DESIGN STUDY ON STABILITY AND SAFETY OF MEDIAN STERNOTOMY FIXATION

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INTRODUCTION

In mid-line sternotomies, many different sternal closure techniques have been proposed including wires, cables, bands, rigid fixation, and combinations of these techniques. Wire closure often yields poor bone union and sternal movement or instability. However, wire closure techniques are still the most prevalent technique in use today. A number of biomechanical studies have compared the stability of various closure techniques.

Biomechanical studies of sternal closure techniques are currently limited by the wide variability in sternum size, strength, and density. Synthesized bone models provide a greater degree of reproducibility, but currently lack the ability to represent the bi-material, cortical and cancellous, composition of natural bone. Finite element analysis (FEA) modeling allows for the consistent and reproducible study of a variety of interrelated material and geometric variables.

The objective of this study was to develop a model for evaluating the mechanical performance of 2 sternal closure techniques, rigid plate fixation and wire cerclage. A design study using FEA was performed to determine the effects of screw length, cortical thickness, and bone quality on the mechanical performance of a rigid sternal fixation system. The study analyzed the sternal separation and stresses that developed in the anterior cortical, intermediate cancellous, and posterior cortical regions. Lateral distraction and Rostral-Caudal shear (longitudinal shear) load cases were analyzed. The fixation systems analyzed were peri-sternal wires and the Biomet Microfixation SternaLock® Blu System.

METHODS

A two-level modeling approach was utilized in the design study. A global model consisting of two sternal halves was constructed to determine forces surrounding the plates or wires and to calculate sternal separation (Fig. 1). A local model consisting of a detailed bone model was constructed to determine stresses that developed in the plate, screws, and sternum (Fig. 2).

The mechanical properties and thickness of the cortical and cancellous bone layers were adjusted for the 2 models to simulate patients with variable bone quality. Medium strength cortical bone properties were applied to the global sternum model (Table 1). The plate was modeled as CP Ti Grade IV with an elastic modulus of 104.1 GPa [3]. The screws were modeled as Ti-6Al-4V with an elastic modulus of 112 GPa [3]. A lateral distraction load of 350 N was applied to simulate coughing [2]. A Rostral-Caudal shear load of 175 N was applied to simulate the average force on the sternum from lifting 25 lbs [2]. Average forces surrounding the plates and the sternal opening were recorded for each loading case.

Figure 1: Global sternum model with Biomet Microfixation SternaLock® Blu System

Figure 2: The local model was divided into cortical and cancellous layers with distinct material properties

In the local model, the screw lengths, bone properties, and cortical thickness were parameterized such that they could be easily changed in the design study. Lateral distraction and Rostral-Caudal shear loading cases were analyzed using the loads determined from the global model. Fixed displacements were applied until reaction
forces matched the desired applied load. Screws were modeled as cylinders with rigid normal fixation to the plate (modeling the screw locking mechanism). The screw length was adjusted to correspond to 50% purchase in the bottom cortical or 80% purchase in the cancellous region. The cortical thickness was adjusted to 0.50, 0.75, and 1.00 mm while the bone thickness was held constant at 12 mm. The strength of the bone was adjusted to low, medium, and high strength as shown in Table 1.

Table 1 – Elastic Moduli of Bone (GPa) [1]

<table>
<thead>
<tr>
<th></th>
<th>Cortical</th>
<th>Cancellous</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>6</td>
<td>0.04</td>
</tr>
<tr>
<td>Medium</td>
<td>12</td>
<td>1.1</td>
</tr>
<tr>
<td>High</td>
<td>25</td>
<td>2.2</td>
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</table>

RESULTS AND DISCUSSIONS

In the global model, sternal separation seen with wire fixation was 48-75 times more than with rigid plate fixation (0.317mm vs. 0.0066mm). Due to the low contact area between the wires and sternum, the stresses from the applied load were concentrated to the wires, with low distribution of load into the bone (Table 2).

In the local models, screw length and bone quality were seen to impact sternal separation and the distribution of load. Longer screws that engaged the posterior cortex resulted in less sternal separation than shorter screws. Additionally, more load was transferred from the plate into the surrounding bone with longer screws (Table 2).

The lateral distraction model resulted in a relatively high stress at the screw neck and stress concentration at the top cortical bone. The FEA results showed most loads are carried by the top cortical bone. In addition, it was shown that approximately 80% of the load was carried by the inner screws of the X-plate. Due to the low stiffness of the cancellous bone there were low stress levels in the cancellous region. Due to the high stiffness of the plate and screws there were low stress levels at the bottom cortical. The L-shaped plate exhibited similar behavior to the X-shaped plate.

The lateral distraction parameter study at 50% cortical purchase showed that increasing bone strength reduced the sternal gap and plate stress but increased the stress in the top cortical. When the screw length was decreased the cortical stress decreased but the sternal gap and plate stress increased. It was noted that the stress in the plate increased by approximately 80% when the screw length was decreased. The shorter screw length resulted in higher stresses in the cancellous region.

The shear loading analysis resulted in much lower stresses and sternal gaps. The results of the parameter study revealed trends similar to those in the lateral distraction loading.

Table 2 – Comparison of Separation and Stress Values for Different Closure Techniques in the Global Model

<table>
<thead>
<tr>
<th></th>
<th>Wire</th>
<th>Rigid Plate Fixation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max. Gap (mm)</td>
<td>0.317</td>
<td>0.0066</td>
</tr>
<tr>
<td>Max. Bone Stress (MPa)</td>
<td>55</td>
<td>--</td>
</tr>
<tr>
<td>Max. Stress in Metal (MPa)</td>
<td>200</td>
<td>--</td>
</tr>
</tbody>
</table>

Table 3: Comparison of Separation and Stress Values for Different Screw Lengths in the Local Model

<table>
<thead>
<tr>
<th></th>
<th>Plate with Long Screws</th>
<th>Plate with Short Screws</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max. Bone Stress (MPa)</td>
<td>79</td>
<td>67</td>
</tr>
<tr>
<td>Max. Stress in Metal (MPa)</td>
<td>100</td>
<td>184</td>
</tr>
</tbody>
</table>

CONCLUSIONS

In general, FEA analysis demonstrated that stresses and sternal gap resulting from lateral distraction was significantly greater than for Rostral-Caudal shear. A comparison of wire closure to rigid fixation showed the stresses in plates was about half of the wire stress when proper screw sizes were used. The stress concentration at the top cortical bone was about 30% higher than the wire model.

The screw length and bone strength are the major factors for stress concentration and gap opening. The evaluation of the stress concentration in wire model needs to be evaluated in a different way because the wire diameter is too small compared to element size used in the bone for the local model.

Selection of the proper screw length to achieve purchase in the bottom cortical is very important in order to reduce the sternal gap, which can be achieved by measuring the sternal thickness. In addition, this model allows for an evaluation of screw location and plate design to be performed in order to design rigid fixation systems with optimal distribution of load. Future work to compare these results with bench testing is warranted.

REFERENCES