

# The Importance of Closure Force and Suture Consistency in Median Sternotomy Closure

## Introduction

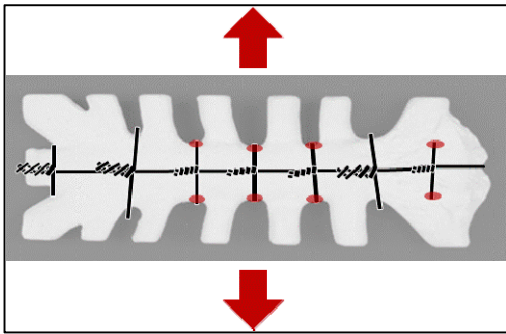
Median sternotomy is the most common method of access during open heart surgery. This component of open-heart surgery can often have the highest impact on patient recovery and healing after such procedures. Therefore, secure closure of the sternotomy is critical to re-establish the protective and respiratory functions of the rib cage and to ensure adequate patient recovery after open-heart surgery. Sternal dehiscence is one of the serious complications that can occur due to insufficient closure of a median sternotomy. It is associated with pulmonary dysfunction, chest wall discomfort, and superficial and mediastinal infections.[1-5] Although relatively rare in the overall cardiac surgery population (less than 3.5% of cases [4-12]), serious morbidities such as dehiscence and mediastinitis increase significantly in a higher risk population. Several of these high-risk factors have been identified, such as high BMI, chronic obstructive pulmonary disease, and prolonged mechanical ventilation.[13-14] Outcome studies have shown sternal dehiscence reaching incidence levels greater than 10% for BMI scores greater than 40.[9] The associated increase in mortality and prolonged morbidity in those patients spur the need to reduce these rates and improve treatment outcomes.[1, 3-5] Reduction in the occurrence of dehiscence and other chest wall complications may be linked to improving the stability of the sternal closure, reducing bone and wire failure, and reducing relative motion between the sternal plates.[23]

## Closure Tightness and Consistency Important for Durable Bone Healing

Until bone healing passes the callus formation stage and fibrous tissue develops, the suture wires are the only protection against separation of the sternal plates in response to physiological loads. Callus formation in the sternotomy begins in response to the trauma and continues for 7 to 10 days, after which the callus begins to calcify and is subsequently replaced by woven bone, cartilage and eventually laminar bone.[15] It has been shown that a smaller, more rigid sternal gap

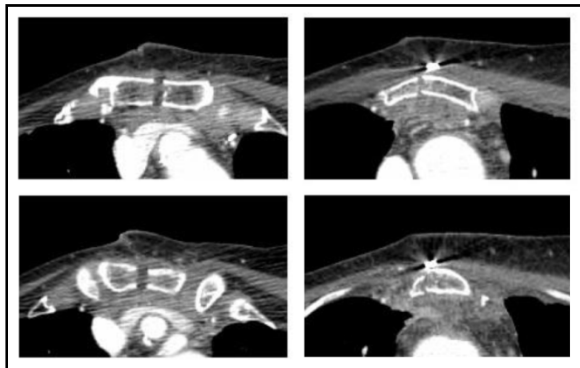
results in a shorter healing time relative to a larger gap, which has been associated with a loose wire closure.[16] When a larger gap is present, a different mechanism of bone growth known as secondary bone formation occurs. In this type of bone formation, cells form in the area between the two sections creating a mixture of cartilage and woven bone, which develops into a fracture callous. This creates a stabilization layer that acts as a scaffold for blood vessels to grow into, and provides the stability and perfusion required for the development of robust lamellar bone material.[17] In effect, the larger gap can result in a longer healing time before suitable bone material is in place to absorb the physiological loads from the suture construct, during which time the sternum is more sensitive to distraction forces. If the movement between the bones persists, the soft callous formation may fail to harden, which will prevent revascularization of the area, and could potentially result in a lack of full healing (i.e. fibrous non-union). In order to ensure sternal healing to full strength in the shortest possible time, it is critical that a wiring method is chosen that will result in the lowest gap possible under regular and transient physiological loads.

Sternal instability can be attributed to motion between the sternal sections due to laxity in the wires. In the extreme, this can manifest itself in wires cutting into the bone, wire breakage, or a combination of both.[18] In the majority of cases, however, sternal instability can result in decreased mobility, compromised respiration, excessive incisional pain, and major complications.[23] In an optimally-closed sternum, each wire suture will engage the sternum equally under distractive loads, and resist an equal amount of force to prevent motion of the sternal halves. Forces across the entire sternum have been estimated to be as high as 150 kg for a cough and 12 kg as a baseline for assisted ventilation.[19] In a closure completed with six suture wires, each wire must therefore be capable of resisting up to 25 kg of force in transient loading. The effect of laxity in certain wires is illustrated in **Figure 1**.



**Figure 1: Sternal load from coughing**

If laxity is present in one or more wires, the other wires will be subject to a proportionally increased load. If two of the wires have laxity present, this will translate to an effective load of up to 150 kg over 4 wires, which equals 37.5 kg per wire, or a 50% increase per wire. This increased force is thus transmitted to the underlying sternal bone, increasing the risk of the wire cutting through the bone or wire breakage. This can result in sternal instability, discomfort and pain due to motion, infection, and possible non-union of the sternal halves. This increased force on individual wires can also increase the likelihood of loosening or rupture of these wires. **Figure 2** is a CT scan of a patient whose sternotomy was closed using manually twisted suture wires, which shows a clear gap between the sternal plates.



**Figure 2: CT image of sternum after manually-twisted wire closure - 2 weeks post-operation**

### Attributes of an Optimal Median Sternotomy Closure

There are several aspects of wire closure which are required to ensure that the patient will have an optimal healing profile after surgery. One of the key predictors for positive outcomes is an accurate median sternotomy. Paramedian sternotomy has been shown to strongly affect

post-operative wound stability.[20] During approximation, it is important that the sternal halves be accurately approximated, with the cut surfaces pulled together firmly. Maximal force at each suture results in less chance of relative motion between the sternal plates during healing.

At the level of the individual suture wire, there are several characteristics that determine the quality of the closure. First, it is critical that the tension applied to the wire be the maximum that the underlying sternal bone structure can withstand. For patients with poor bone quality, the suture wire should not be over-tightened as this can result in bone failure.

### ***Optimal median sternotomy closure characteristics***



- **Sternotomy cutline equidistant from the edge of both sternal plates**
- **Accurate approximation and alignment of the sternal sides**
- **Cut surfaces pulled together firmly**
- **Every suture closed tightly; a loose suture increases load on other wires**
- **Equal force distribution along sternum; all sutures have equal closure force**

Next, the twist should be as uniform as possible, with the highest possible twist density and the bottom of the twist should conform closely to the sternum. Higher twist density (i.e. number of wire twists per unit length) has been demonstrated to increase the strength of the closure.[22] It is also important that the wire does not begin to wrap around itself at the base of the twist, as this precursor to wire breakage will prevent maximal tensioning of the wire, and could create a post-operative failure point. Again, it is important that the closure force be consistent between sutures, to ensure equal loading on the wires.

### ***Optimal twisted wire closure characteristics***



- **Maximal wire tension in the loop of the suture**
- **Uniform twist pattern (i.e. not twisting on itself at the bottom of the twist)**
- **Elimination of the tent shape at the base of the twist (which can result in closure laxity)**
- **Maximal twist density**
- **Consistent closure force between suture wires**

### **Disadvantages with Manually Twisted Wire Sutures**

Manual application and twisting of suture wires with clamps and needle driver is the most common method of securing the sternal halves after a median sternotomy.[21] The main disadvantage of the current method for applying steel wires in the osteosynthesis of sternal sections is the application of tension via twisting of the wires. This action results in sub-maximal wire tension (and thus closure force) as well as inconsistent tension between sutures. Another disadvantage of the current technique is that there is no feedback for the tension applied at each suture. It leaves the potential for variability in the wire-to-wire tensioning, and among different surgeons performing sternal closure.

Most surgeons rely on their experience and “feel” in determining how much closure force to put into each suture wire while twisting to achieve the desired tension. Practitioners report using various visual cues for when to stop twisting the wire, such as a color shift in the wire at the base of the

twist from shiny to dull (which is an indication that the wire is beginning to yield), and looking for one of the wire strands to begin to wrap around the other. The concern with these cues is that the wire has already begun to yield, and less force is required to cause the wire to rupture. Both of these checks are indications that the wire is close to breaking at this critical point in the wire, and if the patient is subsequently closed, there is the potential for post-operative wire breakage.

### ***Disadvantages with manually twisted wire sutures***



- **Difficult to achieve maximal tension in wire loop**
- **Wire twisting introduces stress into the wire at the base of the twist which can lead to breakages**
- **Wire twisting technique is not ideal to eliminate tenting at base of twist**
- **Difficult to achieve high twist density**
- **Twist malformation and potential for wire breakage due to poor twisting technique**
- **Variable closure force between sutures**

The other issue with the manual twisting of sternal wires is that there is a large variability in the applied tension between sutures. This can result in an unequal loading of the wires as indicated in **Figure 1**, and can lead to the overloading of certain sutures. **Figure 4** shows the closure force and variability that exist between manually closed wires, in a sample size of ten manually twisted wire closures by four experienced surgeons on a biomechanical testing apparatus.

## TORQ™ Sternal Closure Device – An Improved Method of Tensioning and Twisting Sternal Wires

The TORQ™ sternal closure device (Kardium, Richmond, Canada) was developed to provide a superior and repeatable tensioning of standard monofilament wire sutures. The device consists of a shaft into which the suture wire ends are inserted, and to which a rotational handle is coupled. Through the rotation of the handle, the wires are wound around the shaft and tension is added to the suture wire. The mechanical advantage in the handle allows the user to achieve maximal wire tension easier than with manual twisting. This produces an increased force on the wires while also ensuring optimal preservation of wire structural integrity, reducing wire breakages during closure and, more importantly, potential breakages after closure.

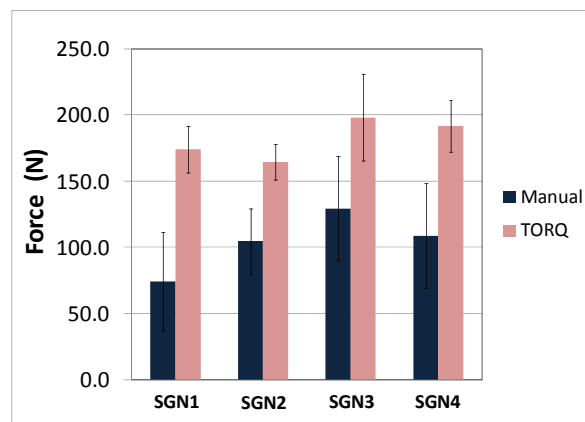
Through the use of multiple TORQ™ devices during sternotomy closure, as shown in **Figure 3**, it is possible to ensure that the wire tension at each suture is maximal, and that the tension is uniform between sutures, before the wires are secured. Once full tension is achieved at each suture location, the device then twists the wire, locking the tension into the suture. By separating the tensioning of the wire from the twist to lock in tension, more tension may safely be applied to the wire without sacrificing structural integrity.



**Figure 3: Multiple TORQs being used in surgery**

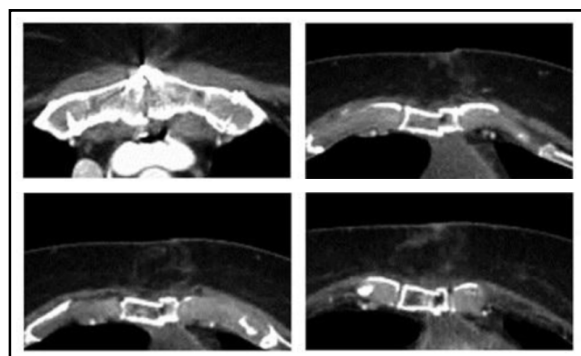
**Figure 4** shows the higher closure force and lower variability that the TORQ is capable of achieving

on a biomechanical testing jig relative to manual closure, when performed by the same four surgeons. The TORQ™ is able to generate a significantly higher closure force ( $p < 0.01$ ), as well as significantly lower standard deviation ( $p < 0.01$ ).



**Figure 4 - Closure Force Comparison (n=10)**

The TORQ™ sternal closure device was used to secure the suture wires of a patient, and a CT scan was obtained of various sternal section two weeks post-operatively. **Figure 5** demonstrates superior apposition and a clear lack of a gap due to relative motion between the sternal sections during the initial healing stages.



**Figure 5: CT image of sternum closed using TORQ™ device – 2 weeks post-operation**

### Conclusion

The use of a mechanical device to assist in the wire tensioning and twisting of stainless steel suture wires during closure of median sternotomy will produce a tighter and more consistent closure. This may result in reduced pain, improved sternal healing, and reduced infections and complications through the reduction of movement between the sternal plates during healing.

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This white paper was co-authored by Marc Delorme, B.A.Sc., Product Manager, and Amy Saari-Roth, M.A.Sc., Biomedical Engineer, who are both employees of Kardium.

The surgeon who performs any sternal closure procedure must determine the appropriate device and surgical procedure for each individual patient. Information contained in this white paper is intended for surgeon or distributor information only and is not intended to inform surgical choices. For additional information, please see appropriate package insert for each device or visit our web site at [www.kardium.com](http://www.kardium.com).

The logo for Kardium, featuring the word "Kardium" in a bold, red, sans-serif font. Above the letters "a" and "i" are stylized red ECG waveforms.

Suite 100 – 12851 Rowan Place  
Richmond, BC  
V6V 2K5  
Phone: 604-248-8891