A Novel Sternotomy Saw Guide Incorporating Integrated Rigid Fixation

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Abstract

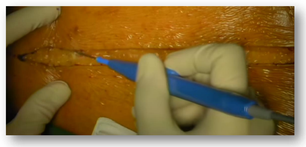
Every year, 700,000 median sternotomies are performed in the US alone [1]. In this procedure, the sternum is dissected to gain access to the thoracic cavity using a bone saw, allowing for procedures such as heart transplantation, coronary artery bypass surgery, and tumor resection. There are many complications that can arise from this procedure, largely due to its reliance on the accuracy of the surgeon performing the cut. If the surgeon deviates from the midline of the bone, complications such as sternal fracture, sternal non-union (where the two halves of the sternum do not properly heal, leaving a gap), and deep sternal wound infection can occur [2]. Attempts have been made to mitigate these risks by using rigid plate fixation to close the sternum after the procedure [3, 4], however, no attempts have been made to improve the accuracy of the incision, itself.

We propose a novel sternotomy saw guide that constrains the motion of the saw blade to the sternal midline. The device is temporarily mounted to the bone using a custom alignment system and a set of cancellous bone screws, creating a channel between which the saw blade travels. Upon completion of the procedure, the device is removed from the thoracic cavity, leaving a set of implant plates that are used to approximate and rigidly fixate the sternum to prevent healing complications. A proof of concept prototype of the proposed device was fabricated, and its efficacy was validated by performing a sternotomy procedure on a commercially available bone substitute. A significant increase in linearity was observed over the current standard of care procedure. In future testing, this device will be trialed with trained cardiothoracic surgeons to assess its viability.

Standard of Care

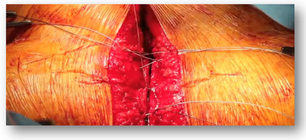
To perform a median sternotomy using the current standard of care, clinicians follow a four-step procedure:

1. **Skin Incision**
   The surgeon manually identifies the top and bottom of the sternum and performs a linear incision with electrocautery, exposing the bone. *(Image [5])*



2. **Sternal Midline Identification**
   The surgeon identifies and marks the sternal midline on the bone using the sternal notch and intercostal spaces as landmarks.
3. **Sternum Dissection**
   The surgeon attempts to "connect the dots" from the previous step, sawing down the sternal midline with a reciprocating sternal bone saw. This can quickly become difficult if the saw goes off-midline and needs to be guided back. *(Image [5])*

4. **Wire Closure**
   Once the procedure is complete, surgeons tighten stainless steel wires through the intercostal spaces to approximate the sternal halves. *(Image [6])*



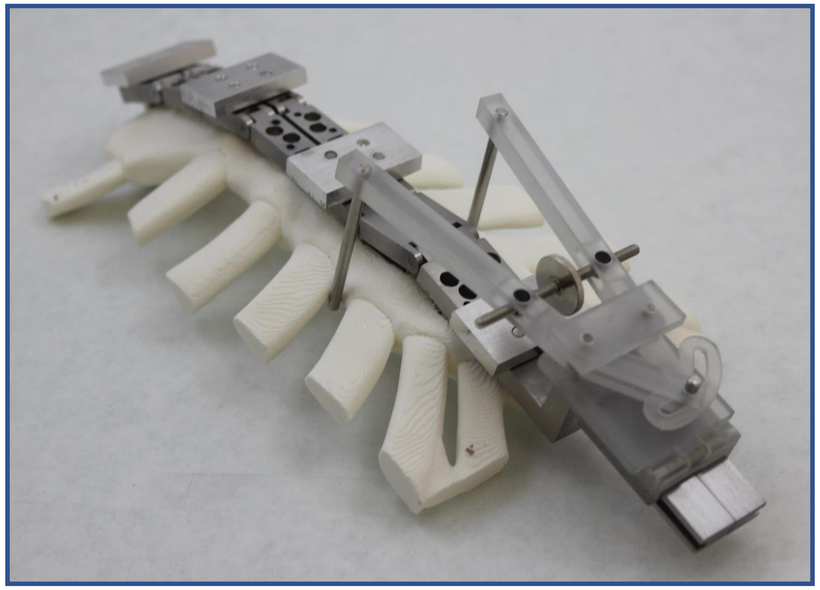
Complications

Typical complications:
- Sternal wound infection (SWI) *(Image [7])*
- Sternal nonunion and sternal fracture *(Image [8])*
- Impaired arm and chest mobility.

Effects of complications:
- 3-5% complication rate [9].
- SWI has a mortality rate as high as 10-35% [9].
- Up to 20 extra days in the hospital
- $500,000 increase in medical costs per patient [10].

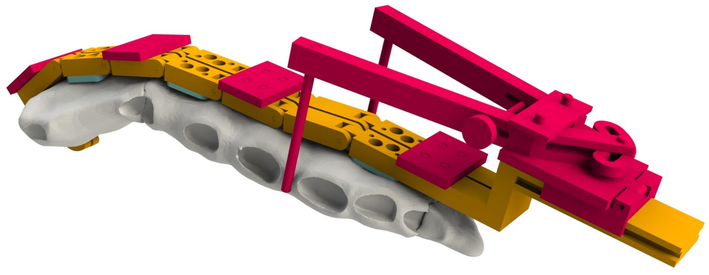
Issues with cutting technique:
- Sternal body is typically between 30-45 mm wide [11]; easy to deviate from midline.
- Non-midline cuts can leave the sternum fragile or cause damage surrounding tissues, ribs, and muscles.
- Can lead to SWI or mechanical instabilities, requiring multiple follow-up procedures.

Issues with closure technique:
- Closure wires can slice/pierce the thinner sternal half after a non-midline incision, leading to SWI
- Wire wire cerclage technique still allows shearing of the sternal halves, leading to sternal nonunion



Proposed Solution

The proposed sternotomy cutting guide consists of three subsystems: the blade guide system (orange), the alignment system (red), and the closure system (blue).

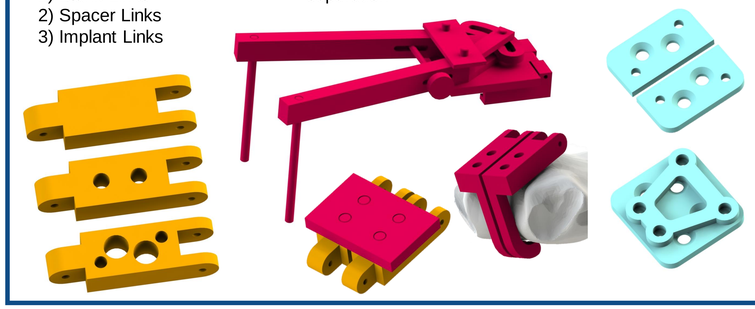


Blade Guide System:
- Two part slot spaced with a gap to constrain the blade
- Each slot half is composed of multiple articulating members to conform to differing anatomy

  1) Blank Links
  2) Spacer Links
  3) Implant Links

Alignment System:
- Sternal notch hook to locate first point on midline
- Intercostal space jaws with symmetric coupling to find second point on midline
- Spacers to maintain slot separation

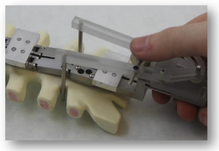
Closure System:
- Pairs of bone plate implants installed using cancellous bone screws
- Closure plate to approximate implant plates during closure and facilitate rigid fixation for healing



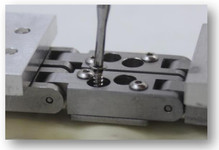
Clinical Workflow

1. **Manubrium Angle Approximation**
   After the skin incision, a custom tool is used to measure the sternal angle in the transverse plane. One of three sizes for the device is chosen accordingly.

2. **Sternal Notch Alignment**
   The hook at the top of the device is attached to the sternal notch, finding one point on the midline.
3. **Intercostal Space Alignment**
   Symmetric jaws at the base of the device are tightened into the intercostal spaces to locate a second midline point.



4. **Bone Screw Fixation**
   Cancellous bone screws fixate the device to the sternum.



5. **Alignment System removal**
   The alignment system components are removed, leaving a channel the width of the saw blade between the two halves of the blade guide system.

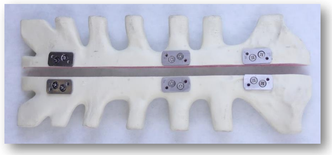
6. **Sternum Dissection**
   The sternum is dissected using a standard sternotomy saw with the channel between the device halves guiding the blade.

7. **Guide Removal**
   Once the surgical procedure is complete. The guide is removed from the thoracic cavity, leaving three implant plates on each sternal half.
8. **Closure Plate Attachment**
   A closure plate approximates each pair of implant plates left from the last step, rigidly fixating the sternum.

Evaluation and Conclusions

- Prototype was evaluated with commercial sternum bone substitutes [12] and compared with the current standard of care.
- Cut linearity improved dramatically (despite authors' lack of medical training) using the device and the incision was easier to perform.

Without Device



With Device

In summary, a novel surgical guide system was designed, prototyped, and tested for sternotomies to minimize nonlinearity of the incision, ensure a midline cut, and facilitate rigid fixation closure. The device was prototyped and tested on sternal bone substitute models against the current standard of care procedure. The proposed guide demonstrated superior performance to the standard of care in terms of incision accuracy and ease of use.

References

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[7] https://lifeinthefastlane.com/sternal-fractures/
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