A Novel Sternotomy Saw Guide Incorporating Integrated Rigid Fixation

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Problem Description

Every year, 700,000 median sternotomies are performed in the US alone [1]. In this procedure, the sternum is dissected to gain access to the thoracic cavity using a bone saw, allowing for procedures such as heart transplantation, coronary artery bypass surgery, and tumor resection.

Following a skin incision, a sternotomy begins with the surgeon locating the sternal midline with a three-point technique, using the sternal notch at the top of the manubrium as one point on the midline and locating a second by manually identifying the midpoint between two intercostal spaces near the bottom of the bone [1]. A line is then drawn to denote the midline by connecting these points, often using the other intercostal spaces or the xyphoid process as guides. The surgeon then uses an electric reciprocating bone saw to follow this line and dissect the sternum. After cauterizing any bleeding at the incision and applying bone wax, the actual surgery within the thoracic cavity can then commence. Once the surgery has been completed, stainless steel wires are looped around the sternum through the manubrium or intercostal spaces and then tightened to approximate the two sternal halves and facilitate closure.

There are many complications that can arise from this procedure, largely due to its reliance on the accuracy of the surgeon performing the cut. If the cut deviates from the midline, creating two asymmetric sternal halves, the steel closure wires can cut or pierce the smaller half and the bone may be more susceptible to sternal fracture [2]. Sometimes, the incision can even deviate enough to cause damage to the surrounding ribs/muscles [3]. Additionally, if the incision is not straight, approximation of the sternum can be difficult, leading to sternal nonunion where there is a gap between the two halves of the sternum after closure. This can cause mechanical instabilities, reduced arm/chest mobility, and an increased risk of deep sternal wound infection [1]. Postoperatively, complications can also arise due to the wire cerclage closure technique, which allows for bone shearing, that may prevent proper healing [4]. While the complication rate for sternotomies is relatively low (3-5%), these complications carry with them a high mortality rate (with some studies reporting up to 50% for deep sternal wound infections [5]). Moreover, sternal wound infections can require further surgeries, adding an average of 20 days of hospital time and $500,000 in medical costs per additional procedure [6].

Commercial devices have been developed to address some of these issues (especially those surrounding closure) through the use of rigid fixation. Products such as SternaLock Blu® and Grand Pre® use rigid, metal plates that are screwed into the bone to hold the two sternal halves together, simultaneously preventing shearing and eliminating the risk of cutting the bone with closure wires. These techniques have been demonstrated to be beneficial in terms of sternal healing and pain reduction compared to wire cerclage [7]. However, no attempts have been made to improve the accuracy of the incision itself, leaving patients at risk of sternal fracture, nonunion, and infection. Our goal was to develop a novel sternotomy saw guide that simultaneously ensures a midline cut, constrains the saw blade to a purely linear trajectory, and incorporates rigid fixation closure.

Proposed Solution

Our proposed device is comprised of three main subsystems: the alignment system, a blade guide, and a rigid fixation closure system (see Figure 1), which address the design goals of cutting on the midline, making a linear incision, and rigidly fixating the sternum upon closure, respectively.

To use our device, the clinical workflow begins in a similar manner to the current standard of care; after the skin incision, a three-point alignment technique is employed to locate the midline. Instead of manually locating these points, however, a hook at the top of our device (Figure 4a, bottom left) is placed on the sternal notch in the manubrium, and a pair of jaws are tightened into the intercostal spaces. The jaws are connected by a coupler curve linkage that enforces symmetric motion, allowing a point on the midline to be precisely located. This alignment assembly is free to slide up and down on the bottom of our device, allowing the surgeon to select which intercostal space to use. A set of four spacer blocks is also included in the alignment system to ensure proper spacing of the two halves of our device to exactly fit the width of the saw blade between them.

Once the system has been aligned to the sternal midline, it is fixated in place with appropriately sized cancellous bone screws which anchor into the anterior cortex and cancellous bone, but do not penetrate the posterior cortex and risk damage to posterior structures. These bone screws mount small metal plates to the sternum that will used at the end of the surgery to facilitate closure. The plates are held to the rest of the device with machine screws. There are three pairs of plates spanning the length of the sternum, with four bone screws per pair.

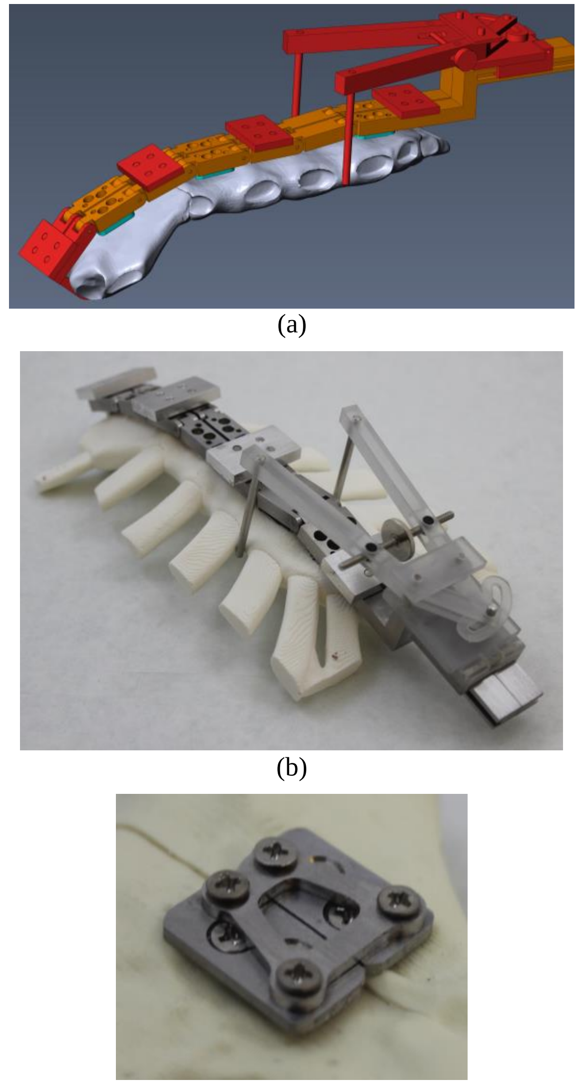
(a) (b) (c)

Figure 1: Complete sternal guide system, shown color coded by subsystem (a) with the alignment system in red, the blade guide in orange, and the closure system teal. A functional prototype is shown in (b) with a detailed view of the closure system in (c).

The alignment system can be removed once the bone screws have been installed, and the surgeon is left with two separate halves of the blade guide, spaced apart by the width of the saw blade. The blade guide is made of multiple articulated hinge pieces, allowing it to conform to varying sternal geometries. The incision can now be performed, using the two inner walls of our device as a slot to constrain the blade, ensuring an accurate cut that cannot deviate due to the mechanical constraints of the device. Since the device consists of two separate pieces, it does not impede immediate access to the blood vessels of the periosteum, allowing electrocautery to be performed immediately after the incision, as in the current procedure. The main surgical procedure can now be performed in the thoracic cavity without removing the device, as it does not interfere with the insertion of retractors.

When the surgery is complete, the blade guide subsystem is unscrewed from the implant plates, leaving just these three pairs of plates screwed into the bone. A final closure plate is used to span the gap and hold the pairs together (Figure 4c). This closure plate is designed with thin enough features such that in an emergency situation, the surgeon can cut through the metal with a pair of clippers to regain access to the thoracic cavity without having to remove any screws. The size of the closure plate assemblies is designed to be comparable to that of current rigid sternal fixation systems, and all components have been fabricated out of biocompatible 304 stainless steel.

Evaluation and Conclusions

To test the proposed device, sternum bone substitute models were purchased (Pacific Research Laboratories, Inc., PN 1025-40) that simulate the mechanical properties of bone, having both a hard, outer cortical shell and a spongy cancellous core. Two sternums were mounted to a rigid platform, and an incision was performed both manually and with the aid of the blade guide using a Stryker 4207 Sternum Saw. The cut linearity and ease of operation were then qualitatively compared.

Figure 2: Results of cutting sternal bone substitute models with and without our device (bottom and top, respectively). A clear difference in linearity can be observed.

When performing the incisions, the blade guide proved far easier to use, as it prevented torqueing of the blade. This device allowed for much smoother motion than the traditional technique, with which it was difficult to get through the bone and required a great deal of force to be applied with a second hand. The proposed blade guide was able to be operated with just one hand, while the other hand was only used to gently support the saw to keep it vertical.

A far more dramatic difference was observed, however, in the quality of the cut. The manual incision showed large deviations from the straight line drawn prior to the procedure, and near the bottom of the bone deviated so much that it was not possible to return to the midline (see Figure 2). The incision performed with the guide, however, showed no observable deviations from the midline. It is worth noting that the authors are not trained surgeons, and thus, our accuracy with the saw was more limited. However, the success achieved with the blade guide in use (despite the lack of experience) illustrates the robustness of the solution.

In summary, we designed, prototyped, and tested a novel surgical guide system for sternotomies to minimize nonlinearity of the incision, ensure a midline cut, and facilitate rigid fixation. The device was prototyped and tested on sternal bone substitute models against the current standard of care procedure. The guide demonstrated superior performance for all three design criteria when compared to the previous procedure. In future testing, the system will be tested on *ex-vivo* animal sternums with trained surgeons performing the procedure. Additionally, the design will be further optimized to minimize procedure time and complexity.

References

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