D human anatomical model to determine the bending angles of implantable devices for osteosynthesis surgical procedure due to bone fracture. We demonstrate our method using clavicle bone. Using the MR images, the clavicle bone is reconstructed with Mimics and Maya. Figure 5 shows the reconstructed computer model.

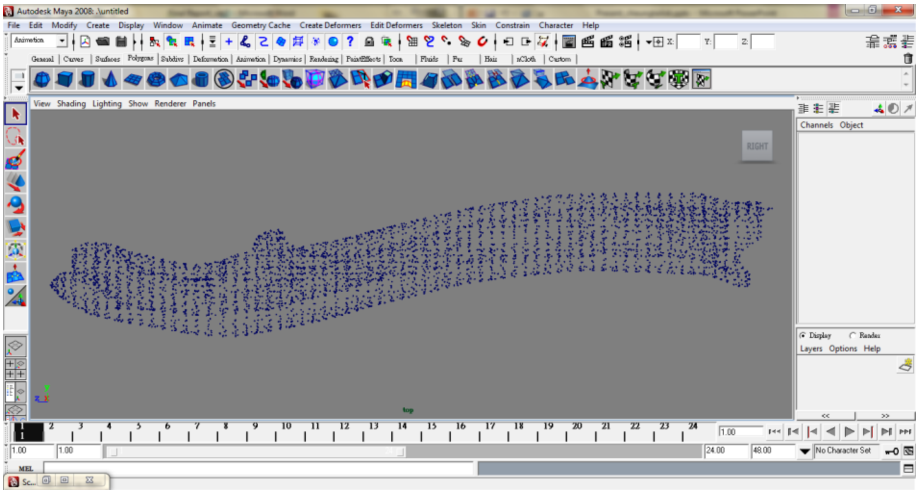

Fig. 5: The reconstructed computer clavicle model.

Assuming the fracture line of the clavicle model is located at the mid-shaft of the clavicle, the planned implant is placed at the mid-line of the bone superior plane. A clavicle implant with 10 segments is selected and the methodology is applied to calculate the bending angles of each segment. The implant is bended to fit with the printed clavicle model. Figure 6 shows that the method can estimate the bending angles of the implant successfully and fitted to the clavicle model successfully.

Fig. 6: Results of the bended implant fitted on the clavicle model.

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