A Cardiac Suspension Unit for Mitigating Thoracic Pressure in Postoperative Open-Sternal Newborns
A Heat Bed and X-Ray Compatible Design

by

Luke Jeffrey M"ac"Lean

A thesis submitted in conformity with the requirements for the degree of Master of Health Science, Clinical Engineering
Institute of Biomaterials and Biomedical Engineering
University of Toronto

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Abstract

Background

Newborns with heart defects require surgery where immediate chest closure may not be possible. Cardiac suspension applies chest-wall traction to mitigate complications but is limited by its unquantified tension, lack of X-ray compatibility, and aesthetic. A designed tensioner unit may resolve these challenges.

Methods

Design requirements are established by chart-review and surveying. Subsystems are evaluated through analytics, FEA, and experimentation. The device is assessed for rigidity, transmission, heat transfer and radiolucency.

Results

Patient data is presented, design requirements are established, and a cantilever design is selected. The framing achieves fixation but with slight deflection. A compensator and non-backdrivable input are developed for the wire system. Transmission friction losses are noted. EB beam modelling identifies Ultem for the cantilever design.

Significance

This research presents the first investigation into the cardiac suspension technique. A prototype was designed, built and tested, and is a strong step towards improving cardiac suspension.
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List of Abbreviations

1. ABS - Acrylonitrile Butadiene Styrene

2. ASD - Atrial Septal Defect

3. BSA - Body Surface Area (m²)

4. BT shunt - Blalock-Thomas-Taussig Shunt

5. CAD - Computer-Aided Design

6. CCCU - Cardiac Critical Care Unit

7. CFD - Computational Fluid Dynamics

8. CI - Cardiac Index = \( \frac{CO}{BSA} \left( \frac{L}{min \cdot m^2} \right) \)

9. CIGITI - Center for Image Guided Innovation and Therapeutic Intervention

10. CO - Cardiac Output (\( L_{min} \))

11. CoP - Center of Pressure

12. CPB - CardioPulmonary Bypass

13. CS - Cardiac Suspension, Chest Suspension

14. CSU - Cardiac Suspension Unit

15. DSC - Delayed Sternal Closure

16. EB - Euler-Bernoulli

17. ECMO - ExtraCorporeal Membrane Oxygenation

18. EPC - Electronic Patient Chart

19. FBD - Free Body Diagram

20. FEA - Finite Element Analysis
21. HLHS - Hypoplastic Left Heart Syndrome
22. HRHS - Hypoplastic Right Heart Syndrome
23. HSC - Hospital for Sick Children
24. IBBME - Institute of Biomaterials and BioMedical Engineering
25. IC - Immediate Closure
26. ICU - Intensive Care Unit
27. IWL - Insensible Water Loss
28. MRN - Medical Record Number
29. NIST - National Institute for Science and Technology
30. ODE - Ordinary Differential Equation
31. PEEK - PolyEther Ether Ketone
32. PEI - PolyEtherImide, Ultem
33. PPS - PolyPhenylene Sulfide
34. PDA - Patent Ductus Arteriosus
35. RACHS - Risk Adjustment for Congenital Heart Surgery
36. REB - Research Ethics Board
37. RN - Registered Nurse
38. TGA - Transposition of the Great Arteries
39. ToF - Tetralogy of Fallot
40. VSD - Ventricular Septal Defect
41. ZoS - Zone of Stability
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1. Beer-Lambert Law (ODE):
\[
\frac{d\Phi_e(z)}{dz} = -\mu_\lambda(z)\Phi_e(z)
\]

2. Beer-Lambert Law (Result):
\[
T_\lambda = e^{-t\mu_\lambda}
\]

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\[
\dot{q}_{net} = \sigma(T_1^4 - T_2^4) \left( \frac{1}{\varepsilon_1} + \frac{1}{\varepsilon_2} - 1 \right)
\]

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\]

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\[
\frac{d^2}{dx^2} \left( EI \frac{d^2w}{dx^2} \right) = q(x)
\]

Fixed-end at x=0 \quad w|_{x=0} = 0 \quad \frac{dw}{dx}|_{x=0} = 0
Free-end at \( x=L \)
\[
\frac{d^2 w}{dx^2} \bigg|_{x=L} = 0 \quad \frac{d^3 w}{dx^3} \bigg|_{x=L} = 0
\]
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  - The Center for Image-Guided Innovation and Therapeutic Intervention
  - The Division of Cardiovascular Surgery
  - The Division of Neurosurgery
1 Introduction

One of the principal research areas for the Center for Image-Guided Innovation and Therapeutic Intervention (CIGITI) is to analyze outstanding surgical challenges in order to design devices which can overcome these difficulties. This project and manuscript will apply this methodology to the assessment, and proposed improvement, of a new critical-care technique at the Hospital for Sick Children (HSC) termed Cardiac Suspension (CS). In the scope of the entire Master’s thesis, this report will address this design process and relevant science broadly. This review will include the limitations of the current technique, the establishment of design requirements, the conceptualization of design alternatives, the associated clinical and technical science, and finally the analytical, numerical and experimental validation of the proposed solutions. Previous work in this lab had developed a conceptual tool for CS, but with several practical limitations. [9] This project will extend upon these previous findings by proposing and validating solutions to the prior tool.

Children born with congenital heart defects often must undergo immediate corrective surgery. [20] These procedures are often highly invasive and require a median sternotomy whereby the breastbone is split to provide the surgeon access to the thoracic cavity. [8] The chest is typically closed post-operatively. [42] However, surgical edema and swelling that result from the trauma of the surgery will increase pressure on the thoracic organs. [2] This increase in pressure may result in several complications including respiratory and hemodynamic instabilities, cardiac tamponade, and low cardiac output. [2] Therefore, the chest is often left opened for a few days to a few weeks post-operatively in a Delayed Sternal Closure (DSC). [42] However, the unsupported chest wall may still create pressure spikes. [8] Consequently, the HSC has developed CS where the chest is pulled anterior to the patient via tensile sutures in order to expand the thoracic volume and mitigate pressure. [8] However, the current methodology presents several limitations including unquantified tension, limited X-ray access and an unprofessional aesthetic. [9] The device developed and presented in this report will aim to resolve these issues.

This manuscript will begin by introducing the area of research of surgical tool design and the broad nature of this field. The value of this topic will then be addressed both for the practical clinical applications and the engineering theory that will need to be considered and developed. In following, a more detailed description of the research problem will be outlined. This will include the clinical and engineering challenges that will be analyzed. The objective of the project can then be discussed in terms of the outcomes that will be considered periodically throughout the design process. Broadly, the design and research methods used throughout this thesis will then be presented along with an outline of how these results will be structured throughout the report. Finally, specific statements of the problem and proposed solution will be offered before beginning discussions on the overall design project.
1.1 Area of Research

Surgical instrumentation is comprised of tools, both mechanical and mechatronic, which facilitate surgical maneuvers through improvements to usability, guidance, or control. Furthermore, the increased interest in customized surgical tools and rapid prototyping has given rise to a new field of engineering research. The field of surgical tool design intends to employ concepts traditional to mechanical engineering design in order to augment surgical approaches. Therefore, the scope of this research is naturally very broad both in terms of the clinical applications and the potential technical considerations. However, all projects must consider both surgical and mechanical issues, and the concepts of reliability, safety, usability, accessibility, and measurement are central to most designs. Consequently, many surgical tool initiatives are framed as quality improvement projects. Therefore, an important component to this field is re-framing simple surgical problems in terms of their technical considerations through analytical, numerical and experimental modelling of both the biological system and the designed device.

This project will specifically focus on developing a new tool for Cardiac Critical Care Units (CCCU) and is addressing an issue within paediatric cardiothoracic surgery. Cardiothoracic surgery is a field of medicine is particularly focused on treating conditions relevant to the heart, lungs and rib-cage. The paediatric sub-specialization will then largely focus on surgically correcting congenital defects in the heart which may otherwise prevent the efficient pumping of blood. [26] The severity of these conditions, and the extent of the procedures, means that managing post-operative outcomes can be a complicated affair. [26] The physiology of the underlying thoracic systems is important to help design therapies for the patient’s recovery. Successful outcomes requires collaboration between cardiothoracic surgeons, CCCU nurses, and intensivists. Understanding the basic work-flow of each of these roles will be important aspect for designing an effective and usable tool.

The principal technical areas relevant to the project cover deformable mechanics (truss analysis), heat transfer, radiography, materials science, mechanical power transmission and measurement. Deformable mechanics is used to design and predict the internal stresses and strains of materials and devices under loading. This is important for establishing safety and aesthetic. Heat transfer is used to study how thermal energy is transferred between bodies which is relevant here to the warming of the newborn. Radiography studies the properties of X-ray imaging and how to ensure radiolucency in the device. Materials science can then consider the mechanical, thermal and radiolucency properties of several materials in order to ensure proper design selections. Mechanical power transmission is concerned with designing gear trains and pulley systems to effectively send energy from source to output. Here, this energy is sent is the form of tensile transmission and strain. Finally, measurement is the science of designing a system to quantify and accurately record the important functional parameters. All of these disparate fields could be considered sub-categories of mechanical engineering as applied to conceptual design.
1.2 Value of the Topic

Any topic of research can aspire to be valuable in order to improve a specific application or to progress the understanding and modelling of the given field. In regard to surgical tool design, the most direct value is the improvements to the clinical care of patients. However, there will also be benefits to the theory which underpins the development of the tool. Clinical environments represent a unique combination of constraints. Therefore, developing an engineering toolbox to design within these requirements will be an important area of theory for this project and future work. This section will briefly address both the practical and theoretical aspects that this project will attempt to address.

1.2.1 Practical Value - Clinical Applications

The central goal of the project is to supplement the care of complex-care newborns by providing therapeutic functionalities during CS that would otherwise be unavailable. The introduction of the device will allow the tension on the child’s chest to be monitored and the implementation of the technique to be standardized. Therefore, through this control, the methodology of CS can be refined in order to optimize patient care. Furthermore, the creation of both a standardized platform and technique will allow for facilitated dissemination of CS to other centres. By avoiding the current practice of hanging the tensile sutures from the heat lamp, the device will also allow X-rays to be more easily taken during suspension. Finally, the improvements to the aesthetic will offer a potential venue to mitigate the parental anxieties that result from seeing their child suspended.

A secondary practical benefit of the thesis will be the development of a stand-alone medical product. This device can then be used as a platform to further develop associated tools, or to provide a potential unit for commercialization. However, the plans for the tool after its validation are outside the scope of the current thesis.

1.2.2 Theoretical Value - Engineering in Medicine

Multi-parameter design is an area that strives to justify trade-offs between several variables in order to make design choices relating to specific components or material selection. [15] The clinical environment is unique in that it imposes a wide array of different stimuli and stressors on tools. Therefore, it is an ideal environment for developing the theory about how to best make design trade-offs. In the scope of CS, the tool will be exposed to X-Ray radiolucency, thermal resistivity, and mechanical stiffness constraints. It must also remain sterilizable and accessible in order to avoid predictable biological and clinical concerns. It is often impossible to simultaneously optimize for all of these objectives. However, this report will aspire to build frameworks which can best justify decisions that balance the various requirements. Ideally, these deliberations can help contribute to the broader theory of multi-parameter design in a neonatal critical-care environment.
Secondly, tensile transmission in the device will occur via a series of gears and a pulley system in order to achieve the desired functionalities. As will be discussed in chapter 3, the design must maintain tension during movements in the tool while also housing a continuous, bidirectional, non-backdrivable input. Due to the combination of these requirements, an original tension transmission system had to be developed for the purposes of suspension. The resultant compensator system is therefore a contribution to the broader field of transmission systems and valuable because it represents a novel mechanism.

1.3 Research Problem

When children are born with a variety of congenital heart conditions, they often require immediate (or near immediate) cardiac corrective surgery to repair the defect. [20] A median sternotomy is required for these procedures. [8] These procedures are highly invasive and result in significant swelling in the thoracic cavity. [40, 34, 24] Upon attempted closure, this edema will create compression on the heart and lungs. [40, 34, 24] The typical course will be to perform a DSC and use diuretics to dissipate the edema until a successful closure can be performed. [48] During this period, the wound is covered with dressing and most patients are successfully closed within a few days. [39] An image of a newborn’s exposed thoracic cavity during a DSC is shown below in figure 1. [39] However, in the most fragile patients, the unsupported chest may continue to compress the thoracic organs and create complications. [8] It is for this reason that surgeons at the HSC began to pioneer the CS technique. [8]

![Figure 1: An image of the dressing covered open-sternum of child during a DSC.[39].](image-url)
A CS procedure is an approach whereby sutures are placed through the sternum of the patient. This suture is then wrapped around the above heat lamp so as to pull anterior to the child’s chest. The intention is to expand the thoracic volume and prevent the collapse of the unsupported chest wall. Hence, the extrinsic pressure on the heart is be reduced which improves cardiac output. A closed pair of needle-drivers is what ties the wire around the heat lamp. This allows nurses to adjust the tension pulling on the chest up to the weight of the child (at which point they would be suspended). An image of a child undergoing suspension is shown in figure 2A.

Figure 2: Images of (A) a CS patient, and (B) a CS setup. Red lines indicate the suspension line.

The technique is widely considered to be a positive last resort for critical patients but it is acknowledged that CS has several outstanding limitations. First-off a formal review has never been conducted to understand the effectiveness or variability in the technique. As such, it is difficult to optimize the current methodology. Secondly, the current setup is highly qualitative. The tension is ‘measured’ based on the feel of plucking the suspension line. Further, there are several differences in the number and placement of the sutures that different surgeons will use. The current setup also prevents X-rays from being taken without de-suspending and re-suspending the patient. This process can be re-compress the heart for a fragile newborns and cause complications. Finally, the current aesthetic is unprofessional and leads to parental anxieties.

The central problem of this research project will be to investigate these limitations and a potential solution for overcoming them. This can subsequently be broken down into several sub-sections. The problem of interest will be to research the current landscape of treating DSC complications and the current state of the CS technique. This includes the issue of establishing what requirements a potential replacement system would need to satisfy. Next, the solutions that could overcome the current limitations need to be investigated and compared. Further, there is the question of how to develop one of these systems and evaluate if it can achieve the necessary functionality.
1.4 Objective of the Thesis

The objective of the thesis is to establish a new approach though a device that can perform CS while overcoming the identified limitations of the technique. The first-step in this process will aim to analyze the current technique in order to best understand and re-frame the considerations as an engineering problem. Once this information is collected, the goal will be to state a series of design requirements, which any proposed solution must satisfy. As such, it can be ensured that alterations will not compromise the usability or functionality of prior approach. Further, by analyzing CS through literature, chart-reviews and surveying, this project will strive to provide one of the first comprehensive assessments of the CS technique.

Secondly, the objective of this project is to design, develop and build a functional prototype of a CS device. The device will be conceptualized from a variety of approaches. Notably, the project will attempt to consider and compare both original and off-the-shelf options which can achieve the design requirements. Next, the selection will be broken down into a set of sub-systems. Each system will be individually designed through analytical mechanics and numerical methods. The established components will then need to be assembled into the prototype. The goal is to manage the bulk of this manufacturing process in-house by means of rapid-prototyping through 3D printing and traditional machining. Each subsystem should effectively accomplish its specific function while also respecting the overall constraints of the design. These include maintaining usability for the medical staff, ensuring the safety of the patient, and remaining compatible with the heat-bed.

The final goal of the thesis will be to evaluate the CS device through a series of bench-top experiments. In particular, the objective of this project is to supplement the current cardiac suspension technique through quantified tension, X-ray compatibility, and a professional aesthetic. As mentioned for the sub-systems, the overall device must also respect the constraints of the CCCU. Children lose significant body heat when the chest is open. Therefore, maintaining the heat-lamp is essential to the patient’s safety. Further, critical patients require frequent and sometimes rapid care. In order to validate the breadth of these requirements, the device will be tested against its thermal, mechanical, radiolucency, safety and measurement capacity. These experiments will strive to justify the tool for compassionate care clinical implementation.

The thesis is intended to develop the design as close to a functional tool as possible. Each of the steps mentioned above are intended to bring the design process closer to this central goal. In terms of contributions to the field, the project will aim to offer insight on feasible approaches to improve care for CS patients, and also outline a plan for how this device should be constructed and implemented. The overall project will strive to build a case-study on multi-parameter design within a clinical environment that may be used by other projects in the future. Finally, the project also intends to build unique mechanisms to solve the various design challenges that may arise.
1.5 Brief of the Design and Research Methods

This research employs the methodology of a design project. The first step is to assess the given problem so as to develop design requirements. Three different approaches will be taken to understand the CS technique and develop the list of requirements. First, a literature review will be conducted and divided between the clinical and the technical considerations. The clinical considerations will address the current reality of CCCU care that will need to be recreated in the device. The technical side will investigate the specific design considerations that will be required to make the device functional and compatible with the CCCU environment.

Next, a survey of health-care workers familiar with the technique will be undertaken in order to best record first-hand experiences. This survey will investigate their perspectives on both the current benefits and limitations of CS. Cardiac surgeons, CCCU nurses and intensivist nurse-practitioners will be included in the review. Finally, a single-centre retrospective chart review will be undertaken in order to investigate the clinical experience of CS patients relative to DSC and Immediate Closure (IC) patients. Very little is currently published on suspension, so this review will serve as a preliminary formal investigation on the technique. [8, 9] The results will serve to identify CS patients as a distinct treatment group, and to better understand any unique healthcare challenges that may inform the design process. Once these three investigation methods are completed, the list of design requirements will be established.

Next, a conceptual design phase will be undertaken that will consider both the overall approach of the tool and then the development of the identified subsystems. Potential options for the overall approach will be generated by investigating current market options and the geometric approaches that a new design may take. Once this list of options is compiled, the results will be compared in a Pugh matrix in order to select a model moving forward. The given system will then be divided into a series of smaller problems where the component selection can be more individually addressed. The design and selection of components will first be analyzed for the principal mechanics that component intends to achieve. Next, the relevant analytical model will be discussed in that section. If necessary, a numerical model, notably Finite Element Analysis (FEA), may also be used to investigate the component selection. Once the components are chosen, the subsystems and the device prototype can then be assembled for further experimentation. If required, these experimental results may inform re-selection of certain components as is typical in an iterative design process.
Finally, an experimental validation phase will be conducted in the form of bench-top tests that can evaluate the prototype. In particular, the deflection, tensile transmission, heat transfer and radiolucency of the tool will be assessed. The deflection will track the deformation of the tool under mechanical loading with a force gauge and electronic level. These results will inform both the safety and the aesthetic of the tool. The transmission through the system will again use an electronic force gauge to determine if tension is accurately being measured by the device. Heat transfer will be determined by measuring temperature at bed level with a laser pyrometer in order to ensure adequate radiant warming for the patient. Finally, X-ray imaging will allow for an assessment of the radiolucency of the tool.

A brief note should also be made regarding the independent value and functions of including the variety of analytical methods, numerical approaches and experimental validations that have been proposed for this project. Each type of assessment serves a unique role and the nature of these applications relates largely to where they occur in the design time-line. When considering initial conceptual designs, either for the tool overall or a certain component, analytical methods are a fast and free way to assess whether or not the concept is feasible. In this way, the analytical methods help to identify pitfalls early on (prior to the investment of time or money) and they help the design engineer to understand why a certain concept may fail. For this reason, analytical methods are used three times in the report to consider the mechanical stiffness, the heat transfer, and the radiolucency. All three of these sections use analytical studies to justify the design choices and to better understand the underlying physics that may challenge that aspect of the device. In the case mechanical stiffness, early observations were noted to not align with the analytical predictions. Hence, in this situation, the following numerical study was an opportunity to overcome certain geometric limitations that may otherwise be difficult to model analytically. Finally, experiments are used throughout the project to serve as bench-top validation and a gold-standard as to whether or not a certain design choice is effective and safe for the respective function. Therefore, all three methods (analytical, numerical, and experimental) serve unique but highly important roles at different stages of the project. At certain points, such as in studies relating to the deflection and stiffness (section 6.4 - 6.5), these three methods may be compared as a way to understand inconsistent results and in order to identify limitations in the design.
1.6 Overview of the Thesis Manuscript

As mentioned in the previous section, this report will take-on a design project approach. It will begin with a clear statement of both the problem under consideration and the proposed solution. Next, a thorough literature review will be presented which covers both the surgical and technical research that will become relevant to the device development. In following, both the health-care worker survey and the chart review will be presented as techniques for informing the design requirements. Both of these sections will present the methods of the investigation, the results and then finally a discussion.

Next, the conceptual design process will be demonstrated. Again, the methodology will be introduced followed by a review of both the commercial and invented options. The results comparing these choices will then be presented in the form of a Pugh matrix, a selection will be deliberated and chosen. Finally, the choice will be split into sub-systems for further review.

The body of the report will then address the framing of the device, the wire system and the cantilever design. Each chapter will begin by comparing and selecting components for that system. If necessary, the component options will be compared on an analytical basis. The selected part will then be evaluated in the familiar format of methods, results and discussion. The deflection will be evaluated in relation to the frame, the transmission in relation to the wire system and the compatibility, for both the heat bed and X-rays, in relation to the cantilever design.

Finally, an overall discussion will examine the strengths and limitations of the prototype. It will also consider the comparisons to commercial alternatives, published literature and the target clinical implications. Finally, the conclusion will address a recap of the problem with the main findings. A brief note on the potential academic contributions and the future work will then complete the manuscript.
2 Statement of the Problem and Hypothesis

A well-defined research question and hypothesis is fundamental for grounding the scientific writing. However, the nature of a design project can make this difficult since each component may require a different level of investigation to achieve the final objective. Nonetheless, each step in a design project is intended to build towards this final solution that can address the perceived practical problem. Hence, for the sake of both academic rigour and to focus the following sections, a specific problem and proposed solution are stated here.

2.1 The Analyzed Problem

Cardiac suspension is an invaluable therapy for critical post-operative newborns which presents several outstanding limitations. Most notably suspension is an impediment for using X-ray, it lacks consistency and quantified tension, and it offers a crude aesthetic that exacerbates parental anxieties.

2.2 The Hypothetical Solution

It is the proposed hypothesis of this research that a Cardiac Suspension Unit (CSU), a custom designed mechanical tensioner, will be able to overcome the three designated limitations while also effectively performing the suspension. This proposed solution can be compatible with the health-care work flows, the heat bed, the X-ray and the unique patient concerns through a careful development and application of the design requirements.
3 Literature Review

A review of academic publications surrounding CS and the related issues was conducted as a first step towards better grasping the problem at hand. In order to develop a successful design, the review needed to cover both the clinical and technical concerns related to the project. The relevant medical topics include the common complications in children suffering from high thoracic pressure, the recent studies surrounding DSC and the little that has been recorded on CS. The pertinent technical areas are largely focused on designing within the clinical environment. This includes how to best ensure the safety and usability while simultaneously maintaining compatibility with the X-ray and heat bed equipment.

3.1 Post-Operative Cardiac Surgery Management

Cardiac congenital corrective procedures can be a traumatic process on the thoracic organs. Consequently, surgical edema, swelling and the surgical operation itself may increase the internal volume of the heart and lungs. Therefore, sternal closure will compress these organs and can diminish cardiac output. In particular restriction of the ventricular filling capacity diminishes the cardiac output while increasing the venous pressure. A variety of complications may result including tamponade, respiratory and hemodynamic instabilities, and heart failure amongst others. This set of conditions has was first reported by Riahi et al. who termed the condition "tight mediastinal syndrome". Since then, several other names have also been reported in literature including squeezed-heart syndrome, cardiomediastinal disproportion, atypical tamponade or simply 'tight syndrome'. This last term has been used in the most recent publications and will therefore be used for the remainder of this report. The consequences of tight syndrome are often life-threatening and have been reported in up to 30% of neonatal sternal closures. Therefore a variety of therapies have been developed to attempt to expand the thoracic volume, decrease the internal swelling and ultimately hasten the recovery from tight syndrome. This section will address the common complications and and underlying pathophysiology of this condition. DSC after negative-fluid balance will then be discussed since it is the primary form of treatment for severe tight syndrome. Finally, the history and potential for CS will be addressed.
3.1.1 Common Complications and High Thoracic Pressure

During an unsuccessful sternal closure attempt, several dynamic organs in the thoracic cavity will become volumetrically constrained. [40, 10] Perhaps most concerning, the ventricles of the heart will be prevented from properly filling. [10] This is problematic for heart function in two ways. First, a decrease in stroke volume will impede the net circulation and indirectly signal for an increase in the heart rate. [44] The reduction in blood flow can trigger a sympathetic response through a series of chemoreceptors in circulation. [44] However, net cardiac output cannot be compensated because of the effect reduction in pre-load on the myocardium. [1] Cardiomyocytes have their sarcomeres arranged differently to skeletal muscle. [43] Further, expansion of the ventricle acts to order the sarcomeres and increase the contractile stroke strength. [43] This phenomena is exhibited below in figure 3. [4] The Frank-Starling curve represents how increased stretch of the myocardium (represented by the ventricular end-diastolic volume) will lead to a higher contraction force (represented by a non-linear and non-proportional increase in the stroke volume). [4]

---

**Figure 3:** An example of the illustration of the effects of pre-loading on myocardial contraction. (A) A Frank-Starling curve comparing the stretch to the contraction force. (B,C) The ventricular pumping. [4]
The compression on the heart will be associated with a decrease in arterial pressure with an increase in Central Venous Pressure (CVP). [48] However, it is worthwhile to note that tight syndrome is distinct from typical pericardial tamponade. [34] Here, this occurs due to extracardiac fluid in the pericardial space with normal cardiac space. [50] The removal of this fluid restores normal cardiac output. [40]

In the most critical cases, low CO can send a patient into cardiogenic shock. [11] In fact, the motion constraints on the lungs and heart can culminate in many complex and dangerous conditions including low CO, heart failure, tamponade, arrhythmias, low ventilation, hemodynamic and respiratory instabilities amongst others. [20] In order to better investigate a typical presentation of tight syndrome, Hashemzadeh et al. studied the intraoperative and postoperative indications for DSC in 126 patients. [20] These results are summarized below in table 1.

Table 1: The Presentation of Tight Syndrome as Indications of Delayed Sternal Closure [20]

<table>
<thead>
<tr>
<th>Event Location</th>
<th>Complication</th>
<th>Number of Patients</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operating Room (OR)</td>
<td>Hemodynamic Instability</td>
<td>75</td>
<td>59.52 %</td>
</tr>
<tr>
<td></td>
<td>Intractable Bleeding</td>
<td>8</td>
<td>6.34 %</td>
</tr>
<tr>
<td></td>
<td>Cardiac Edema</td>
<td>3</td>
<td>2.38 %</td>
</tr>
<tr>
<td></td>
<td>Arrhythmia</td>
<td>2</td>
<td>1.58 %</td>
</tr>
<tr>
<td>Intensive Care Unit (ICU)</td>
<td>Hemodynamic Instability</td>
<td>23</td>
<td>18.25 %</td>
</tr>
<tr>
<td></td>
<td>Intractable Bleeding</td>
<td>6</td>
<td>4.76 %</td>
</tr>
<tr>
<td></td>
<td>Tamponade</td>
<td>3</td>
<td>2.38 %</td>
</tr>
<tr>
<td></td>
<td>Cardiac Arrest</td>
<td>3</td>
<td>2.38 %</td>
</tr>
<tr>
<td></td>
<td>Arrhythmia</td>
<td>3</td>
<td>2.38 %</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>126</td>
<td>100 %</td>
</tr>
</tbody>
</table>

It is clear from the table that hemodynamic instabilities are the prominent indication for a compressive complication both in the OR and the ICU. These instabilities were typically noted upon an unsuccessful attempted closure. [20] This is consistent with the previously proposed pathophysiology where the attempted closure is creating the initial restriction on the ventricle. [1, 8, 40] The other noted indicators were significantly less common but they all indicate some form of cardiac constriction. Arrhythmias, tamponade, and cardiac arrest can all be caused by ventricular compression. [10] Intractable bleeding and significant cardiac edema can exacerbate this restriction in the thoracic cavity. [20] In other studies, respiratory instabilities were also reported as an alternative indicator for high intra-thoracic pressure. [48] Ultimately, the consistency of these indications with the restriction model offers support for the underlying methodology of DSC and CS. By leaving the chest-wall open in DSC, the thoracic volume is significantly less constrained than in an IC. [20] In CS, the anterior traction on the chest wall further expands the thoracic volume in order to mitigate potential restriction on the heart. [8]
3.1.2 Delayed Sternal Closure

The premise of a DSC is to postpone the chest closure until the accumulated intra-thoracic edema can dissipate and tight syndrome can consequently be avoided. [48] The most common pre-operative anatomicies which end up requiring a DSC are those which require the most significant surgical alterations, the longest Cardio-Pulmonary Bypass (CPB) and the longest cross-clamp times. [14] These qualities are associated with the highest intra-operative swelling and therefore the highest propensity towards cardiac compression. [23] A negative fluid balance is held for a few days with the use of diuretics before a sternal closure is reattempted. [48] When possible, the skin will be closed without sternal closure which has been shown to slightly reduce the risk of mediastinitis and sepsis. [14, 34] The median time until final closure in patients undergoing DSC is 2 days with skin closure and 3 days without. [48] Without, skin closure the chest wound is covered with a dressing that is frequently changed. [39] The chest cavity can be periodically rinsed with Betadine. [33] With appropriate care and safe-guards, the risk of sternal infection is typically reported as only marginally higher than in IC closure patients. [20]

In order to investigate the effectiveness of DSCs, Talbutt et al. tracked the net fluid balance of 117 DSC patients from surgery until four days after successful closure. [48] The fluid balance timeline of a 7-day DSC patient is shown below in figure 4. [48] A 95% confidence interval is shown for the recorded fluid balance across all patients. [48] Although a negative fluid balance is always initially pursued, the decision-point to attempt a sternal closure is based largely on hemodynamic and respiratory stability. [20] Therefore, closure is attempted early and often. [8, 20, 48] Unsuccessful closure was shown to not cause significant harm in this newborn population. [48]

![Figure 4: Post-operative Daily Fluid Balance and the time-line to a successful DSC.](image-url)
The results in figure 4 demonstrate that nearly all patients were able to undergo successful sternal closure only after fluid balance dropped below a predictable threshold of around -20cc/kg/day. [48] Once closure was achieved, the Cardiac Index (CI) of the patients increased by 59%, systemic blood pressure increased by 18%, and cardiac filling pressure was largely unchanged. [48] However, 35.7% of patients died before successful closure and 67.2% of these deaths were linked to low CO. [48] This relationship may be linked to a failure of the operation rather than a problem with the sternal closure. However, there is an outstanding need to develop and improved system for mitigating low CO and cardiac compression.

3.1.3 Cardiac Suspension

CS is a specific technique developed at the HSC in order to support patients with persistent instabilities, even when the chest remains open in the CCCU. [8, 49] Very little has been reported in the literature specific to the indicators, outcome and effectiveness of CS. [9, 49] However, alternative forms of critical-care sternal traction have been reported in literature dating back as far as 1970. [34] Variations of these approaches are demonstrated below in figure 5. [40, 24] In the first reported use of sternal traction, the stainless steel wires, typically used for closing the breastplate, are threaded through the closed skin and looped around a central iron rod. [40] In turn this rood is fastened to a pulley system on an orthopedic bed. [40] This setup is shown in figure 5A. [40] In a more recent variant, a full-thickness parasternal nylon suture is applied around the IC sternum while being attached to the fluid stand. [24] The motion of the stand then controls the applied loading. [24] The authors argue that even with IC, this technique offers the equivalent physiological benefits as a DSC. [24] A schematic illustrating this technique is shown in 5B. [24]

![Figure 5: Examples of sternal traction. (A) Original Method by central iron rod, [40] and (B) Recent method by full-thickness suture. [24]](image-url)
Although there are slight differences between each method, CS and the sternal traction variants all operate under a similar premise. Upon the application of an anterior or an anterior-lateral load, the rib-cage will move to expand the thoracic volume. [8, 40] This occurs because the rib-cage moves along a predictable track. [19] Upon distention, the ribs will rotate about the frontal and sagittal axes. [30] The nature of both these movements guarantees a positive increase the in the net thoracic volume. [30] Both of these rotations have colloquial names in biomechanics based upon their appearance. [19, 30] The roll about the frontal axis is termed the pump handle rib motion and this is exemplified in figure 6A. [19] Similarly, the sagittal role is termed a bucket handle rib motion which is illustrated in figure 6B. [19] While the extent of interplay between these two motions may differ between individuals, their existence ensures that any combination will act to reduce compression on the thoracic organs. [30]

Figure 6: Biomechanical tracts of rib motion. (A) The pump handle motion about the frontal axis, and (B) the bucket handle motion about the sagittal axis [19]

Very little has been published on the actual CS technique. [9, 49] However, there have been a few prior attempts to complement the approach. [9, 49] The first was termed a cardiac corset which was applied when patients undergoing particularly long open-sternum periods. [49] The intention of the corset is to maintain the geometric integrity of the rib cage. [49] New born ribs contain a larger proportion of costal cartilage than the bonier thorax found in adults. [17] Consequently, during periods of extended open-sternum, the structural integrity of the thorax may bend under its own weight and flatten the thoracic cavity. [17] This collapse results in a reduction in the thoracic volume and has been termed 'pancaking' by the HSC nursing staff. [49] An image of the cardiac corset being applied to a patient who is also undergoing CS is shown in figure 7A. [49] This corset has been applied clinically with qualitative success for the past few years. [49] Another project aimed to develop a CSU to quantify the tension in the traction lines. [9] Basic structural designs were developed and mock prototypes were produced. [9] However, no functional unit was ever built. [9] The basic conceptual design is shown in figure 7B. [9]
3.2 Clinical Tool Design

Engineering design within any particular sub-discipline will face a unique set of constraints and challenges. This is particularly true in the clinical and critical-care environments where there abundance or technology, patient concerns and staff roles. [7] It is important to review the technical models and design heuristics which uniquely exist in this environment. [7] In particular, the literature on how to best accommodate staff, imaging and life support should be reviewed and presented. This section will begin by evaluating the guidelines for safe and usable designs in a health-care setting. Then the basic physics and modelling of radiation in X-ray and heat transfer in warming beds will be reviewed. The underlying science of these technologies will allow for the CSU to be designing in a compatible fashion. Further, more clearly defining ICU design constraints will improve the development of design requirements and the bench-top experiments used for validating the final prototype.
3.2.1 Safety and Usability in Critical-Care

The safety of any engineering project or design is central to allowing the implementation of whatever the initiative may be. In most fields of engineering, the safety of the tool is carefully guided by standards and guidelines that tightly control the factors of safety and probability of failure of the tool. [13] While this still applies in health-care, the situation is complicated by the fact that medical device regulation is controlled by bodies such as Health Canada and the Federal Drug Administration. [21] Groups like the International Standards Association (ISO) then setup policies which can be interpreted by these organizations. [29] ISO14971 is a risk-management statement where the effectiveness and potential benefits of the tool must outweigh the potential harms. [29] This balance is then validated and interpreted by regulatory officers. [29] However, since the CSU is primarily a structural device, some more concrete design standards can be incorporated from structural engineering. [13] In particular, a factor of safety (FoS) is a number which represents the ratio of the perceived maximum load that a device can support compared to its anticipated functional load. [13] As general rules, truss structures will typically want a FoS of at least 2 or 2.5, and a lifting apparatus should have a FoS of at least 8. [13] Both sets of these guidelines will inform establishing design requirements for the CSU.

Another important factor to consider for the safety of the patient is the sterilizability of the tool. [49, 8] In critical-care generally, and particularly when the chest is open, mediastinal infections, blood-borne illness and sepsis are all ever-present concerns. [20, 48] In order to mitigate these risks, the device must be designed in such a way as to allow for effective cleaning protocols. [49] Therefore, the implementation can avoid exposing an already sick child to post-operative infections. Processing of the medical tool can undergo different approaches to achieve stabilizability. [18] Indirect instruments like the CSU can be cleaned with chemical treatments but this may indirectly expose the patient to risks through secondary contact. [49] The simplest and most common sterilization method would be to autoclave the tool. [18] This is where the device is exposed to high heat, pressure and steam that destroy potential micro-organisms that could be on the tool. [18, 31] This is carried out in fairly large autoclave chambers which are present at most large medical centers. [18] However, a general limitation with most chemical and thermal sterilization methods is that they may cause damage to electronic and robotic systems. [31] Hence, in order for any device to be truly sterilizable then it should be purely mechanism based. [31]
Finally, the usability of the tool should be addressed so that it can best integrate with healthcare staff and previously existing practices. Former introduction of medical tools undertook a 'change management' approach where consistent re-training of staff was used to overcome the radical changes in practice associated with medical innovation. [7] However, this methodology is considered largely ineffective due to the high turnovers in medical staff and medical devices. [7] Hence, the research field of human factors was developed in order to better match the design of medical tools to the people interacting with them. [7] In particular, this research aims to develop heuristics, guidelines and validations which can coach the development and introduction of new medical tools. [7] Although a complete human factors analysis is outside the scope of this thesis, it seems pertinent to incorporate the paradigm of centralizing usability in medical tool design. Further, a specific hierarchy of usability methods has been developed to guide problem-solving and this is shown below in figure 9. [7] These are general guidelines on the nature of solutions that will be most effective, and will be considered throughout this design process. Items 1 and 3 are particularly relevant to this project. Forcing functions are aspects of the tool which anticipate and prevent human error by design. [7] Standardization is the idea of optimizing processes through consistency and this is one of the objectives of the CSU application.[7]

**Hierarchy of Effectiveness**

1. Forcing Functions and Constraints
2. Automation and Computerization
3. Simplification and Standardization
4. Reminders, checklists, double checks
5. Rules and Policies
6. Training and Education

### 3.2.2 X-Ray Compatibility

Another important objective for the CSU is to provide X-ray compatibility. Children undergoing a DSC may require several chest radiographs throughout their stay in the ICU in order to track the health of internal thoracic organs. [8, 49] The device must not impede the ability of the X-ray to take these images. This will require careful selection of materials in any space between the patient the X-ray unit. [5] Fortunately, material scientists study this property using an attenuation coefficient to model the opacity of a given material. [5] This attenuation coefficient stems from the Beer-Lambert law which is a physical law to model the transmittance of electromagnetic radiation across a given material. [25] This can be written as an Ordinary Differential Equation (ODE) as is shown on the following page.
The Beer-Lambert Law

Where:

\[ z = \text{The axis parallel to the beam} \]
\[ t = \text{The thickness of the material} \]
\[ \Phi_e(z) = \text{The radiant flux at position } z \]
\[ \Phi_i = \Phi_e(z = 0) = \text{The flux of incident radiation} \]
\[ \Phi'_e = \Phi_e(z = t) = \text{The flux of transmitted radiation} \]
\[ T = \frac{\Phi'_e}{\Phi_i} = \text{The net fractional transmittance} \]
\[ \mu = \text{The attenuation coefficient at wavelength } \lambda \]

From this, the transmission event can be modeled as a first-order linear ODE as follows: [38]

\[
\frac{d\Phi_e}{dz} = -\mu(\lambda)\Phi_e(z)
\]

(1)

Using the integrating factor \( e^{\int_0^z \mu(z')dz'} \) gives a setup for the reverse chain-rule

\[
e^{\int_0^z \mu(z')dz'} \left( \frac{d\Phi_e}{dz} + \mu(\lambda)\Phi_e(z) \right) = 0
\]

\[
\frac{d\Phi_e}{dz} e^{\int_0^z \mu(z')dz'} + \mu(\lambda)\Phi_e(z) e^{\int_0^z \mu(z')dz'} = 0
\]

\[
\frac{d}{dz} (\Phi_e(z) e^{\int_0^z \mu(z')dz'}) = 0
\]

Integrating both sides and substituting in \( \Phi_e(z = 0) = \Phi_i \) and \( \Phi_e(z = t) = \Phi'_e \) will then give:

\[
\Phi'_e = \Phi_i e^{-\int_0^t \mu(z)dz}
\]

\[
T = \frac{\Phi'_e}{\Phi_i} = e^{-\int_0^t \mu(z)dz}
\]

Considering the problem at a specific wavelength \( \lambda \) and for a constant \( \mu \), the transmittance then simplifies to:

\[
T\lambda = e^{-\mu\lambda}
\]

(2)

This solution will be used later in the design process to estimate the radiolucency offered by different material choices. A choice that is overly radio-opaque could impede imaging, hinder clinical care and compromise the objective of the CSU.[5]
Notably, materials have attenuation coefficients that are specific to particular wavelengths of the electromagnetic spectrum. [22] In the visible spectrum, these differences are associated with colour but in the X-ray spectrum they will determine the radiolucency of the material for imaging. [5] Clinical X-ray operates in the range of $10^{-8}$m and $10^{-11}$m. [46] Therefore, a material must have a low attenuation coefficient in this range. [5] In general, most carbon-based materials, plastics and thermoplastics are considered to be radiolucent and have been used in medical applications in the past. [5] However, groups like the National Institute for Standards and Technology (NIST) have compiled much more detailed data on a variety of materials across wavelengths and densities. [22]

### 3.2.3 Heat Bed Compatibility

A secondary consideration of compatibility for the project is to ensure that function the radiant warmer is not compromised. [49] Children with their sternal wound open, will undergo significantly higher heat loss than closed-chested patients. [8, 16] This occurs because the warm thoracic cavity is exposed to the ICU space and will therefore radiate more body heat. [16] Convective losses will also be higher as the warmer air surrounding the patient rises to be replaced with colder air from the CCCU environment. [16] In order to compensate for these losses, patients are placed under a heat lamp (around 750$^\circ$C) which will radiatively warm the newborn. [12] Therefore, any device placed between the heat lamp and the patients should not interfere with the thermo-stasis of the newborn, and should be resilient to high thermal loads. [49] Given these requirements, the tool will be developed within the space and thermal constraints of the Dräger Babytherm bed. This is one of the most popular radiative heat beds in North American CCCUs and the model used at the HSC. [12, 49] An image of this bed model is shown below in figure 8A. [12]

The Stefan-Boltzmann law is used to model radiative heat transfer between two different bodies of different temperatures. [36] The law states that total radiant heat energy is proportional to the fourth power of the temperature of that body. [36] It also assumes there are minimal losses in the intermediate medium and the objects are black bodies. [36] To compensate for the black-body assumption, an emissivity coefficient is used to represent the ratio of heat emitted proportional to a perfect black body. [36] This law then becomes: [36]

$$\dot{q}_{net} = \frac{\sigma (T_1^4 - T_2^4)}{\varepsilon_1 + \varepsilon_2 - 1}$$

(3)

Further, the metabolism of the newborn will generate its own heat in an effort to maintain homeostasis. [16] The metabolic heat generation in a newborn can be estimated with the Brück model where $q_v$ is the heat generation, $m$ is the mass, $t_n$ is the age in days, and $V$ is the volume. [16] This model is shown in following: [16]

$$\dot{q}_v = \frac{m(0.522 \cdot t_n + 1.64)}{V}$$

(4)
Based on these two models, and using a numerical software package to estimate conductive heat losses, Fic et al. were able to estimate the skin temperature distribution of a newborn with a realistic geometry. [16] A Computational Fluid Dynamics (CFD) model was used which considered the air to be an ideal gas under the loading of gravity. [16] Therefore, the only convective losses considered were the result of the buoyancy of the warmed air around the newborn. [16] The results are shown in figure 8B and they indicate a thermal concentration at the breastplate. [16] Typically, this heat concentration has been suggested to contribute to the development of Insensible Water Loss (IWL) in newborns. [6] However, this could also have certain advantages in a patient with high heat losses in an open sternal wound, and a net excess of edema in the thoracic cavity. [16, 49] Therefore, the design must ensure to not compromise this radiant warmer while the fluid balance of CS patients remains closely monitored. [48]

Figure 8: Radiant heating of newborns. (A) An image of the Dräger Babytherm Unit, and (B) Numerical analysis of skin temperature in a radiantly heated newborn. [12, 16]
4 Initial Investigations and Design Requirements

As noted in the literature review, very little has been published specifically on the methods and nature of CS. [49] Hence, there is value in investigating accessible sources to gleam information on these patients and this technique. Notably, patient charts and the health-care professionals who care for these patients are the most accessible sources to better learn about CS. First, a single-center retrospective chart-review will be conducted in order to learn more about these patients, their specific care needs based on clinical data, and how they compare to the better understood DSC and IC patients. Then, a standardized set of survey interviews will be probe staff familiar with the CS technique on their opinions regarding the CSU. In particular, this survey will inquire about their experiences, their thoughts on design requirements and their opinions on the potential new functions that the CSU could offer. Each study will begin by reviewing the individual premise and hypothesis, followed by the methods of collection, the summarized results and a discussion on how this impacts the CSU. Once both studies have been completed and reviewed, a set of design requirements will be finalized. The following CSU designs will then be based on, and constrained within, these hard requirements for the tool.

4.1 Single-Center Retrospective Chart-Review

The principal goal of a retrospective chart-review is to better define the clinical challenges faced by the underlying population while also testing an underlying hypothesis. The objective of this study is to investigate the ways in which the CS population is distinct from the DSC and the IC patients. In particular, it is hypothesized that the CS population is a well-selected group by the cardiac surgeons such that CS patients are more fragile and have a higher propensity towards complication than most DSC and IC patients. However, given the nature of CS therapy, it is further hypothesized that CS patients with a similar degree of fragility post-operatively will have slightly better outcomes than an equivalently fragile DSC patient. This separation of the two populations based around a grouped clinical fragility (a statistical representation of thoracic compression) and their propensity towards complication is represented in figure 9. By collecting information on the complications suffered by patients and their operations, the clinical status of patients can be contrasted between the three treatment groups and some statistical modelling will be attempted in order to visualize separation of the treatment groups. Stated plainly, it is hypothesized that the CS patient group is much sicker than the other populations but will undergo a similar course of care to their DSC counterparts. Further variables such as the treatment lengths, number of operations and the types of operations will also be investigated in order to better understand what style of care the CSU should be prepared to accommodate. Holistically, the review will provide one of the first formal investigations into the complications, operations and care of CS patients.
4.1.1 Patient Selection and Entrance to the Study

A procedure needed to be developed in order to select patients for inclusion in the study. This includes both the consideration of patient charts, through a series of inclusion and exclusion criteria, and the methodology for entering these patients into the study. In following, the methods for identifying the charts which satisfy this criteria are the final step establishing the study cohort. The selection criteria applied in order to consider a patient for review can be listed as follows and were initially listed in the HSC Research Ethics Board (REB) application.

1. The patient must have undergone a sternotomy while being treated at the HSC.
2. The patient must have undergone their first sternotomy operation at SickKids between March 1 2016 and March 1 2017.
3. The patient was excluded if they died in the operating room during surgery and could not be admitted to a critical-care unit.
4. Any patient whose chest underwent any type of chest suspension was sorted into the CS treatment group.
5. Any patient whose chest was left-open, either postoperatively or re-opened in the CCCU, without undergoing any form of chest traction, was sorted into the DSC treatment group.
6. All other patients (i.e. those whose chests were closed in the OR and who never underwent CS) were sorted into the IC group.
As a brief note on criteria (3), it became quickly apparent that all cardiac surgery patients at the HSC will be kept alive throughout their surgery such that they could be admitted to critical-care. Therefore, this criteria is satisfied by all patients at this center and was not functional in excluding any charts. Therefore, moving forward in the review, this criteria was essentially ignored as it had no practical bearing on patient selection and identification. Secondly, by criteria (4), the CS treatment group will act as a super-category over the IC and DSC groups. This means that any patient who underwent CS, whether or not their skin or sternum was open at the time, was sorted into this CS group. This super-category was important for resolving sorting conflicts between the groups, and for isolating the patients who underwent chest traction.

Once the selection criteria was established, a procedure needed to be developed that could identify patients who satisfied the above requirements in order to enter them into the study. The initial intention was to collect 135 charts in total of which 50 would be IC, 50 would be DSC and 35 would be CS patient charts. The necessary requirements (procedure and critical-care treatment) are not easily sortable within the current Electronic Patient Chart (EPC) database. Therefore, an alternative dataset needed to be employed for the purposes of chart identification.

Fortunately, the cardiology research group at the HSC had a previously established database of cardiac surgery patients who had undergone a median sternotomy at some point during their care at the hospital. This database had been compiled for the purposes of a previous and unrelated study at the HSC. Furthermore, an informal coding system was used to identify patients that had undergone either a DSC or chest traction in the critical care unit. This coding was included in the database as free-text comments which could easily be sorted through to separate patients with a VBA (Visual Basic for Applications) script. The fidelity of this coding system was not perfect, but it did offer a first-pass approach for sorting sternotomy patients according to their postoperative treatment. Therefore, patients initially entered this study by identification through this cardiology research database. Beginning in March 2017 and working backwards in time, the first 50 patients that were believed to be IC and DSC patients were identified for inclusion in the study. Only 18 CS charts could be identified between March 2017 and March 2016 for inclusion in the study. A list of the Medical Record Numbers (MRNs) for these 118 charts was compiled and the corresponding charts were requested from the EPC. The imperfect fidelity of the pre-categorization in the cardiology research database was recognized prior to requesting these charts. However, it was determined that the notes in the patient chart would be used to confirm or correct the categorization of the included patients. After a complete review of all charts, only two patients needed to be re-categorized from the CS group to the DSC group. Therefore, the final chart review included 50 IC patient charts, 52 DSC patient charts and 16 CS patient charts.
Once the 118 patients had been identified based off the selection criteria, had entered the study through the procedure described here and their treatment categorization had been confirmed or corrected by reviewing the chart, the next step was to collect data on each patient. The information collected on each patient, for the purposes of comparing the treatment groups, is described in the following section.

4.1.2 Data Collection and Statistical Methods

A set of 118 pediatric cardiac surgery patient charts were reviewed from a year-long period spanning from March 2016 to March 2017. The majority of patients were below a year of age at the time of first operation. A recent one-year period was chosen, as opposed to more historical data, in order to align the results with the current standard of care. This chart group included 50 IC patients, 52 DSC patients and 16 CS patients. Because only about 1 in 6 post-operative cardiac patients undergo DSC, and 1 in 18 CS, these patients group needed to be preselected from a loose database in the cardiac research group at the HSC. [8, 9, 49] All patients needed to have undergone a median sternotomy and have not died in their initial procedure to be included in the study. As noted, this second requirement became largely irrelevant. However, some inaccuracies with the database listings were corrected and re-sorted as necessary with the transcripts in the EPC database. A single-center review was employed because CS is only minimally employed outside of the HSC and in order to maintain general consistency with the technique between patients. All applications for EPC study were processed and approved through the HSC cardiovascular surgery department, the HSC cardiac research group and the HSC REB.

For each patient, the congenital anomaly/diagnosis, the operative treatment and the post-operative metrics were recorded. Many patients present with multiple associated congenital anomalies so these were separated into 15 groups based upon what was used in prior DSC chart review literature. [20, 48] These include cardiomyopathy, Atrial Septal Defect (ASD), Ventricular Septal Defect (VSD), Patent Ductus Arteriosus (PDA), Hypoplastic Left Heart Syndrome (HLHS), Tetralogy of Fallot (ToF), valvular defects, coarctation, univentricular, Transposition of the Great Arteries (TGA), prosthetic failure, arrhythmias, mediastinitis, Total Anomalous Pulmonary Venous Drainage (TAPVD), Hypoplastic Right Heart Syndrome (HRHS) and ‘other’ conditions.
Similarly, the treatments and operative procedures that the patients received were also divided into 15 categories. The categories of procedure are ExtraCorporeal Membrane Oxygenation (ECMO), ASD repair, VSD repair, PDA ligation, Norwood procedure (stage 1), tetralogy repair, valvuloplasty, coarctation repair, Fontan procedure, TGA switch, heart transplant, fenestration, chest exploration, TAPVD repair, Blalock-Taussig (BT) shunt, and other procedures. Next, the recorded post-operative data included the total CardioPulmonary Bypass (CPB) time, the total cross-clamp time, the Risk Adjustment for Congenital Heart Surgery (RACHS) category, the number of operations, the days of open chest, the length of hospital stay, the total cardiac arrest time and whether or not the patient died. Overall, these metrics are meant to capture the patient’s condition, course of treatment and outcomes. The specifics on the diagnoses and treatments are largely unimportant for this analysis but three of the post-operative metrics should be briefly explained. The CPB time and the cross-clamp time are recordings of how long the patient was under mechanical circulation. The RACHS category gives an indication of the severity of the condition and hence the fragility of the patient.

Because this chart-review will generate a large amount of data, several different processes will be undertaken to analyze the results. First, the continuous variables collected as post-operative metrics will have their medians compared between the three treatment groups. This will offer an indication of the treatment time-line for the different patients and assess whether any significant differences exist. Secondly, each of the binary metrics will be compared between the three treatment groups based on their relative frequencies. This will allow for an identification of whether any diagnoses or treatments are particularly more common in patients that will develop tight syndrome. This will help to test the underlying hypothesis that treatments likely to produce more surgical edema will be more common in the CS population. Finally, some basic statistical modelling was attempted in order to study the propensity towards complication amongst the three treatment groups. This included both a logistical regression comparing the cross-clamp time to the propensity of death, and a zero-inflated Poisson regression which looked at the probability of ‘n’ operations after a certain length of hospital stay. As will also be noted in the analysis, both of these regression models were unable to demonstrate statistical significance given the size of this review. Therefore, these results will not be extensively included in the following section. Lastly, the overall findings will be discussed focusing on any conclusions regarding clinical care and any relevance to formulating design criteria for the CSU.
4.1.3 Key Findings from the Review

The results will begin by presenting the averaged results of the collected data as contrasted between the three groups. Only the most notable and distinctive results will be shown in the body of the document. These are the results that will inform both the unique aspects of the CS treatment group and the unique requirements for the CSU that would not have been captured in prior literature reviews. However, for the sake of completeness, a complete summary of all collected data will be exhibited in appendix A.

First-off, the continuous post-operative averaged metrics can be compared between the three treatment groups in order to understand distinctions in their course-of-care. A summary table of these continuous metric results is shown below in table 2. Because the distribution of these results was highly left-skewed, it is more appropriate use the median of the data set for averaging as opposed to the mean. This is because median results are more resistant to skew-effects. Distributions of this data demonstrating the left-skew are shown in appendix A. First off, the median number of operations varies significantly between the three groups. The DSC patients undergo two operations for every one that the IC patients undergo. At 3.5, the CS patients are almost double again. Length of stay in critical-care also seems to follow this pattern. The CS patients have twice the total stay of the DSC patients, and both groups are significantly higher than the IC patients. These results are also proportional to the open-chest time where CS patients are double the DSC patients. In terms of cardiac arrest time, the CS patients had the only median-result that was non-zero at 5.5 minutes.

Table 2: Median Values for Notable Continuous Metrics across the Three Patient Populations

<table>
<thead>
<tr>
<th>Recorded Continuous Metric</th>
<th>Immediate Closure</th>
<th>Delayed Sternal Closure</th>
<th>Cardiac Suspension</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Operations</td>
<td>1</td>
<td>2</td>
<td>3.5</td>
</tr>
<tr>
<td>Length of CCCU Stay (Days)</td>
<td>5</td>
<td>23.5</td>
<td>47</td>
</tr>
<tr>
<td>Open-Chest Time (Minutes)</td>
<td>0</td>
<td>4</td>
<td>8</td>
</tr>
<tr>
<td>Cardiac Arrest Time (Minutes)</td>
<td>0</td>
<td>0</td>
<td>5.5</td>
</tr>
</tbody>
</table>

Next, the summary results of the collected binary data will be presented. This included both the diagnostic and the procedural data. Here, the simplest and most accurate way to compare the three groups is by contrasting the fraction of each group with a particular diagnosis or procedure. 30 data points were collected in all and the most dramatic results are shown here, for the sake of discussion, in figure 10. However, in an effort to conduct good research practices by including all data, fractional results for all binary data are presented in appendix A.
In terms of diagnoses, both HLHS and arrhythmias were significantly more common in the CS population than in other patients. In fact, while only about 1 in 20 of the IC and DSC patients had HLHS, nearly 1 in 2 of CS patients were associated to this condition. Arrhythmias were a little more common in the IC and DSC populations (at 8.3% and 21.2%) but still significantly more common in the CS patients at 43.8%. Intuitively, both of these results should seem reasonable since both have associations to high surgical edema. HLHS is an extreme congenital defect which often requires a 3-stage Norwood procedure to correct. [37] This extensive surgery may therefore generate higher levels of thoracic pressure while also leaving the heart in a weaker, and thus more susceptible, state. Conversely, arrhythmias may actually be an indication of early tight syndrome where the heart attempts to self regulate against compression and low CO. These results also line-up with the procedural findings, where Norwood procedures, a treatment for HLHS, were more common in CS patients. Valvuloplasties were also more common, and this is another highly invasive procedure that can be associated to higher surgical edema and a weakened heart, and therefore would be hypothetically linked to tight syndrome.

![Figure 10: Distinctions between the Three Groups in (A) Diagnosis and (B) Operative Treatment. The groups are IC (Green), DSC (Blue), and CS (Red).](image)

Finally, the two regression models discussed in the methods section were attempted. Although both regressions demonstrated loose trends, neither was able to show statistical significance between the three groups. This failure can largely be contributed to the complexity of the variables and systems under investigation which is then coupled with a relatively small study population. Therefore, given these results, it is impossible to extract meaningful results or conclusions from these attempted regressions and they will be omitted from the remainder of this thesis work.
4.1.4 Impact on the Device Development and Requirements

The principal conclusions to draw from the findings of the chart review are that CS patients have longer hospital stays, with more operations, in a more fragile state and while also undergoing more extensive treatments than the IC and DSC patient groups. None of these conclusions are surprising but this does represent the first data-collection to validate these claims. These results further suggest and reinforce certain requirements for the CSU. The long critical-care stays imply that the tool should be durable and applicable for long treatment courses. This includes ensuring the reliability of both the device structurally and the wiring for lifting. Secondly, the extent of the procedures associated with CS suggests that the device should be able to be primed pre-operatively if needed. The higher number of re-operations means that the device should be able to be easily removed and reapplied as needed. It should also be quick to sterilize between these procedures so as to avoid mediastinal infection. Furthermore, the higher incidence of cardiac arrest events means that a quick-release system for code-based events is essential. Lastly, the overall profile and complications within the CS group suggests that these patients are more clinically fragile. Therefore, the CSU should attempt to minimize the trauma associated with suspension. In particular, the device should attempt to minimize de-suspension and re-suspension events unless absolutely necessary. The fragile condition also suggests there is an increased need for X-ray imaging to track a patient’s thoracic health. Combining these last two observations, the chart review supports that the CSU should be X-ray compatible, without a de-suspension/re-suspension, would be a valuable functionality.

4.2 Healthcare Worker Survey

Although the chart-review served an important role in better outlining the nature of CS patient care, a more direct methodology will be required to establish a specific list of hard design requirements. The clearest resource for this purpose is the knowledgeable staff at the HSC who are experienced with CS. Therefore, a series of health-care worker survey interviews took place in order to better define the design requirements for the CSU. The purpose of these interviews was three-fold. First, to inquire on the experience and the opinions of the staff regarding CS and its functionality. In most industrial engineering projects, it’s important to note the position of staff prior to proposing change in order for the adoption of the new tool to be successful. Secondly, the specific requirements regarding space, accessibility, cleaning and usability are to be investigated. These questions will allow a list of basic structural design requirements to be established. Finally, the opinions of the staff regarding potential new functionalities were explored. This will allow the project to be directed so that it contributes the greatest clinical benefit and so as to best justify its own purpose as a quality improvement project. This section will begin by describing the methodology of the survey. Next, a summary and analysis of the results will be offered. Finally, the hard list of design requirements will be established and discussed. The creation of well-defined requirements and constraints is one of the most important steps in designing an effective device.
4.2.1 Design of the Survey

In order to best capture interactions with the suspension technique, members in various roles of the health-care team needed to be included in the survey. Four professionals were chosen to encompass this purpose: two cardiac surgeons, an intensivist nurse-practitioner and an ICU Registered Nurse (RN). All selected participants were extremely familiar with the technique. Both cardiac surgeons had helped to develop suspension in its current form and the nurses had developed the cardiac corset which compliments the technique. [8, 49] The participants were questioned about their experiences with the technique, the indications and method for implementing suspension, their thoughts on the design requirements, and their opinions on potential new functions. Their experience includes how long they’ve worked with suspension, their support and apprehensions about the technique, and when they normally see a suspension implemented. The indications used to elect for cardiac suspension used a list of predictable conditions that they were asked to validate. Surveyed participants also added their own thoughts if indicators were missing. The design requirements questioned included the geometry of the current method, the necessary accessibility to the patient (in and out of emergencies), and the compatibility with surrounding equipment. Finally, the new functions section asked them for their reactions to a series of potential new abilities that the CSU could be developed to provide. All questions were phrased to evoke specific and direct answers either in the form of yes/no responses or numbers. This allows the results to be more easily generalized, less biased and applied to developing hard design requirements.

4.2.2 Summary of the Results

An extensive amount of information was captured and a complete review of these results has been organized and provided in appendix B. The key findings and important outcomes will be discussed here. As anticipated, all participants had many years of experience with the technique and largely supported it’s implementation as a last-resort therapy in complex-critical care newborns. However, several anxieties were expressed regarding the crude implementation and aesthetic of the current method.

Regarding indicators, all participants acknowledged that this is a gray area which ultimately comes down to a judgment call by the surgeon. Further, the length of time for which suspension is applied is not pre-determined. If arrest events occur then suspension may need to be removed and reapplied several times over the child’s time in critical-care. However, there were certain patterns that participants agreed tended to align with suspension. Above all, hemodynamic instabilities, and occasionally respiratory instabilities, are the top decision-making indicator for the surgeon. Cardiac failure and observed swelling in the chest occur less commonly but are also used to elect for CS. Further, HLHS patients undergoing Norwood procedures are an extremely common demographic to undergo CS.
Participants were generally consistent in that about 100 patients will undergo DSCs at the HSC per year, and about a third of these will undergo suspension. Further, any complex-care congenital-corrective case may lead to the necessity for CS. Also, the decision to implement DSC or CS can happen intra-operatively or post-operatively depending the condition of the patient.

Next, the participants were all generally consistent on the design requirements that they believed were important. The CSU should be able to accommodate between one and four suspension wires in order to remain consistent with current approaches. It was noted that different surgeons will implement suspension with slight variations but that these forms largely fall into three categories which are illustrated and described in appendix C. Since the current wires are largely vertical, the participants noted that the CSU should apply loading between 0° and 20° such that the tension is primarily anterior to the chest wall. The patient should be accessible from both sides while the device is applied. It should be X-ray compatible by being height adjustable and radiolucent. Further, having the tool be sterilizable was largely considered to be an important ability. Transportability was also valued in order to allow switching between bed units. A quick release of <5s was deemed acceptable but <3s would be ideal. The tool should also allow at least 90% heating and light functions from the radiant warmer and bili lights. Finally, the CSU cannot compromise the hard surface under the bed because this is important for chest compressions during cardiac arrest events.

Lastly, while the participants were open to most of the new ideas that were proposed as potential functionalities of the CSU, they were also very clear on which they felt were the most important. Having a sensor to accurately capture wire-tension was by-far considered to be the central goal of the device development. Having orientation measurement, or automated control over tension and orientation, were considered potentially advantageous but largely unnecessary. Further, concepts like pre-programmed closure or predictions of closure likelihood were considered interesting but potentially more academic in nature at this stage. Physiological feedback to the wire tension was discussed but some apprehension was raised that this could be dangerous. Standardized suture placement was also well-received but considered out-of-scope with the central concerns. Lastly, it was very important that the CSU remain compatible with the cardiac corset.

The principal findings of the survey interviews have been re-summarized and this list is provided on the following page. Some of these results clearly link to the design requirements, but others, such as the indicators for implementation, help to better understand the nature of CS beyond what was extracted from the chart-review. As a final note, brief patient visitations were also undertaken, with an accompanying clinician, in order to better comprehend the serious state of the patients, and any aspect which may have otherwise been missed in the chart-review and survey.
Summary Points of Healthcare Provider Interviews

- Interviewees: Two cardiac surgeons, one critical-care nurse-practitioner, one ICU RN.
- Average experience with CS: 13.5 years
- Estimated Frequency: 1/6 (DSC), 1/18 (CS)
- Key Concerns: Technique reliability, Aesthetic, Reliability
- Indicators: A gray area for judgment call. Some common themes are listed below.
  - Hemodynamic instabilities
  - Respiratory instabilities
  - Complex congenital corrections
  - Tamponade/Cardiac Edema/Swelling in the Chest
- Some variation exists with the technique (see appendix B), but the design requirements were generally consistent.

4.2.3 Discussion on Establishing Design Requirements

At last, a final set of hard design requirement can be defined so as to inform and constrain the remainder of the design process. Based on the results of the survey, and with the subjective insights from their opinions, a list was composed which is shown in table 3 on the following page. Where necessary, points from literature (such as a structural FoS) were used.

The device must include at least 4 points of suspension so as to match current methods. Each line should approach the chest at an angle between 0° and 20°. Further, the device itself should contain several degrees of motion and adjustment in order to provide adequate accessibility. Any components over the child’s chest (henceforth called the cantilevered components) should be adjustable between 60cm and 40cm above the plain of the bed. This will simultaneously allow for complete accessibility to the patient’s sides when raised, and space for an X-ray unit to enter when lowered. Also, any cantilevered components should be quickly removable in the case of an emergency event, likely by swinging 90° out of the way. The device should include a quick-release method to remove all sutures and components in less than 5 seconds. The target for radiolucency is 99% and the target for heat and light transmittance is at least 90%. Bending should be maintained under 5° and an overall structural FoS of 8 should be achieved. [13] The tool should be able to maintain 4kg, or about 40N, per line. [8, 9] This is consistent with prior research on design requirements, and is consistent with clinical observations. [8, 9] Finally, the tool should be designed so as to be autoclavable for rapid sterilization. This means that the device cannot be electrical or robotic and must be entirely mechanism-based. [31]
Table 3: Summary of CSU Design Requirements established from Healthcare Professional Interviews

<table>
<thead>
<tr>
<th>Function</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Suture Placement</td>
<td>4 Sutures at 15° each</td>
</tr>
<tr>
<td>Head Motion and Accessibility</td>
<td>90 In-Plane, 60cm to 40cm vertically</td>
</tr>
<tr>
<td>Quick-Release</td>
<td>&lt;5 seconds</td>
</tr>
<tr>
<td>Radio-translucence</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>Structural and Thermal Stiffness</td>
<td>Bending &lt;5°, Safety Factor &gt;8</td>
</tr>
<tr>
<td>Heat and Light Conductivity</td>
<td>&gt;90%</td>
</tr>
<tr>
<td>Tension per Wire</td>
<td>4kg or 40N</td>
</tr>
<tr>
<td>Cleaning</td>
<td>Autoclavable (i.e. non-robotic)</td>
</tr>
</tbody>
</table>

To be very clear, the above table represents an averaging of the information collected during the survey interviews. As can be seen in the full results of appendix B, participants were generally consistent when questioned about the desired design requirements. When conflicts did present one of three systems was used to reconcile the issue. If a participant was not confident about their answer (and explicitly stated this lacking confidence), then their assertion could be omitted. If the assertions were close, then a median was used. If the assertions suggested different functionalities, then the more stringent of the two requirements was used. In this way, the above results attempt to be an unbiased representation of the interviews. However, it should be acknowledged that the subjective nature of interpreting survey results means that bias will always be present and that this is an unavoidable limitation.

The following sections will now conceptualize designs that can be compared to the above list. This will be relevant at both the macroscopic level of the overall design, as well as the selection of individual components. None of these choices can be allowed to compromise the aforementioned requirements unless it somehow circumvents the entire application of that constraint. For instance, components not within the path of the X-ray do not need to be radiolucent. There are also soft requirements that will be kept in mind throughout the design process. These are good to include but not essential to the functioning. For instance, the human factors rules (e.g. forcing functions are the ideal approach to problem-solving) and as much of a professional an aesthetic as possible would fall within this category.
5 Conceptual Design

The purpose of the next section will be to consider the variety of approaches which the CSU could take, along with the associated device shapes, and then compare these options. This stage will be essential for guiding the remainder of the design process. Once a particular methodology is selected, the tool can then be broken down into sub-systems for functional analysis and the individual components can be compared, selected and tested. This conceptual design process will begin by generating a series of potential options for the CSU. This will require investigating commercial options that are available that are similar to CSU, and the development of original concepts. This list can then be compared internally and one of the options selected. This overall concept will then act as a platform for the remainder of the design process. This section will then conclude by discussing the relevant degrees of freedom offered in the design choice, and the most logical approach for separating the device into subsystems.

5.1 Methodology of Options and Comparison

This phase of the design will undertake a three step methodology by going through the steps of (i) option generation, (ii) comparison and (iii) selection. The potential options for the CSU overall design will be considered from two angles. First, commercial options that are currently being promoted to treat tight syndrome, cardiac compression or rib-cage support will be considered. These off-the-shelf components of the potential of resolving practical or conceptual challenges later-on in the design. Secondly, original design options will also be considered by evaluating the different spatial directions which loading could take. By considering suspension as a series of tension loads on the newborn chest, then the variety of structures that could support this loading can be considered from the geometric angles. The different parts of the Dräger bed which could anchor this device need to also be noted. Once a list of the reasonable options has been compiled, the options need to be contrasted in reference to the previously established design requirements. This analysis will employ a Pugh matrix to qualitatively assess the options in terms of their ability to meet the tool functionalities. The points of consideration will include the ability to quantify tension, their nursing accessibility, the bulkiness, the reliability/safety, and the X-ray accommodadons. Each option will then receive a rating of (–),(-), (+) or (++) for each option and then the results will be summed per option. Although this is not the absolute decision point, these results will then guide the decision making process. A methodology will then be selected and the Degrees of Freedom (DoF) necessary to accomplish the full CSU functionality will be established. Finally, the system will be divided conceptually according to what best accomplished four main aspects of the CSU. These aspects are the (i) mechanical tensioning, mechanical stiffness, the thermal resiliency, and the X-ray compatibility. This division will allow the system to be developed and validated on a function-by-function basis.
5.2 Similar Commercial Options and their Limitations

There are three previously existing treatments whose effects are comparable to CS, and whose off-the-shelf components are worth considering in the scope the CSU design. The first option is the implementation of sternal struts which maintain separation of the sternum during the DSC but placing rigid supports between the breastbone halves. An image of a child with inserted sternal struts is shown below in figure 13. From the inside of the chest, these struts apply internal lateral traction which prevents compression on the heart and lungs. In particular, the struts prevent the thorax from rolling, and hence collapsing, inwards by rolling about the vertical axes under their own weight. However, these struts are limited because they do not prevent flattening of the chest in newborns which is another important method of compression. With no anterior traction or side-wall support, the thorax will still have a tendency to 'pancake’ and restrict cardiac function.

A second option for supporting thoracic volume post-operatively is the cardiac corset. This device wraps around the child’s chest to maintain a healthy morphology and prevent pancaking. By supporting a round cross section and preventing flattening, the thoracic volume will be maintained and compression improved. The corset is also advantageous because it can support an extremely gradual closure by slowly tightening the sternum over several days. However, the corset is also limited in that it cannot increase thoracic volume above its healthy maximum because it only support the correct cross-sectional area. In cases of significant intra-thoracic swelling and edema, a hyper-expanded thoracic volume may be required to mitigate compression. Anterior-traction on the chest will still be required to increase thoracic volume above its typical DSC level. This is why CS is often paired with the corset. Once again, an image of a child supported by both CS and the corset is shown in figure 7.

Figure 11: An image of sternal struts placed under the dressing to support the chest-wall and prevent cardiac compression in a DSC newborn. [39].
The final commercial worth considering is the original method of sternal traction. There are many similarities between sternal traction and the current CS methodology with the differences between the wires used and points of external fixation. It is worthwhile to note that different techniques have appropriated the term sternal traction and what is described here are aspects have the technique which are consistent between several sources. The first key difference is that the suspension lines tend to be trans-sternal stainless steel wires that are then attached to a grouped unit like a steel rod. This is again shown in figure 5A. These lines may actually be the wires used to close the sternum or be full-thickness chest wall sutures. The central unit is then attached to a pulley system like an orthopedic bed. Notably, this setup was originally developed for adult patients and limitations in neonatal orthopedic beds may prevent this pulley system from being appropriated to CS applications.

5.3 Developing Alternatives

Next, the drastically different approaches that a CSU device could undertake need to be considered. In particular, the extent to which different geometries, different directional approach vectors, and different fixation points are possible for the traction lines needed to be deliberated in order to generate an overall list of options for the CSU. The commercial options discussed previously should be kept in mind during this conceptualization process. However, it is notable that none of those methods included quantifying tension on the chest which is the principal target-function of the CSU. Therefore, none of these options can be applied directly.

The sternal traction method is the closest to current CS. A pulley-based external fixation system may also provide the necessary platform to include tensile sensors and spatial adjustments in the frame. Further, it is a easy-to-understand method which will help with usability. However, an attachable device would need to be built for compatibility with the Dräger bed and so it can be applied and removed as needed. This approach could fundamentally take two directional approaches. An inferior-superior approach would consist of a foot-based cantilever that would hang over the child’s chest and carry all four suspension lines. The alternative would be medially approaching cranes from the side of the bed, each with an individual suspension line. Images representing both the foot-cantilever and the side crane methods are shown in figures 14A and 14B respectively.

![Figure 12: CSU Structural Design Options: (A) Foot-Cantilever, (B) Side Cranes, (C) Heat Lamp Fixed, (D) Internal](image-url)
As noted previously, the cardiac corset lacks the ability to provide anterior traction which is why it is not directly applicable. However, it works in conjunction with current CS that attaches traction sutures to the heat lamp above for fixation. These anterior approaching wires suggest that a device could be developed to provide tensile quantification. It would need to attach to the heat-lamp in order to provide an alternative fixation point to the heat lamp grill. This would also help to improve the safety and reliability of suspension by not relying on the structural support of this grill. The CSU would then be attached to the top of the heat-lamp where the stress would be distributed to the Dräger cantilever. These completely vertical wires would maintain significant consistency with the current approach and therefore be easy to introduce to staff. A representation of this approach is shown below in figure 14C.

Finally, a variation of the sternal struts could be developed. The internal-support method would require a few adjustments to meet the same applications as suspension. First-off, the internal CSU would need to provide loading both laterally like the struts but also anterior like suspension. An expanding wedge with a fulcrum above the chest-wall could accomplish this and a sketch of this geometry is shown below in figure 14D. Of course, this internal CSU would need to work collaboratively with the cardiac corset in order to maintain the structural stability of the side-wall if any flattening of the chest occurred.

5.4 Results - Pugh Matrix

The four design options generated in the previous section based on their ability to meet the design requirements established in chapter 4. Five of these functionalities will be considered in the form of Pugh matrix outlined below in table 4. The considerations to be evaluated include the ability to quantify tension, the general patient accessibility, the overall bulkiness, the structural reliability and permissiveness to accommodate X-ray imaging. These methods will also be compared to the current cardiac suspension technique.

Table 4: Pugh Matrix of Equal-Weighted Functional Criteria for Comparing the Design Options for the CSU Structure

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Current CS Method</th>
<th>Foot-Cantilever</th>
<th>Side Cranes</th>
<th>Heat Lamp Fixed</th>
<th>Internal Support</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quantifies Tension</td>
<td>No (−−)</td>
<td>Yes (+)</td>
<td>Yes (+)</td>
<td>Yes (+)</td>
<td>No (−)</td>
</tr>
<tr>
<td>Nurse Access</td>
<td>Good (+)</td>
<td>Good (+)</td>
<td>Poor (−)</td>
<td>Good (+)</td>
<td>Impeded (−)</td>
</tr>
<tr>
<td>Bulkiness</td>
<td>Negligible (+)</td>
<td>High (−)</td>
<td>Medium (−)</td>
<td>Low (+)</td>
<td>Low (+)</td>
</tr>
<tr>
<td>Reliability (Safety)</td>
<td>On Heat Lamp (−)</td>
<td>Controllable (+)</td>
<td>Controllable (+)</td>
<td>On Heat Lamp (−)</td>
<td>Controllable (+)</td>
</tr>
<tr>
<td>Accommodates X-Ray</td>
<td>No (−−)</td>
<td>Yes (+)</td>
<td>Yes (+)</td>
<td>No (−−)</td>
<td>Yes (+)</td>
</tr>
<tr>
<td>Total</td>
<td>-3</td>
<td>+3</td>
<td>+1</td>
<td>0</td>
<td>+1</td>
</tr>
</tbody>
</table>

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First, the current CS method can be considered in terms of the relevant design requirements. Evidently, it fails in several of these areas. Most notably, the current technique is completely incapable of accommodating tension measurements or X-ray imaging. Furthermore, the bulk of the structural reliability is placed on the Dräger bed and the heat-lamp grate. Both of these were not built to be load bearing and could present a risk to the patient in high tension situations. However, common CS is a good way to allow for constant nurse accessibility and for not requiring any additional equipment besides sutures and needle-drivers.

Next, the foot-cantilever approach presents several strengths which could compliment CS. By using a pulley-system for tensioning the wires, it presents an intuitive platform for quantifying tension. Secondly, by having an adjustable height, nursing accessibility to the patient can be maintained at a level equivalent to CS while also allowing X-rays to be taken when lowered. The safety of the tool would be directly on the nature of the design which is excellent for ensuring patient safety. However, this approach does present the draw-back that it would be bulkier than previous methods. Side cranes present many of the same strengths as the foot-cantilever approach. They would be a great platform for quantifying tension, accommodating X-ray imaging and ensuring patient safety. However, they would still be bulkier than some of the other options and they present the additional challenge of blocking the nurse accessibility. Because the cranes approach the patient medially, they would directly impede procedures like dressing changes, and even emergency measures. Therefore, the foot-cantilever approach seems to be superior to the side-crane concept.

A heat-lamp fixed device includes many of the same advantages as traditional CS. It provides easy access to the patient and would be a low-scale solution for easier transport. Furthermore, it has the added benefit of being able to quantify tension since the sensors could be included in the head structure. This is what makes this choice viable for replacing modern CS. However, many of the same challenges are still outstanding. A heat-lamp fixed approach would still place much of the structural reliability on the Dräger bed itself which creates a liability in mechanically loading a structure not designed for this purpose. This could be considered a danger to patient safety. Also, there is no trivial way to employ a heat-lamp fixed solution while also accommodating X-ray. Therefore, the patient would need to be de-suspended and re-suspended for each image which could become traumatic. Hence, while this option offers certain advantages over traditional CS, it seems to be the weakest of the conceptualized solutions.

Finally, the internal strut would offer a low-weight, structurally reliable and X-ray compatible solution to CS limitations. However, the technique is so drastically different from suspension that it would be difficult to quantify mechanical loading at all, let alone in a way that is analogous to anterior-chest traction. This method may also prevent or impede the nurses ability to treat and dress the sternal wound. This technique may be too drastically different to functionally replace CS.
5.5 Discussion and Selection

In summing each column of the Pugh matrix, a loose score can be associated to each of the previously discussed conceptual designs. From the results in table 4, it is clear that the current CS technique is by far the most limited as anticipated. The heat-lamp fixed solution is also not particularly advantageous, and the side-crane and internal solutions are also limited. Overall, the foot-cantilever approach scored the highest and seems to offer the best all around solution give the requirements considered here. Both this ordering and these overall conclusions are consistent with the result deliberations offered in section 5.4.

Therefore, from this point forward, the CSU will be developed in the style of a foot-cantilever approach. This means that the device will be fixed at the end of the bed, inferior to the patient, and reach over the patient’s chest in the style of a cantilevered beam. Wires that control the tension on the traction sutures will then run along this beam. These wires will arrive to a back-spine of the device where a pulley system will enable both their tensioning and their measurement. Furthermore, this spine must be height adjustable in order to allow for both nurse accessibility and X-ray imaging at different times. In order to avoid de-suspending the patient, the pulley-system will need to compensate for any potential variations in tension during this height movement. Additional DoFs will also be included in order to allow for customization in arranging the traction lines, and to allow for for quick removal of the device in emergency situations.

A conceptual listing of all included DoFs will also be addressed here and they are illustrated in the Computer-Aided Design (CAD) model images in figure 15. The spine will include a vertical-linear prismatic joint in order to allow for height adjustments in the cantilever. Further, a Horizontal-linear prismatic join is included on the back brace so that the CSU cantilever can be moved out of the way during emergency events. Further, a vertical-rotation rotary joint is included at the base of the cantilever so that the beam can be swung out of the way if necessary to prevent it impeding a surgeon accessing the patient. At the end of the cantilever, there are four finger-like projects which are each used to connect one traction line. The method of this connection will be developed later, but what is important here is that each finger is connected by a pin-joint. This will allow for adjustments in the orientation of each finger. The tension of each line will be controlled independently meaning that each traction vector is controllable in direction and magnitude. It is worth noting that each of these degrees of freedom, seven in total, will be lockable by a compression fixation. This means that each joint contains a clamp that will prevent accidental motions in the tool, protect the patient and hold traction orientations as needed.
5.6 Subsystem Breakdown

Finally, the system needs to be subdivided into its functional groupings in order to organize the design process. A CAD image of the overall structure of the CSU is shown below in figure 16 and the overall structure is identified by point (1). The base and fixation are indicated in by identifier (4), and along with the overall framing, this will be the most important subsystem for ensuring the rigidity and stability of the tool. These aspects will contribute to both the professional aesthetic and the safety of the tool. Thus sub-system will be developed in chapter 6. Next, the identifier (3) is showing where the compensator and tensioner will be attached to the CSU. These are components of the overall wire system that is responsible for transmitting tension between the tensile measurement and the patient. This wire guide system, the compensator and the tensioner will be presented in chapter 7. The head structure is indicated by (2) and this includes all of the cantilever components. The location of the quick-release and the adjustable fingers is a component of this head structure and is indicated by (5). All of the components of the head-structure are primarily responsible for maintaining compatibility with the heat bed and X-ray imaging. A discussion on the design of the head structure, along with the thermal and radiolucency evaluations, is presented in chapter 8.

Figure 14: A breakdown of the CSU conceptual design into sub-systems.
6 Frame Construction and Support

This section will describe the design of the CSU framing along with the associated fixation components. Given the foot-cantilever approach selected in chapter 5, these will be fundamental aspects of an effective CSU. The device must be strongly connected to the bed, rigid in its overall construction and stable to disturbances. The framing has been developed to address these concerns. This section will begin by discussing the nature of the framing and bearing that were used for this prototyping. In following, the qualitative evaluation of different fixation strategies will be reviewed. Several different options were considered for connecting the CSU to the bed so a brief time-line of the considered methods will be included. This will also include how the framing was chosen to ensure the stability of the device. Next, some weak joints were identified early-on. The process of analyzing and correcting this joint is resolved by addressing the underlying mechanics which lead to the weakened joint. Once the frame is constructed, it must then be evaluated for it’s ability to resist bending. The methods of this assessment will be described and be followed by the analytical, numerical and experimental results. Finally, these outcomes and their consequences on the CSU will be discussed.

6.1 Framing Geometry and Bearing Selection

The tool prototyping used T-slotted aluminum framing in order to quickly build and customize different structures. T-slotted framing connects together and to other components by using channels in the members to lock with screws and nuts. This framing allows for rapid connections and adjustment which therefore creates a more efficient prototyping period than traditional machining while still being structurally more rigid than 3D printed plastics. It is also light-weight because of both the material and the cross-sectional shape. Further, a suite of compatible bearings allow for simple installation of the necessary DoFs of the tool. By using straight members, a Cartesian geometry, with right-angles at connective joints, was the simplest way to build the tool. Further, right-angle connections at the head of the device and spine connection, as opposed to curves, allow for a greater range of motion in the vertical adjustments of the device. The general geometry that the tool undertook can be seen in the previous figure 16. Notably, aluminum is not radiolucent so it could not be used for the cantilevered structure and the material selection for this component is described in chapter 8. All of the bearings selected for this project use a compression to lock the device at desired points. The handles are set on threaded holes which act to clamp down on the t-slotted framing thus preventing accidental motions. Finally, the components are all made of materials, mostly aluminum and stainless steel, that can survive high temperatures and pressures. This means that the framing is autoclavable in order to allow for rapid and effective sterilization.
6.2 Tolerancing of Fixation Pins

An important aspect to the framing is that way that it locks into the Dräger bed. This connection will provide fixation from any accidental bumps and stability during the loading that it will endure. Several different methods were attempted to achieve the connection in a way that would be usable for staff, be strongly connected in place, and be completely static across the range of CSU load (up to 40N). The first connection that was attempted was a backside clamp that is shown in figure 17A. It had two handle that rotated clamps into position at the foot of the bed. A set of holes on the underside of the bed would then act to stabilize the tool. However, this approach became difficult because even though the clamps were easy to use, the alignment of the bottom holes was not. This presented a usability issue before testing of rigidity and stability, so this version had to be scrapped.

Next, a single cross-beam approach which connected into the top-side of the bed was developed and is shown in figure 17B. Two pins were attached at the edges of the frame to slide into these pre-made holes. However, the irregularity of these holes meant that the pegs initially had an imperfect fit which was corrected by adding a taper to the sides of the peg. This taper is shown in figure 17C. This fit was altered several times until it was optimized for the bed and the results improved slightly. However, the seal only happened at one particular point on the taper and this allowed the pegs to act like pin joints within a 5° range of motion. This created a snapping effect between two bistable points of the device which would be unacceptable aesthetically and from a safety capacity for clinical practice.

In a final effort to alleviate the motion, a reverse collet pin was designed and it shown in figure 17D. In this design, a central shaft is driven down the lumen of the tool which forces a set of leaves to expand. The pin is inserted with the leaves closed, and the leaves opening in the holes then forces the device to stabilize in place. This initially corrected the stability issues that previous designs had encountered, but the collet pin was slipping under high loading on the device. This occurred because the friction in the channel from the expanded pin generated an insufficient moment to balance the tool against the loading of the suspension lines. Therefore, a new method was required that would remain static even at high loadings.

An obvious, albeit bulkier solution emerged to extend the framing on the sides of the device. With a four-foot design, the device had extended its Zone of Stability (ZoS). A Zos is an 2-dimensional area on a surface, here the bed, that if the Center of Pressure (CoP) of the device remains within it, then it will be stable. This occurs because high vertical loadings can now be applied at all corners of the bed, and therefore generate large stabilizing moments for any load in between them. Loose fitting pegs were then added to all four corners in order to prevent inadvertent horizontal motions. This full-frame design is shown in figure 17E.
Figure 15: Attempts at structural fixation: (A) Bench-top clamp, (B) 2-pin cross beam, (C) typical pin, (D) reverse-collet pin, (E) full 4-pin base with identified weak joint

6.3 Corner Joint Reinforcement

Once the overall device was stabilized and locked, a new structural problem became evident. One of the internal joints of the framing, indicated by the red box in figure 17E, was insufficiently strong to bear its expected loadings. This weakness could be attributed to the shape of the joint used and the nature of T-slotted framing. A corner bracket, with one screw to each beam, initially connected the cross and side brace in a right corner. The strong axis of the corner bracket was aligned with a back brace so as to minimize deflections and rotations about that axis. However, the nuts in the T-slot would slide along their channel under high load creating a loose fitted joint. This loose fit then allowed a series of small rotations at the corner joint which ultimately destabilized the tool. Therefore, in order to strengthen the join, additional brackets were added to prevent linear or rotary motions about any of the cardinal axes. The axes and the newly designed joint are shown in figure 18. Flat brackets were added between the back and side beams to prevent rotations about any axis. A internal fixation piece then prevents any linear motion along the y-axis. Finally, two corner brackets were added between the back brace and the feet (and indirectly the side beam through the flat brackets) in order to prevent translations along the x or z axes. Ultimately, this combination of brackets was successful in fortifying the joint against and potential motion or slippage. The collapse that had been observed previously had been completely removed.
6.4 Analysis and Methods for Rigidity Evaluation

Now that the frame and fixation have been designed, and the evident, issues resolved, it must be evaluated based on the requirements on the CSU. The primary outcome to evaluate the stability and rigidity in the device is the deflection in the cantilever head. Design requirements established in chapter four stated that the objective is to obtain a deflection of less than $5^\circ$. This goal is meant to both ensure a positive aesthetic in the tool to mitigate parental anxieties and to ensure the tool is safe for patients against any undesirable motions. In order to assess this outcome, the tool will be analyzed for the cantilever deflection against the loading at the suspension head. This will be re-assessed three times using analytical, numerical and experimental methods.

Initially, an analytical truss modelling was performed to assess rigidity. From observation, it was believed that the primary point of deflection was torquing in the back cross-beam. Therefore, in order to predict the amount of twisting, the CSU was sketched out as a rigid-body truss which is shown in figure 19A. A range of tension up to a maximum loading of 40N, from the design requirements, is applied at the end of the cantilever. As will be discussed in chapter 7, a spring also hangs off the back of the CSU carrying the same load. A static solution is then computed to determine the torque and resultant twisting in the cross-beam necessary to balance these loadings.

Next, an experimental setup was built to determine the actual deflection in the cantilever against loading. An electronic force-gauge was attached to the suspension line, and an electronic level was placed on the cantilever. The spring was also attached, in the full wire system described in chapter 7, in order to remain consistent with the analytical model. A set of data was then collected comparing these two values over a similar range of tension loadings.
Finally, it will be shown in the results that there is a significant discrepancy between the analytical and experimental solutions. In an effort to reconcile this difference, and to better understand what may be causing the deflection, an FEA of the back cross beam was performed. The hypothesis was that the cross-sectional shape of T-slotted framing creates issues with the analytical solution that the FEA should be able to resolve. ANSYS was used to compute this numerical deflection. Both ends of the cross beam were assumed clamped as boundary conditions (based on the reinforced joint), and a moment was applied on one face at the center of the beam. The deflection of the top surface was then computed over a range of moments. These moments were then converted back to the associated loading at the suspension in order to compare these results with the analytical and experimental outcomes. Once all three evaluations are complete, the results will be discussed in order to consider what, if anything, may be producing discrepancies.

It should again be highlighted that analytical, numerical and experimental results presented here each serve a unique role and at different points within the design process. The analytical approach was attempted first, immediately after the rough geometry and the choice to use T-slotted aluminum had been established. An analytical approach to deflection is a simple mechanical problem but can serve as a powerful tool to identify weak aspects of the design. This was performed preemptive to purchasing the materials or constructing the frame. Therefore, a predictably weak frame could be avoided. The analytical method represents a prudent design strategy. However, before a full setup had been established, but once the construction had begun, there were evident discrepancies between the analytical model and the qualitative observations. The nature of these differences will be discussed further in the following sections, but it was this initial contrast which led to the use of FEA. Therefore, the numerical method served as a second-pass approach for assessing and justifying the design choices. Finally, the experimental validation is a true testing of the actual device. These results will be presented side-by-side in the following sections because it is informative, for improving the design, to discuss and understand the cause of conflicting results. However, this simultaneous presentation is not intended to indicate that these evaluation methods were conducted at the same time. Each method served a distinct role at highly disparate times in the design process, but their comparison is meant to introduce another functionality of these tests.
6.5 Bending Results

First, the analytical model will be addressed by using it to predict the twisting in back cross-beam of the CSU. A sketch of this truss model is shown below in figure 19A. The twisting in the purple beam will be computed. The reinforced corner is assumed to lock the end in place and therefore there is assumed to be no twisting at the boundary. Finally, the yellow truss is assumed to be rigid. Based upon the design requirements, the maximum loadings are taken to be:

\[ F = F_{\text{patient}} = F_{\text{spring}} = 40N \]

Further, the relevant dimensions and material properties are taken to be:

\[ L_1 = 7\text{cm} \]
\[ L_2 = 57\text{cm} \]
\[ L_3 = 27\text{cm} \]
\[ J_Z = 3.68 \cdot 10^{-8}m^4 \]
\[ G = 26GPa \]

Where the lengths are as indicated in the sketch, \( J_Z \) is the polar moment of area, and \( G \) is the shear modulus. With this information, a simple balance of moments can be computed where the spine meets the cross-beam. This is indicated as \( M_{\text{reaction}} \) in the drawing. At this point, the torquing from twisting in the shaft will be equal and balanced with the applied load from the CSU. Based on this equivalence, the twisting in the shaft can be computed.

Figure 17: Analytically modelling twisting in the cross-beam with (A) a sketch of the 3D problem, and (B) the cross-section of the cross beam
The moments are balanced as follows:

\[ \sum_{i=1}^{n} M_i = M_{applied} - M_{reaction} = 0 \rightarrow M_{applied} = M_{reaction} \]

\[ M_{applied} = F \times (L_2 - L_1) = 20N \cdot m \]

\[ M_{reaction} = J_Z G \frac{d\theta}{d\psi} \]  \hspace{1cm} (5)

\[ \therefore d\theta = \frac{M_{reaction}}{J_Z G} \cdot dx \rightarrow \theta = \frac{M_{applied} \cdot L_3}{J_Z G} = \frac{F \cdot L_3 \cdot (L_2 - L_1)}{J_Z G} \]

Substituting in the values noted previously gives the following results:

\[ \theta_{max} = 0.32^\circ \]

\[ \theta(F) = \frac{0.008^\circ}{N \cdot F} \]

Notably, these results were much smaller than what was being qualitatively observed in the prototyping. Therefore, the next step was to conduct an experimental trial of cantilever deflection against applied loading. An electronic force gauge measured the applied suspension load while the angle of deflection was measured by the electronic level. The data was recorded simultaneously and plotted in figure 20. The results were generally linear which is consistent with the analytical model. However, there was a non-zero offset which implies the tool setup had a slight tilt. More importantly, the deflections were significantly higher than the maximum deflection predicted by analytical methods. Notably though, one positive is that all angles recorded were below the design requirement of 5\(^\circ\). Nonetheless, further investigation is required to explain the discrepancy between the analytical and experimental results.
Intuitively, these results suggest that bending is occurring at some other position besides twisting in the cross-beam. It is possible that the bearings and joints along the spine are creating small rotations which cumulate in a significantly noticeable deflection but this was not immediately apparent upon observation. Another possibility is that there shape of the cross-section of a T-slotted bar is creating issues with the analytical methods. The analytical model for twisting (equation 9) uses the polar moment of area. The value is computed as:

\[ J_Z = \int\int_A x^2 + y^2 \, dx \, dy \]  

(6)

As can be noted from this equation, the area on the outside of a cross-section contributes quadratically more to the polar moment of area than the interior area. This makes sense in terms of rotational stiffness if the applied moment is evenly distributed over the surface area. Typically, this can be approximated as being true, but, in the case of T-slotted framing, a significant portion of the area is suspended on the extremity while also not being load bearing. Therefore, the actual rotational stiffness could be significantly lower than what was assumed analytically. In order to investigate, an FEA model of a T-slotted frame was developed. Both boundaries were assumed fixed due to the reinforced joint and a series of loads were applied at the center of the beam. The beam was the length of the cross-beam and the applied loads were between 0N and 20N-m. This was the maximum applied torque found in the analytical section. The result was captured every 10N-m and a linear regression of the data was found. These numerical results are plotted alongside the analytically derived function and the experimental data in figure 21.

Figure 18: Scatter Plot of End-Loading (N) against Deflection (°) in the Cantilever
The numerical results are once again highly linear and intermediary to the analytical and experimental outcomes. This result suggests that the issues with polar moment of area may have contributed to part of the discrepancy between the analytical and experimental results. However, there are clearly secondary issues at play as well. Notably the bearings and joints along the spine may not be tight enough to prevent all rotation at those points. Further shimming of these points and perhaps replacement of these components may be required. The impact of these rolls on the overall design will be elaborated in the next section. Finally, an exaggerated representation of torquing in the cross-beam from the FEA is shown below in figure 22. The coloring represents the local strain in shaft.

Figure 19: A Comparison of the Experimental, Numerical and Analytical Modelling of Loading (N) against Deflection (°) in the Cantilever

Figure 20: FEA results as an exaggerated illustration of deformation in the cross-beam under torque in (A) an isometric view and (B) a side view
6.6 Discussion on the Structural Integrity of the Tool

From the previous results it remains clear that there are outstanding points of rotation and deflection in the tool. It is likely that slight spacing at the linear bearing and the rotary joint at the head is allowing for this deflection. Normally this spacing allows for smooth movement at these joints, but if the deflections are significant then they can be tightened in a process called shimming. This is where pieces are inserted behind the brake-pads in order to compress the internal member. Of course, this process would also increase friction in the desired movements. Given the three moving joints on the spine, these are also the three most likely places for deflection to be occurring. Figure 23 illustrates where these rotations are by dividing the problem between $\theta_{\text{head}}$, $\theta_{\text{back}}$, and $\theta_{\text{cross}}$. Future investigation would be required to identify the relative contributions of each of these angles.

Secondly, it is worth noting that the problems observed here are innately part of the design of the tool. The nature of a single vertical spine allows the rotations along its length to accumulate. In this way, the rotations are serial and will build on each-other up until the head structure. Creating multiple supports in parallel could help to mitigate this issue in future designs. However, it is worth highlighting that the current results, even if not fully mapped, are within the pre-established design requirement of 5° of deflection. Therefore, these results will be deemed acceptable for the time being and the design process will continue onto the wire guide system for tensile transmission.

Figure 21: Potential points of rotation in the CSU frame while under loading.
7 Development of the Wire System

This section will present the design, development and testing of a wire system that can meet the various design requirements of the CSU. This system must apply loadings to the suspension lines up to 40N, measure the tension, compensate for motions, and be simple for the staff to use. Further, it must accomplish these functions in a purely mechanism-based fashion in order to meet the autoclavability requirements. Therefore, the chapter will begin by discussing the overall layout of the wire system and the compensator mechanism that was created for this purpose. This compensator employs a series of pulleys in order to balance both loadings and motions in the device. Then the selection and analysis of a tensioner input will be deliberated. This input must coil and tighten the wire on the traction line in a manner that is continuous, bi-directional and non-backdrivable. In following, the selection of a measurement system is mentioned including a comparison between springs and weights. Finally, the guide system itself is addressed with the design approach and the cabling selection process. The wire system will then be evaluated experimentally in regards to its ability to transmit and accurately measure the traction applied to the patient. The experimental setup, methods and transmission results will be presented and then a discussion on these outcomes will consider their impact on the overall CSU device.

7.1 A Pulley-Based Tension & Length Compensator

First, a pulley-system needed to be arranged in such a way as to transmit tension to the traction lines of the patient and then measure this applied loading. Further, it must maintain this motion when the cantilevered structure is raised and lowered during X-ray imaging sessions. After various iterations, a floating pulley system was eventually arranged which has the ability to transfer tension while also compensating for motions. An illustrative sketch of this mechanism is shown in figure 24. This diagram is color coded in order to simplify the identification of various components. The system is based around two wires where the proximal wire (yellow) is closer to the user, and the distal wire (blue) connects to the suspension suture. An input (solid blue) coils the proximal wire which turns around the floating pulley (solid yellow), back around a static pulley (green) and two a spring gauge (dark yellow). This spring gauge can then be used to read the tension on the proximal line. Similarly, the distal line will approach from the patient, roll down and around the floating pulley, and then around a set of other turns before being clamped off. By considering a Free Body Diagram (FBD) around the, it can be shown that the forces on the distal and proximal lines are equal. Consequently, this means that the loading recorded by the spring should be exactly equal to the loading applied to the patient. To show this is true, four forces can be considered applied to the floating pulley which must all be in balance, as shown in figure 24A, and these are $F_{\text{Patient}}(F_P)$, $F_{\text{Compensator}}(F_C)$, $F_{\text{Input}}(F_I)$, and $F_{\text{Spring}}(F_S)$. The balance of forces calculation, demonstrating this equivalence of the spring and patient line tensions, is shown on the following page.
\[
\sum F_{pulley} = (F_{Patient} + F_{Compensator}) - (F_{Input} + F_{Spring}) = 0
\]

\[
F_{Distal} = F_{Patient} = F_{Compensator}
\]

\[
F_{Orange} = F_{Input} = F_{Spring}
\]

\[
2 \cdot F_{Patient} - 2 \cdot F_{Spring} = 0 \rightarrow F_{Patient} = F_{Spring} \quad QED
\]

The above shows that the tensile loading applied to the traction lines of the CS patient should be equivalent in magnitude to what is measured at the proximal spring scale. Furthermore, it can be shown that this setup is able to compensate for motions in the CSU. The inclusion of the spring is powerful because it maintains the autoclavability of the device in a way that an electronic tensile sensor could not. Nonetheless, springs also introduce a limitation that the application and measurement of tension is fundamentally length dependent. When the cantilever is moved up (to provide nurse accessibility) or down (to allow X-ray imaging) the lengths of wire in the pulley-circuit are susceptible to change. This could unintentionally change loadings applied to to the patient. Therefore, the pulleys have been arranged in such a way as to compensate, and ultimately prevent, length changes in the wires and spring. This length compensation will thus maintain tension on the patient during cantilever motions and this is illustrated in figure 24B. In this diagram, the proximal wall is static (green) and the distal wall is dynamically moving down (red). During this motion event, the change in the position of the floating pulley can be considered to show that it does not move. As such, the length of the yellow wire doesn’t change and the overall tensions in the circuit remain constant. This derivation is shown in following where \( \Delta x_{FP} \) is the change in height of floating pulley, and \( \Delta l_i \) are the changes in blue wire length at other indicated points in the circuit. The change in height of the pulley will be the opposite of the sum of the changes of lengths in the rest of the circuit. Therefore, the derivation goes as follows:

\[
\Delta x_{FP} = -\sum_{i=1}^{4} l_i
\]

\[
\Delta l_1 = \Delta l_2 = -D
\]

\[
\Delta l_3 = \Delta l_4 = D
\]

\[\therefore \Delta x_{FP} = 2 \cdot D - 2 \cdot D = 0 \rightarrow x_{FP} = 0 \quad QED\]

Therefore, there is no overall change in length in the floating pulley. This means that there will be no length change in the proximal wire, and thus no change in length in the spring gauge. Resulting from Hooke’s law (equation 11), the loading from the spring, \( F_{Spring} \), will also not change. From the previous FBD analysis, this also means that the loading on the patient, \( F_{Patient} \), will remain constant. Thus, this pulley-system design succeeds in compensating for both length and tension.
Hooke’s law is given as follows to relate changes in wire length to potential changes in tensile loading.

\[ F = -k \cdot \Delta x \] (7)

![Figure 22: Illustration of the compensator mechanism showing in (A) the force-balance between the two sides of the circuit and (B) the length conservation in movement](image)

### 7.2 A Bidirectional Non-Backdrivable Tensioner

Next the considerations of the input method must be considered and discussed. This is a mechanism, again to maintain sterilizability, which must coil the proximal wire in order to apply tension to the CSU wire system. This input should be easily usable by staff and be able to coil the wire in a continuous, bi-directional and non-backdrivable fashion. Continuous means that the tension can be altered over a range of values which will support the usability of the tool and also guarantee the possibility of fine-tuning tensile loading. Bi-directionality means that the system can both increase and decrease the tension on the line without needed to de-suspend and re-suspend the patient. This could become important over the suspension treatment while experimenting with whatever loading works best for the patient. Finally, non-backdrivability means that the system can only be altered (i.e. driven) from the operator side of the input. The innate tension in the circuit must be innately prevented from uncoiling and de-tensioning itself. This will be important for maintaining tension on the patient’s chest over the course of the treatment. Since meeting all of these requirements can be difficult without the benefit of motors, several different mechanisms needed to be considered over the course of the design process. Figure 25 on the following page demonstrates some of the different approached that were evaluated for the purposes of tensioning, and maintaining tension, on the cabling.
The first approach that was attempted was a ratchet-based tensioner shown in figure 25A. These inputs are often used on clothes lines and can maintain very high loadings without being backdriven. A series of asymmetric spoke are pushed around a locking pin which is held in place by a unidirectional spring. Therefore, the device can only be driven in one direction unless the locking pin is removed. The ratchet is not continuous but the tensile increments were acceptable enough to be low enough for the design. It was non-drivable thanks to the locking pin too. The issue arose with it’s inability to easily de-tension the patient. When the locking pin is removed, the system would rapidly uncoil in an uncontrolled fashion. This presents a danger to the fragile patient and the ratchet approach has to be rejected.

The second method considered was a worm-gear input. This is where a screw shaft is turned and motion slowly advances a spur gear. This system is innately non-backdrivable because any motion by the spur gear will only apply loading axially to the screw which cannot create any rotation. Therefore, the system is self-locking in a bi-directional fashion. Further the system allows for continuous inputs as desired. The issue arose because the gear ratios on worm gears (the ratio of input to output turns) is typically very high in the range of 20 to 24. This meant that additional gear would need to be added to step-up the gear ratio which was adding complexity and potential malfunctions into the design. In order to avoid these potential complications, the worm gear system was set to the side while other options were investigated.

Next, a planetary-gear system was considered. This is where a set of spur gears can be compactly arranged about a central axis in order to produce very high gear ratios. This suffered from the same issues as the worm gear, on top of not being truly self-locking, but it did contribute to the development of a better alternative. An offset planetary gear system is a variation on the traditional setup where the outside planetary gears are driven around as opposed to driving the lead axial gear. Further, the two axial gears have tooth numbers that are actually incomparable with a proper helical gear design, but are instead specially chosen to create a self-locking feature. However, the secondary axial gear is still driven around to turn a shaft and coil the wire. This system is shown open and closed in figure 25C and 25D respectively.
Ultimately, this system is continuous, bidirectional, non-backdrivable and has a good gear ratio. Therefore the offset planetary gear system was chosen for the CSU application. A more detailed explanation of how the internal mechanism works will now be provided here. In traditional planetary gear systems, also known as epicyclic gearing, a central axial ‘sun’ gear is driven as an input. This then drives planetary gears around a carrying ring which can then drive another compatible output sun gear. This setup is highly compact and can be used to create high gear ratios where the power difference makes it effectively non-backdrivable. The offset planetary gear system reverses and alters to concept to create an authentically self-locking system at much lower gear ratios.

An illustration of the offset planetary mechanism is shown below. Figure 26C represents the three-dimensional spatial arrange of the gears in the peg-head but figure 26A and 26B provide two-dimensional outlines of this same mechanism in order to more clearly explain the forward driven and backdriven characteristics of this system. When the system is forward driven (turned by the operator), the outside planetary gears (yellow) are forced to rotate about the central axis. This causes them to roll along the guide gear (blue) which is perfectly aligned with the planetary gears and causes them to turn about their own axes. Now, the planetary gear is rolling into the output sun gear (red) which has a slightly improper teeth count for correct gear meshing. The rolling yellow gear will therefore pushing the red gear slightly forwards and the system will be coil the wire. This works identically in either direction which means the system is bidirectionally continuous in the forward driven case.

Figure 24: Mechanism Schematic of the Bidirectional non-backdrivable tensioner. (A) Forward driven schematic, (B) Back driven schematic, and (C) Three-dimensional representation.
However, if the tension on the wire attempts to back drive the system, then the sun gear will again clash into the mismatched planetary gear. Now that the planetary gears are not rotating about the central axis, they will come into contact with guide gear in such a way as to lock between the two axial gears. The resultant force will be directed through the axis of the gear and radially to the central peg axis. Thus this force cannot drive the planetary gear about either axis and it will innately lock itself in place. Therefore, the system is bi-directionally non-backdrivable in the backdriven case. Consequently, this system is an ideal input option for the CSU application. This mechanism was originally designed and patented by the Wittner company for the purpose of preventing de-tensioning on cello strings.

7.3 Spring Sensor Selection

Next the method for measuring the tension on the lines must be considered. Based on the initial concept for the compensator, a spring gauge needed to be selected. This gauge needs to be able to measure loadings between 0N and 40N with an accuracy of at least \( \pm 1 \text{N} \). Further, it should be light weight and not exceed 12 inches when fully extended. This last spatial constraint is to ensure that it can fit in the channel behind the device while not interfering with the Dräger bed. Given these requirements, a few different different scales were considered before setting on the 5kg dial hanging scale from McMaster-Carr. This spring works up to 49N, has the desired accuracy, and works over a 10 inch range. The scale denotes the loadings in both pounds and kilograms as opposed to newtons. This is common in medical applications and could help the tool to be more understandable to new users. Therefore it was well suited for this application. An image of the selected spring gauge along with the associated scale is shown below in figure 27A.

![Image of spring gauge and scale]

Figure 25: Selection of a measurement system. (A) The selected spring-gauge, [35] and (B) an alternative weight-based system. [3]
It is worthwhile to address that a second option was also considered to replace the spring scale. A weight-based counterbalance system could also be used to apply force to the traction line and keep track of the amount of weight. Furthermore, this would be a length independent system which would completely circumvent the compensator concerns that were discussed in section 7.1. An image of a stackable weight system that was strongly considered for this application is shown in figure 27B.

Given that the weight system clearly has some advantages over the spring, a formal comparison of these two options was performed. A table summarizing the main pros and cons of each alternative is shown below in table 5. The spring-gauge is a lighter option which may be easier to operate when it is coupled with the tuning pegs. On the other hand, the counterbalance system alleviates the need for the pulley-system compensator and will therefore create less friction issues. This friction could lead to operating issues and sensor inaccuracies that were not accounted for in the previous compensator derivations. However, the counterbalance would overall be more expensive, create a potential injury to staff and include a larger set of pieces. All of these could damage the usability of the system. Given that the spring is mechanically complex but simple from the work flow perspective, it was decided to continue developing the spring model. Human factors heuristics suggest that building complexity into the tool as opposed to the training is a safer and ultimately more effective design method. Building with the springs places the challenge on the designer to build an effective tool, as opposed to expecting the work-force to never make mistakes.

<table>
<thead>
<tr>
<th>Design Option</th>
<th>Spring-Gauge</th>
<th>Weight Counterbalance System</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pros</strong></td>
<td>Lighter</td>
<td>Mechanically Simple</td>
</tr>
<tr>
<td></td>
<td>Easy to operate (i.e. Good usability)</td>
<td>Less friction issues</td>
</tr>
<tr>
<td><strong>Cons</strong></td>
<td>More turns, more friction, more inaccuracy</td>
<td>Most expensive</td>
</tr>
<tr>
<td></td>
<td>More mechanically complex</td>
<td>Potential injury to staff</td>
</tr>
<tr>
<td></td>
<td></td>
<td>More separate pieces</td>
</tr>
</tbody>
</table>

7.4 Wire-Guide Design and Wire Selection

Next, the design of the overall wire-guide system needs to be addressed. Several custom components needed to be CADed and printed using the Objet500 Connex printer. The materials used were Acrylonitrile Butadiene Styrene (ABS) and ABS simulating materials (VeroBlack and VeroWhite). The components that had to be printed were responsible for guiding the wire along its path. The wire travels along the cantilever and then into a series of turns which were outlined as being the compensator design. The floating pulley of the compensator then slides along one of the conveniently located T-slots of the extruded aluminum framing. The two channels on the sides and the back of the static spine are used to balance the four wire channels.
Figure 26: Demonstration of key features in the wire guide system including (A) CAD of the bottom of the spine which holds input pegs, several wire turns and a flank for stabilizing, (B) CAD of the top of the spring holder with several wire terms and a wire termination, and (C) a picture of the compensator setup.

Long-elliptical curves were used for these wire turns in an effort to reduce friction and the likelihood of the wire catching. The components also include support flanks to reduce deflection in the truss, and fixation points for the spring gauges. There are four main wire guide components. One is attached to the top and bottom of each of the upper and lower pieces of the vertical spine. In order to demonstrate the design style of these pieces, images of the two components attached to the static (lower) spine are shown in figure 28A and 28B. The bottom piece had a flank to prevent deflection in the upper spine, it has holes for pressure fitting the tuning pegs, and series of exposed curves for guiding cabling in the lower portion of the compensator. Similarly, the top piece acts to hold spring gauges in place with small screw holes, guide the wire through the upper compensator and provide an end fixation point for the distal cabling. A real image of the compensator setup, with all components attached, is shown in figure 28C. A complete set of technical drawings for all custom-designed and printed components (and the machined cantilever beam to be discussed in chapter 8) are provided in appendix D.

Table 6: A Comparison of design options for the Cabling used to transmit Tension in the CSU

<table>
<thead>
<tr>
<th>Option</th>
<th>Radiolucent</th>
<th>Tensile Strength (MPa)</th>
<th>Diameter (mm)</th>
<th>Maximum Load (N)</th>
<th>Factor of Safety</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coiled Steel Cable</td>
<td>No</td>
<td>482.6</td>
<td>0.63</td>
<td>150</td>
<td>3.8</td>
</tr>
<tr>
<td>Polyester Rope</td>
<td>Yes</td>
<td>625</td>
<td>4.76</td>
<td>444.8</td>
<td>11.1</td>
</tr>
<tr>
<td>Nylon Cable</td>
<td>Yes</td>
<td>82.7</td>
<td>0.8</td>
<td>166.3</td>
<td>4.2</td>
</tr>
<tr>
<td>Kevlar Rope</td>
<td>Yes</td>
<td>3620</td>
<td>0.965</td>
<td>578.3*</td>
<td>14.5</td>
</tr>
</tbody>
</table>

*Note: This yield strength was reported with the product but is lower than the typical yield strength of Kevlar. This is assumed to be due to the construction of the wire and the manufacturer imposing their own factor of safety.
Lastly, the cables used to transmit tension in the CSU needed to be chosen. A comparison of the main options are shown in table 5 along with some of the main points of comparison. 40N was used as the maximum anticipated loading per wire in order to calculate the listed FoSs. Traditional steel cabling could not be used because it would impede X-ray imaging through the head. Polyester rope seemed reasonable but only at large cable diameters that would have been problematic for the pulley system. Nylon cables were also considered but they were generally not strong enough and too elastic. Nylon tends to stretch under loading which is poorly suited for a length based measurement system such as a spring. Finally, the decision was made to pursue Kevlar rope to act as the cabling. This polymer based cable will be stronger than steel, be radiolucent to the X-ray and does not stretch significantly within the anticipated tensile region. Furthermore, Kevlar was a reasonably priced option so it has been used to wire both sides of the pulley system.

7.5 Method for Assessing Tensile Transmission

The main purpose of this wire-guide system is to transmit tension in the circuit from the measurement to the traction lines at the patient. Therefore, the next step is to setup an experiment to evaluate the effectiveness of this tensile transmission. Furthermore, this experiment will simultaneously be assessing the linearity and accuracy of the spring scale in recording the tensile output at the patient end. First, the entire compensator and device were setup in the typical fashion described in this chapter. Next, an electronic force gauge was once again attached at the patient end in order to accurately record the output traction loading. An image of this part of the experimental setup is shown in figure 29A. Next, the Kevlar wiring was attached to the input pins and the tension in the circuit was increased over a range of expected values. The tension recorded by the spring scale and the electronic gauge were recorded in pairs so that they could be compared. The setup of the full compensator, as used in this experiment, is once again shown in figure 29B.

As will be demonstrated in the results section, some issues relating to tensile transmission created concerns that the compensator may have been creating unwanted friction in the circuit. In order to evaluate the validity of this hypothesis, a secondary experimental setup was tested. The compensator was removed and the spring gauge was attached directly between the input peg and the distal wire. The procedure of recording the measured tension at both end in pairs was then repeated. This setup without the compensator is demonstrated in figure 29C.

A third trial was also conducted to qualitatively assess the system’s reaction at higher-than-expected loadings. This would highlight any points of weakness which could risk to patient safety. There was also an observed snapping effect in the spring gauge. By removing the spring and connecting the distal line directly to the input peg this issue was removed and the structure under loading could be observed. An image of this setup with no spring gauge is shown in figure 29D.
7.6  Results comparing Input-to-Output Loading

First the results with the full compensator will be addressed and they are shown in figure 30 over a series of seven trials. The uncertainty of both the spring scale and the electronic force gauge are indicated by error bars for each trial and the ideal results (perfect equality) is also indicated for sake of comparison. Normally, investigations of sensor linearity consider the sensor recording to be the dependent variable to the independent true value. Here, the axes have been flipped to reconsider the problem as one of actuation efficiency. The spring is both the sensor and the actuation meaning that an alternative, and more intuitive way to consider the data is that the spring applied a load which is then transmitted to the patient. Under this paradigm, the scatter plot clearly indicates that there are significant tensile losses in the circuit. This loss is believed to result from friction in the wire guide system. As the wire is tightened, it catches on corners or surfaces which then bear part of the load. In cumulation, this offset can become quite significant as is observed here. Although elliptical curves were used to minimize this effect, it is clear that proper pulleys will likely need to be installed in order to make the measurement and the overall device functional. Pulleys roll around their own bearings with minimal friction, and can therefore shield the Kevlar rope from friction with the printed surfaces. There was also a decent amount of scatter in the previous results which could be associated to the friction and sticking as well. Therefore, pulleys could also help to resolve this issue. What is unclear is whether or not the compensator is part of what is contributing to this problem or if it’s exclusively the lack of proper pulleys. This question is why a second experiment was conducted with the compensator removed in order to evaluate it’s effect on the inefficient tensile transmission that was observed here.
Figure 28: Results comparing the Input Load at the Spring to the Output Load at the Patient. Seven trials were conducted.

Another, simpler, trial was attempted where the compensator was removed in order to eliminate the majority of the wire guide system. This meant that the cable only turned at three places and the trial was repeated to see if reducing the channel length and the number of turns would improve the results. The outcome is shown in figure 31 and is largely comparable to the previous experiment. This suggests that these three turning points may be key points of friction in this problem. This is a logical conclusion because they are also three of the sharpest turns in the circuit. These results also suggest that the innate design of the compensator is not creating the error found in the previous results. The next step on this part of the project is to install a proper pulley system within the wire guides and to repeat the experiment.

The graph with the no compensator results includes a scatter of the data with each data point including error bars to represent the inaccuracy of both the spring and electronic force measurements. A line of best fits is included to better visualize the trend, and the ideal result is again plotted simultaneously. Seeing both of these lines side-by-side allows for the difference between them to be clearly observed. It is worth noting that inaccuracies or non-linearity in the spring gauge could also be creating these results. In order to eliminate this possibility, the spring gauge was tested with the electronic gauge outside of the CSU. In this situation the results were consistent with each-other as should be expected from the manufacturer. Hence, the issues observed here are not innate to the spring gauge but must be linked to friction in the wire-guide system of the CSU.
Briefly, a third qualitative experiment to observe tensile transmission at higher loading. As the loading was increased, the drop of tension at each turn became apparent. Just by feeling the wires, there were clear decreases in the loading of the wire at different points. This adds further, albeit observational, evidence that friction at tight turns is what is creating the tensile losses in the wire-guide circuit.

### 7.7 Discussion on the Effectiveness of the Tensioner System

Overall, the results shown here indicate that there are outstanding challenges to be addressed with wire guide system but there are also implicit successes. The system was fully designed, built and able to carry tension from the spring to the patient-side. The amount of loading was controllable via a non-backdrivable input pin. Also, the presence of the compensator did not affect this ability to control the tension applied to the patient. Further, the source of the tensile losses was identified over three experiments. Ultimately, the remaining challenge is one of measurement accuracy and power transmission. To resolve this issue, a full set of frictionless bearing will need to be installed in order to achieve a proper pulley system. This will be required before any consideration of clinical application. Nonetheless, the results of this prototype indicate that the methods developed here can be an effective approach for controlling the magnitude of sternal traction in CS.
8 Design of the Cantilevered Components

This chapter will discuss the various considerations that were involved in designing the cantilever structure of the CSU. This last sub-system interacts with several of the design requirements thus making it a multi-parameter problem to solve. The cantilever itself must not bend under the mechanical loading of the traction lines, even while under the heat of the radiant warmer. Further, it cannot impede allowing this heat transfer to reach the child. The cantilever will also be in between the patient and the X-ray unit during imaging so it must be built entirely out of radiolucent materials. Therefore, balancing the mechanical, thermal and radiolucency requirements of this component becomes a multivariate design problem. As a brief note on terminology, ‘the cantilever structure’ includes all components suspended over the patient which includes the beam, the finger-like wire-guide projections and the emergency release clips. However, ‘the head’ refers only to the beam.

This section will being by considering the deflection of the beam under loading in order to determine the necessary material properties to meet the design requirements. The feasible materials will then be considered and chosen based upon their ability to transmit X-rays and stay stiff under heating. In following, the other components connected to this head structure will be developed. The fingers and their clamping mechanism will be presented. In following, the potential choices for emergency release clips will be deliberated. Finally, two sets of evaluation will be undertaken to assess the functionality of the designed cantilever structure. First, the ability for the heat-lamp to warm the patient will be determined both analytically and experimentally. In following, the effectiveness of the X-ray to capture images will be assessed. Ensuring compatibility with both the heat-bed and the radiant warmer will be essential for creating an effective CSU.

8.1 Analytical Determination of the Head Requirements

First the material properties needed for the head structure to satisfy the design requirements need to be established. Specific to this sub-system, the intention is to maintain bending below 1°. This then leaves a 4° buffer for bending in the truss and the CSU can still achieve the initial design requirement of keeping bending under 5°. Before material properties can be modeled and targeted, the shape of the beam needs to be selected. The beam was designed to be an I-beam along most of it’s length. This cross-sectional shape acts to minimize the weight of the beam against its bending stiffness, and will consequently minimize deflection. However, the portion of the beam near the foot of the bed will have a rectangular cross-section in order to allow the head to be screwed into the frame. An illustration representing the side-view and front-view of this partial I-beam is shown in figure 32. However, a proper technical drawing of the head structure (which was eventually used for machining) is presented in appendix D.
Now that the shape of the beam has been established, the deflection of this head structure can be modelled. The beam is modeled as an static Euler-Bernoulli (EB) beam. An EB model assumes that all planes of the beam remain perpendicular to the central axis and do not rotate relatively. The beam is long and slender here so this is a fair assumption. A Timoshenko beam model but that level of complexity is not required here. A sketch of the loading and boundary conditions is shown in figure 32.

![Figure 30: Side-view and Front Profile Illustrations of of the Euler-Bernoulli Beam Model with Gravity and Point Loading](image)

The beam is assumed to be under it’s own weight of gravity with a point-load of 40N at the far tip. Further, the boundary is taken to be completely fixed with no deflection or rotation on this surface. This is reasonable because the actual beam is screwed into a flat surface on the truss, and is standard for a cantilever beam model. The other end is assumed to be entirely free. From this modelling the necessary relationship between the stiffness and the density of the selected material, in order to maintain end-point deflections below 1°, can be determined. The basic mathematic model can be written as:

\[
\frac{d^2}{dx^2}(EI \frac{d^2w}{dx^2}) = q(x) \tag{8}
\]

\[
\theta = \frac{dw}{dx}
\]

The boundary conditions at the fixed end, no rotation or deflection, gives:

\[
w|_{x=0} = 0
\]

\[
\frac{dw}{dx}|_{x=0} = 0
\]
The boundary conditions for the free end, no internal shear stress or internal moment, gives:

\[
\frac{d^2 w}{d^2 x} \bigg|_{x=L} = 0 \\
\frac{d^3 w}{d^3 x} \bigg|_{x=L} = 0
\]

Where \( E \) is the Young’s modulus in GPa, \( I \) is the second moment of area in m\(^4\), \( w \) is the deflection of the beam in m, \( x \) is the distance along the beam in m, \( L \) is the total length of the beam in m and the free-end point, \( q(x) \) is the loading distribution in N/m, and \( \theta = \frac{dw}{dx} \) is the angular deflection. With this model, the deflection at the end point can be computed for a range of Young’s moduli and densities. These results are plotted in figure 33.

![Graph](image)

**Figure 31:** Analytical Results of the Euler-Bernoulli Bending Model plotting Young’s Modulus (\( E \)) and Density (\( \rho \)) against End-Point Deflection (\( \theta_L \))

As can be seen in the above results, the density value is largely irrelevant. This is because the weight of the beam is largely negligible to its stiffness which makes sense given the I-beam cross section. In order, to maintain a deflection below 1° at the end-point, the selected material requires a stiffness of at least 1GPa. Now that this property threshold has been established, materials meeting this requirement can be considered in terms of their radiolucency and thermal performance. A final material selection can then be made based on the combination of these factors. The discussion on how to best considerate these parameters simultaneously is presented in the following section.
8.2 Material Selection

Now that the required material mechanical properties have been established, the material selection can proceed to consider the X-ray and heating compatibility. A table of potential material groups, sorted by Young’s modulus and density, is presented in figure 34A. It was previously determined that while the density is largely irrelevant, the selected material must have a stiffness of at least 1GPa. As such, a yellow line has been drawn onto the material selection table in order to eliminate all options below this stiffness from consideration. From the remaining options, metals, ceramics and composites are groups which all primarily contain radio-opaque materials. Therefore, these options are not well-suited for the CSU application. High stiffness thermoplastics, like all plastic polymers, tend to be radiolucent as desired. Three thermoplastics that are often used in other medical applications, and have sufficient stiffness, are PolyPhenylene Sulfide (PPS), Ultem also known as PEI (PolyEtherImide), and PolyEther Ether Ketone (PEEK). These three materials will be considered for selection by reviewing their thermal performance.

The selected material will need to be resistant to heat in order to prevent both bending under the heat lamp and potential deformation ware during autoclave sterilization. Fortunately, thermoplastics as a class have excellent thermal performance as materials. The stiffness of the three materials under consideration over a range of high temperatures is shown in figure 34B. The device should be resistant to temperatures up to 100°C. Further, it should maintain a thermal FoS around 1.5 to 2. As can be seen from the table, the stiffness of PPS begins to drop around 100°C making it a poor choice. Both PEEK and Ultem satisfy the performance requirements described here. However, Ultem is both a less expensive and higher FoS choice. Therefore, Ultem was chosen for constructing the head piece. This component was then machined by a series of milling processes.

Figure 32: Material selection considerations for the cantilever with (A) stiffness to density comparison and [47] (B) thermoplastic performance [28]
8.3 Adjustable Finger Clamp Design

A locking mechanism needed to be developed to the four fingers at the head of the device. The four fingers allow for adjustments to be made between different clinicians, but they should be fixed in place while under tension. To create this lock, a clamp was built on top of the tool where a button screw knob would push down on a bridge that would then apply pressure to all four fingers simultaneously. Unfortunately, the problem was spatially constrained such that there was minimal surface area in contact between the bridge and each of the fingers. To solve this problem, the fingers were narrowed and a larger plate was inserted between the bridge and the fingers. Therefore, the effective area between the fingers and the lock was increased. By increasing the area, under the same normal force, the static friction holding the fingers in place will increase. This redesign allowed the clamp to lock the fingers much more effectively. Further, the fingers and the plate were tightly fit so that constant friction, while the fingers are unlocked, would stabilize the fingers and allow for easier positioning. An exploded CAD illustrating these components is shown in figure 35.

Figure 33: An exploded isometric view of the finger clamping design in the cantilever

8.4 Quick-Release Clips

Another challenging aspect to the design was the development of a quick-release connection for suture placement. A piece needs to be chosen which can link the suspension wire in the CSU and the suture connected to the child’s chest. The difficulty is finding a solution that is easy to setup for the surgeon, easy to remove for the nurse and otherwise has a high holding strength. The current technique employs needle-drivers to secure the line but this is unacceptable for the X-ray and is a crude aesthetic. Until now, the device has been using U-hooks (figure 36A) which secure a loop of the suture around a hook. This is easy to take down and holds most lines past their break strength. However, it requires that the surgeon tie loops and there was an initial concern that this would be difficult if not annoying. Therefore, there is incentive to consider alternatives. Ultimately, after discussion with cardiac surgeons, it became apparent that a loop actually already existed in the current method that could be attached to the U-hook making it an ideal option. However, since other options were considered, they will be briefly addressed in order to provide a complete review.
One possibility was to use a similar methodology but to simplify the setup was to use an intermediary like a suture ring. This ring would be setup pre-operatively with the desired loop to connect to the U-hook. The surgeon could then easily fasten the suture from the chest of the patient to the suture ring. This option is represented in figure 36B. Another option was a V-clip where the suture end would slide through, and be compressed in a V-channel. However, without a pre-tied knot in the line, the fastening strength of this method was quite poor. A CAD of this piece is shown in figure 36C. Finally, a last considered possibility were compression clips shown in figure 36D. When untouched, the clip has two teeth that are compressed together under tension thereby providing a holding strength to anything placed between them. They are plastic so they will be translucent in the X-ray, and they are simple to operate for setup and removal. However, their holding strength is less than that of the U-hook so they ended up being rejected.

![Figure 34: Main options for a quick-release clip. (A) U-Hook, (B) U-Hook and Suture Link, (C) V-Clip, and (D) Compression Clip.](image)

8.5 Thermal Evaluation

The following section will evaluate the compatibility of the current CSU device, and cantilever structure, with the Dräger heat bed. It is important that the radiant warmer still be effective at providing heat for the open-chested child. Therefore, it needs to be ensured that the CSU being placed between the patient and the heat-lamp will not impede this function. An open-chested patient will radiate significantly more heat than usual, and this could be life-threatening to the patient if their body-temperature dropped too low. There is always a risk that placing a device over the patient could shadow them, and prevent this warming effect. Therefore, the effect of the heater with and without the CSU present will be compared using analytical and experimental methods.
8.5.1 Methods and Experimental Setup

Two different approaches will be used to evaluate the degree of heat transfer across the CSU relative to normal. First, the radiant heat transfer can be modeled analytically as radiant heat transfer between the heat lamp and the patient. This radiant heat is presumed to travel along straight lines. In the case with the CSU present, the heat is assumed to be conducted through the CSU and then re-radiated towards the patient. Around the CSU the heat will still radiate normally. This modelling will undertake a two-dimensional framework to simplify the problem. As such, convection will be ignored even though it is understood that convection play an important roll in the thermal losses experienced by the patient. However, this analytical approach still has value since it will offer insight into the degree to which the incoming radiated energy will be impeded.

In following, an experimental approach will be used to determine the actual difference in radiant heat transfer between having and not having the CSU. The heat lamp will be turned on in both situations and the temperature at the mattress level will be recorded. A spot on the bed directly under the CSU is marked for measurement in order to maintain consistency and to record the position most significantly impacted. A laser pyrometer, pre-calibrated for use at low temperatures, was used to measure the temperature at this position. This tool is typically used to measuring heat generation in a Magnetic Resonance Imaging (MRI) unit, and it measures the black-body radiation coming off of a non-reflective surface. The pyrometer has a lens which is used to focus incoming InfraRed (IR) radiation onto a electrical detector whose signal can be used to determine the temperature. Measuring the temperature at a distance is convenient for this project where placing a thermocouple or other device on the bed could impact the measurement.

A temperature measurement will be recorded every 25 seconds in both cases. The temperatures can then be plotted against time to observe whether the presence of the CSU affects the rate of heating at the mattress level. This will give an indication of the heat transfer to that point, and consequently the heat transfer to a patient at that position. It is hypothesized for both fo the methods described here that the CSU will not pose an issue for heat transfer. It is fairly thin member and should not impact a significant portion of the radiated heat. Further, 3 dimensional effects will only reduce any impact caused by the CSU.
Similar to with the deflection analysis, it seems worthwhile to explicitly justify the inclusion of analytical methods for heat transfer. Evidently, there are limitations that exist with any analytical approach. However, the use of analysis, prior to the purchasing, machining and construction of the cantilever can be an important concept. By loosely modelling the heat transfer analytically in such a way as to establish a bottom threshold, the feasibility of this design approach could be assessed prior to significant investments of money and time. As will be discussed in the following section, the approaches here present two significant limitations in that they omit non-vertical radiation and the effects of conduction in an open environment. However, the consequence of omitting these effects means that the predictions offered here compute a lower-bound for the comparative heat incident to the patient. Therefore, even while acknowledging the limitations, mathematical analysis of the heat transfer was valuable in the design process for checking the basic concept of using a cantilever approach. Further, analytical approached like the one used here also help to give the design engineer a better understanding of the physical effects which may impact the device, the radiative warming and the patient themselves.

8.5.2 Heating Analysis and Results

First, the analytical approach for modelling heat transfer will be presented. Two dimensional diagrams representing the heat transfer process with and without the CSU in places are shown in figure 37A and 37B respectively. In these diagrams, the heat lamp is represented by the red rectangle, the patient by the blue ovals and the CSU by the orange rectangle. The power transfer from the radiant heat will be computed for both situations.

For the situation without the CSU, the total heat transfer can be computed directly from the Stefan-Boltzmann law for black bodies. Therefore, emissivity is approximated near 1 for both surfaces. The temperatures of both bodies and the area of the heat lamp are known to be:

\[ T_1 = 750^\circ C = 1023K \]
\[ T_2 = 37^\circ C = 310K \]
\[ A_T = .0053m^2 \]

Note that in the Stefan-Boltzmann equation, the temperatures must be used in kelvin. Further, the Stefan-Boltzmann constant is \( \sigma = 5.67 \cdot 10^{-8} \frac{W}{m^2K^4} \). From this, the total heat transfer can be computed, as:

\[ q_1 = \sigma(T_2^4 - T_1^4)A_T \]
\[ \therefore q_1 = 325W \]
Hence, in the case with no CSU, the power transfer baseline was estimated to be 325W. Next, the heat transfer can be recomputed with the CSU present. In this situation, the CSU will capture a portion of the incident radiation, re-radiate a portion to the patient and dissipate the rest to the environment. It does this based on it’s thermal conductance and Fourier’s law which can be written as:

\[
q = -kA \frac{dT}{dx} = -kA \frac{\Delta T}{t}
\]  

(9)

Here, \( k \) is the thermal conductivity and \( t \) is the thickness of material over the temperature change \( \Delta T \). Hence, the patient will receive energy that has passed outside the CSU, \( q_o \), and inside the CSU, \( q_i \). Note that the CSU covers an area of \( A_{CSU} = 7.4 \cdot 10^{-4} \text{m}^2 \). Assuming that the patient maintains the same temperature due to metabolic heat generation, heat blankets and reduced convective losses, then \( T_5 = T_2 = 37^\circ C \). With this information, the new total heat transfer to the patient from the heat lamp, \( q_2 \) can be computed as follows:

\[
q_2 = q_o + q_i
\]

\[
q_o = \sigma(T^4_1 - T^4_5)(A_T - A_{CSU})
\]

\[
q_i = -k_{CSU}A_{CSU} \frac{T_3 - T_4}{t_{CSU}}
\]

\[
q_{\text{incident}} = -k_{CSU}A_{CSU} \frac{T_3 - T_4}{t_{CSU}} + q_{\text{Loss}} = \sigma(T^4_1 - T^4_3)A_{CSU} = \sigma(T^4_4 - T^4_5)A_{CSU} + q_{\text{Loss}}
\]

Where \( q_{\text{Loss}} \) is the losses dissipated to the environment from the radiative heat initially incident on the CSU. A distinction is mad between \( q_i \), which is the heat passing internal the CSU to the patient, and \( q_{\text{incident}} \), which is the heat incident on the CSU. Some of \( q_{\text{incident}} \) will be lossed to the environment as \( q_{\text{Loss}} \) and not all of it will reach the patient so this distinction is important. There are three unknowns to solve for in the prior equivelancy. These are \( T_3 \), \( T_4 \), and \( q_{\text{Loss}} \). While this may initially be slightly daunting, it becomes clear after a little searching that these equations only have one physically meaningful solution. This solution is that the CSU is all the same temperature (and the same temperature at the patient), and all the incident radiative heat is being lost to the environment. This makes physical sense because the heat lamp and the patient act together to maintain the CSU cantilever in constant temperature. This solution can be written as:

\[
T_3 = T_4 = T_5 = 37^\circ C
\]

\[
q_{\text{incident}} = q_{\text{Loss}} \rightarrow q_{i} = 0
\]

\[
\therefore q_2 = q_o = \sigma(T^4_1 - T^4_5)(A_T - A_{CSU})
\]

\[
\frac{q_2}{q_1} = \frac{\sigma(T^4_1 - T^4_5)(A_T - A_{CSU})}{\sigma(T^4_1 - T^4_5)A_T} = \frac{A_T - A_{CSU}}{A_T} \approx 86\% 
\]
Therefore, this result indicates that 86% of the radiative heat transfer will reach the patient. It also indicates, by the nature of these calculations, that none of this heat is passing through the CSU, but all of it is going around. The final result was just a proportion of the exposed area after to before CSU implementation. This is likely unrealistic since some heat transfer will curve around the CSU in the form of convection. Therefore this result is likely lower than reality and should only be taken as a loose approximation. Nonetheless, the result of 86% is already very close to the design requirement goal of 90%. Since this was believed to be an under-estimation of the true heat transfer, this result is optimistic of a successful experimental result.

Figure 35: An analytical setup for radiant heat transfer to a newborn (A) Without, and (B) With the CSU.

The next step is to undertake the experimental evaluation of heat transfer across the CSU. The methodology was carried out as described in the previous section. The procedure of recording the mattress temperature every 25 seconds was repeated with and without the CSU over a 10 minute long trial. Both of the temperature results were then plotted against time and are displayed below in figure 37. Overall, the results were fairly consistent in the studied range. The presence of the CSU created a slightly higher variability in the measurements at high temperatures but both trials reach 33°C by the end of the 10 minutes. This data suggests that the CSU is not a significant impediment to radiative heat transfer. However, it could be valuable to repeat this experiment with more trials in order to better understand the nature of the mentioned high-temperature variability.
8.5.3 Functionality of the Warmer

In summary, both the analytical and the experimental results seem to indicate that the current design of the CSU is compatible with the Dräger Baby therm heat warmer. The outcomes of the evaluations indicate that sufficient heat will still reach the patient. The analytical results suggested this efficiency to be 86% and the experimental results showed a negligible difference. Therefore, it does not seem that the CSU design and cantilever need to be altered to accommodate higher radiative heat transfer. However, there still could be a benefit in performing further experimentation around the heat transfer. Higher trialing, and more samples, would offer a better indication of the variability in temperature observed when the CSU was present. Working at higher temperatures, or over longer trialing intervals, could also help to highlight any issues that were not present at this stage. Finally, working with CCCU nurses to develop an experiment to match clinical protocol could help to offer a more realistically meaningful result.
8.6 Radiolucency Evaluation

This next section will consider the final evaluation of the tool which relates to its radiolucency. The nature of the cantilever design means that material will always be placed over the patient’s chest. Therefore, in order for the tool to be compatible with X-ray imaging, it must allow for those frequencies of the electromagnetic spectrum used in chest radiographs to pass through it. Good radiolucency of the tool can be ensured through proper material selection as has been considered previously in section 8.2 with the choice of using thermoplastic polymers for the beam. Further, printed components like the finger extensions are made from ABS which is another radiolucent plastic. The next stage is to validate these design choices. This text will present both analytical and experimental methods for assessing this functionality. The analytical derivation will then be demonstrated and the consequences to the design will be discussed.

8.6.1 Analytical and Experimental Methods

The analytical method will use a Beer-Lambert model (equation 1) for the electromagnetic dissipation in the cantilever. The image will be taken in the front portion of the beam where the cross-section is that of an I-beam. A depiction of X-ray transmittance through a cross-section of the front cantilever is shown in figure 39A. Normally, Beer-Lambert’s law is requires it be considered at specific wavelengths, or as a vector calculation over a range of wavelengths. However, this model can be simplified by using a lumped parameter for the attenuation coefficient within that range. Thus, the model can be altered to compute the overall transmittance across a range of wavelengths. This can be done by considering the average transmittance between $\lambda_1$ and $\lambda_2$ as follows:

$$T_{\lambda} = e^{-\mu_{\lambda}}$$

$$\frac{\int_{\lambda_1}^{\lambda_2} T_{\lambda} d\lambda}{\lambda_2 - \lambda_1} = \frac{\int_{\lambda_1}^{\lambda_2} e^{-\mu_{\lambda}} d\lambda}{\lambda_2 - \lambda_1} \rightarrow T_{\lambda_1 \rightarrow \lambda_2} = e^{-\mu^*}$$

Where $T_{\lambda_1 \rightarrow \lambda_2}$ represents in the mean overall attenuation in the range from $\lambda_1$ to $\lambda_2$. However, the value of $\mu^*$ is not the mean value, but instead an experimentally determined value that satisfies computing average transmittance given a particular distribution of radiation between $\lambda_1$ and $\lambda_2$. Knowing that X-ray units use wavelengths between 10nm and 0.01nm ($10^{-8}$m to $10^{-11}$m) these values have been experimentally determined by NIST, per unit density, for a range of materials. Using this simplified model, the predicted transmittance will be computed at the thickest point of the beam in order to assess the usability of X-ray through the beam. A second approach for assessing the beam strength would be to evaluate the transmittance experimentally using dosage tests. A Fluke survey meter can measure the radiation rate and accumulated dose for X-rays and is used in maintenance by biomedical engineering. If measured rates and dosages are comparable with the CSU, then the device would be satisfactory. This assessment is being setup with the engineering department at the HSC but the results will be outside the scope of this thesis.
An image of the X-ray unit that is used in conjunction with the Dräger bed is shown in figure 39B. It’s unique shape allows it to slide in-and-out of the heat bed. A reflection tray is then placed under the patient to return and capture the image. Therefore, this is also the unit for which the CSU is being designed to be compatible.

Figure 37: Analysis of CSU head radioluency. (A) A diagrammatic representation of transmittance across the beam, and (B) The X-ray unit used with Dräger beds. [9]

Once again, it is worth remarking on the value and function of including an analytical method, this time for the consideration of radioluency. Like in the prior situations relating to deflection and heat transfer, the analytical modelling occurred early in the design process as a way to verify design decisions prior to significant investments of time or money. This was particularly important in relation to radioluency as prior to this analysis, the notion of radioluency could only be discussed in a highly qualitative way. The material of Ultem was selected in relation to its radioluency requirement because it belongs to a family of materials termed the thermoplastics. The majority of these materials are understood to be radiolucent, but it would be a poor design approach to not associate this assertion to numbers. Even though limited like the prior analytical attempts, the modelling presented here allows for an estimation of quantified radioluency in the context of this specific application. Ultem, in of itself, is an expensive material and it is therefore prudent to investigate easily accessible mathematical models for phenomena like radiation transmittance. By quickly computing such a model with a set of reasonable engineering assumptions, the design could then proceed with a higher degree of confidence in the material selection and design decisions. Further, as in the other scenarios, considering such physical models also allows the design engineer to better understand the underlying physics in case should challenges arise with later testing.
8.6.2 Analytical Derivation and Results

In order to analytically estimate the minimal transmittance across the beam, the shape and material properties of the Ultem cantilever must be known. This approach assumes the attenuation of the air is negligible. Note that this is reasonable since the attenuation coefficient of air is only $\mu_{Air} = 10^{-4}$ which will be insignificant in the attenuation calculation. The I-beam is thickest along its web and this strip will therefore have the highest attenuation. The thickness of the web is 2.54cm. The material properties for Ultem for X-ray imaging were found to be:

$$\frac{\mu_{Ultem}}{\rho_{Ultem}} \simeq 10^{-2} \frac{cm^2}{g}$$
$$\rho_{Ultem} = 1.27 \frac{g}{cm^3}$$
$$\therefore \mu_{Ultem} \simeq 1.27 \cdot 10^{-2} \frac{cm^{-1}}{}$$

With the above previously stated data, the transmittance across the beam can be computed by substituting these values back into the simplified Beer-Lamber model:

$$T = e^{-\mu \tau}$$
$$\overline{T} = e^{-2.54cm \cdot 1.27 \cdot 10^{-2} cm^{-1}}$$
$$\overline{T} = 97\%$$

Therefore, based upon the above calculation, the minimal transmittance anticipated across the web of the beam will be 97%. This is an excellent result and well above the established design requirements. However, this validation should be re-confirmed by an experimental bench-top assessment as outlined in the methods section. Scans should also be qualitatively assessed by radiologists and surgeons prior to any application on a patient.
8.6.3 Discussion on the X-Ray Compatibility

Overall, the results presented here are a very promising indication that the current tool is well designed to achieve X-ray compatibility. However, there are several limitations that are worth noting which could hinder these results. First-off, a screw knob controls clamps on the adjustable fingers. This knob has an internal thread with a metal shell that is parallel to the X-ray beam direction. Although thin, this metal will likely appear as a small, thin circle on X-ray imaging. Whether or not this will impede diagnostics or be a negligible effect will need to be a subjective call made by diagnosticians. Taking baseline images to show to clinicians in order to collect feedback will be the best way to assess this issue. Secondly, the previous calculation assumes that maximum attenuation occurs in the web, but the fingers placed between the flanges could hypothetically create higher attenuation. This is unlikely since most plastics are highly and comparably radiolucent but it would be worth exploring in the experimental tests. This also leads into the fact that the attenuation coefficient used here is an estimate. This can very significantly depending on the manufacturing of the polymer or the consistency of the radiation distribution. If the radiation distribution at NIST was different for X-rays than that used at the HSC, then this could change the value of $\mu^*$. Once again, the best way to overcome any potential inconsistency or uncertainty would be to complete the experimental dosimetry validation. A subjective assessment of imaging scans, with and without the CSU, by clinicians should also compliment this bench-top testing.
9 Overall Discussion on the Design of the CSU

Now that the various sub-systems of the CSU have been considered in isolation, it is worthwhile to consider the final CSU prototype in its entirety. This section will begin by discussing the strengths and limitations of the current tool mode. Next, the device will be placed in the larger framework of commercial and academic alternatives. In particular, the relevancy to other published literature will be presented. Finally, the potential clinical implications will be touched upon in order to better understand how the applications of the tool may develop. In all, this review will provide a holistic assessment of the functionality and outcomes of this device and thesis project.

9.1 Strengths and Limitations of the Current Design

Next, a short review of the successes and outstanding challenges related to the current tool design will be presented. First, a full-prototype was built which is securely and stably fastened to the Dräger bed-frame. Further, the weight of the device is low enough to allow for good portability and the deflections are below previously established design requirements. The wire system was developed to allow for compensation and measurement in the traction sutures. I showed to be successful at transmitting tension across the device in a non-backdrivable fashion. Quick-release clips and adjustable DoFs were included to as to ensure usability with the hospital staff. Also, initial results indicate that the CSU is successfully compatible with both the Dräger radiant heat-bed warmer, and the X-ray imaging unit. Outside of the device, this research also presented the first formal investigation on patients who undergo CS and the challenges they face. Overall, it is a strength of the project that it successfully setup and addressed a multivariate design problem.

However, there are several notable limitations which should be addressed before any attempt at clinical roll-out. The primary issue of concern is the low efficiency in tensile transmission. In order to resolve these tensile losses, frictionless bearing pulleys should be installed at the identified corners of tension loss. This would prevent the device from catching at these turns and dropping off in loading. Secondly, a formal experimental validation of the tool with X-ray scans is lacking. Dosimetry testing and subjective clinician reviews would address this issue. Next, the device is still deflecting more than what is aesthetically ideal. Although it is below the 5°threshold, this angling could contribute to parental anxieties. Therefore, a replacement or tightening of the joints hypothesized to be causing this twisting would be in the benefit of the tool. The final validation of the tool also requires usability testing with the relevant staff prior to roll-out. This would include the nurses, surgeons, intensivists, and perhaps also the respiratory therapists. Finally, something that was discussed, but outside of the scope of this work, is the development of standardized protocols for CS suspension. This could include the suture placement, the locations of the sutures, and the tensile magnitudes in the traction lines. These clinical guideline could help to improve CS outcomes and to disseminate the technique to other major paediatric centers.
9.2 A Brief Commentary on the Time-line and Functions of Analytical, Numerical and Experimental Methods

In this report, evaluation methods took the form of analytical modelling, numerical methods such as FEA, and bench-top validations through experimentation. While sometimes presented in the same section, it is important to clarify that each of these methods served unique functions at different points in the design process. Analytical methods served as a first-pass approach to evaluate design choices prior to the investment of significant amounts of money or time. Mathematical models were used to assess the anticipated deflection of the device, and the lower-bounds of heat transfer and X-ray translucency. Although each of these efforts presented limitations in the models, they all served as a powerful tool for pre-validating design choices. These fast methods are beneficial in helping to avoid pitfalls that could otherwise have been predictable and avoidable. These approaches were used very early in the design process since they were intended to anticipate issues. However, analytical methods also serve a secondary function in allowing the design engineer to better understand the underlying physical phenomena that may be interacting with their device. Hence, moving forward into later stages of the design process, the engineer can better anticipate and respond to challenges that they may be encountering.

Numerical methods then serve as a second-pass approach for evaluating a design when the limitations of the analytical methods seem too great, but a software package could readily be applied. This only occurred once in this project while examining deflections in the truss. The unusual cross-section and internal loading of the t-slotted framing seemed to be creating issues with the analytical modelling. Hence, during construction but before the completion of construction, FEA was used as a method to re-evaluate these deflections. Further, the discrepancies between the analytical and numerical results also provide indications as to what may be causing issues with the actual device. Finally, experimental methods are the last-stage and gold-standard for evaluating the device. When significant issues are observed in any of the evaluation stages, (whether it be analytical, numerical or experimental) this is an opportunity for the engineer to engage in iterative design, address the concerns and prevent future issues.
9.3 A Re-examination of the Design Requirements and the Current Design Specifications

Next, the device and the results of the evaluations should be compared back to the design requirements that were previously established in section 4.2.3. Effectively, this comparison will require taking the results from the separate trials and then composing a list of design specifications according to the same functional requirements listed in table 3. As a reminder, this initial set of design requirements were established based off feedback collected during a set of health-care professional survey interviews. However, it has become apparent, throughout the design process, that many of the design requirements previously listed in table 3 could be loosened without impacting the effectiveness of the tool. In fact, it would seem responsible to loosen requirements that are needlessly stringent, as meeting these standards could be compromising other functionalities in the tool. Therefore, the goal of this section is both to reassess the design requirements and to list the design specifications of the current device that was tested throughout the thesis. Both sets of information are presented below in table 7 with the original design requirements for comparison.

Table 7: Old and New Design Requirements compared to Design Specifications

<table>
<thead>
<tr>
<th>Function</th>
<th>Old Requirement</th>
<th>New Requirement</th>
<th>Design Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Suture Placement</td>
<td>4 Sutures at 15°</td>
<td>4 Sutures at 15°</td>
<td>4 Sutures at ~15°</td>
</tr>
<tr>
<td>Head Motion (In-Plane)</td>
<td>90°</td>
<td>Removable</td>
<td>Double Removable</td>
</tr>
<tr>
<td>Head Motion (Vertical)</td>
<td>60cm to 40cm</td>
<td>60cm to 40cm</td>
<td>60cm to 40cm</td>
</tr>
<tr>
<td>Quick-Release</td>
<td>&lt;5 seconds</td>
<td>&lt;5 seconds</td>
<td>Very fast (Untested)</td>
</tr>
<tr>
<td>Radio-translucence</td>
<td>&gt;99%</td>
<td>Functional Imaging</td>
<td>Analytically 97%</td>
</tr>
<tr>
<td>Heat and Light</td>
<td>&gt;90%</td>
<td>Functional</td>
<td>Satisfactory (Qualitative)</td>
</tr>
<tr>
<td>Bending Stiffness</td>
<td>&lt;5°, Safety Factor &gt;8</td>
<td>&lt;5°, Safety Factor &gt;8</td>
<td>5° at 35N</td>
</tr>
<tr>
<td>Tension per Wire</td>
<td>4kg or 40N</td>
<td>3kg or 30N</td>
<td>5kg or 50N (with loss)</td>
</tr>
<tr>
<td>Cleaning</td>
<td>Autoclavable (i.e. non-robotic)</td>
<td>Cleanable</td>
<td>Autoclavable (non-usable)</td>
</tr>
</tbody>
</table>

Now, the proposed changes to the design requirements as well as the performance of the current prototype will be discussed on a point-by-point basis. The number of sutures and their approximate angle remain a reasonable standard and the current tool does achieve four independently controlled sutures at approximate angles of 15° from the vertical. Of course, this angle of approach will be affected by how centrally placed the fixation point is on the patients chest. The head rotation of 90° could be loosened to consider any motion which removes the cantilever from the space above the patient. The current tool actually accomplishes this requirement in a redundant fashion with both a 90° head rotation and horizontal linear bearing. The vertical motion, for both X-ray and nurse accessibility, is still a strict geometric requirement and it is accomplished by the range of the vertical linear slider. In following, the 5 second standard for release remains arbitrary but reasonable. It is speculated that the U-clips selected should easily accomplish this standard but this was never formally tested.
Continuing on, the radiolucency standard of 99% is also arbitrary, and just a qualitatively functional image is a more reasonable standard. The analytical result of 97% offers an optimistic indication that this will be achieved but future experimentation is required. Similarly, the 90% standard for heat and light was arbitrary and a qualitatively functional standard of transmittance would be more reasonable. The experimental results and observation indicate that the device satisfies both of these requirements. The bending stiffness of 5° remains a reasonable standard for aesthetic, but the device only satisfies this requirement at a loading of 35N as opposed to the previous standard of 40N. Reasonably, this loading standard was an estimation and 3.5kg, or even 3kg, would be fine loading maximums. In this case the device is satisfactory in bending, but there are outstanding limitations with its ability to transmit tension. However, the current device is setup to measure loadings up to 50N which is sufficient for any of the above requirements. Finally, the autoclavable standard that was previously suggested should probably also be loosened considering that many of the other tools in the CCCU environment (including the bed itself) are not sterilized. Therefore, just having a tool that is cleanable (through disinfectant wipes) should be sufficient. The current tool is technically autoclavable without damaging the tool, but it would be difficult to implement this without a laborious process of reassembling the tool. Reducing this standard to be cleanable could avoid these issues while also reopening the possibility of using motorized and electronic components. Robotic approaches could help to resolve other outstanding issues with the tool related to separate functionalities.

9.4 Relevance to the Field and Comparison to Commercial Alternatives

The current tool is the first to specifically address the issues surrounding the CS technique. Further, in terms of this field of study, it was the first to define a full-set of design requirements for such a too, and the first to capture data on the CS patient population. This includes the typical treatment time-lines, conditions and treatments. However, the CSU does relate to several of the other previously existing commercial alternatives. While performing a similar function to the original sternal traction (with fixation to the heat-lamp), the CSU version is the first to quantify tension in the traction lines. Further, the CSU is setup to be applied to newborns as opposed to adults. As such, it is also the first variation of the technique to be made specifically compatible with the heat bed and X-ray units. Compared to sternal struts or the cardiac corset, the CSU applies a different type of loading structure. By applying the tension anterior to the chest, the CSU will expand the chest morphology differently than the other commercial alternatives. However, the approach of the CSU will not interfere, and is thus compatible, with the sternal struts and cardiac corset. Applying these methods simultaneously could help to distribute the loading on the thorax and thereby reduce the trauma experienced by the vulnerable patient.
9.5 Relation to Published Literature

First-off, this research presents the first single-center retrospective chart review on the CS patients. This makes this data the first to indicate, in a formal way, the common complications, treatment and care received by this patient group. It also indicates that patients undergoing CS are more fragile than those just undergoing DSC or CS, which suggests that surgeons are making accurate calls at identifying critically ill patients. These chart-review outcomes are similar in structure to those presented by Pye on DSC patients. Further, this project contributes a case-study to the literature on multivariate analysis between the mechanical, thermal and radiolucency material properties. The approach used here for determining the cantilever-beam material, for instance, could be applied to other related problems. The work also developed and analyzed several mechanisms which could have applications in other areas. The compensator mechanism is original and conceptual approach could be applied to other measurement systems requiring length compensation in a mechanistic way. The offset helical gear system described here could similarly find other applications where the input must be bidirectional, non-backdrivable and continuous. Also, the design requirements established here reflect the first survey interview, albeit a small group, conducted with CS staff. The work described in this manuscript was presented at two seminars. One was at the HSC and the other at the Institute of Biomaterials and BioMedical Engineering (IBBME). A poster presentation was also prepared and presented at the IBBME Annual Research Conference. Finally, a journal article is currently being prepared for the ASME Journal of Medical Devices.

9.6 Clinical Implications

Lastly, it seems valuable to address the potential clinical role that the CSU could play. Through the assessment of the design requirements and the conceptual design, this project has established a methodology which could overcome several of the key limitations that exist within the current CS technique. The building of a structure to replace the heat lamp as a fixation point could help to offer safety and reliability. Further, the replacement of a crude methodology with a more professional aesthetic could help to mitigate parental anxieties. The design of the compensator and measurement system will also allow this technique to be more standardized. This standardization could allow surgeons to improve the technique in a more quantified approach. The compensation will allow for the X-ray and nurse accessibility to exist simultaneously. These methods will allow the patient’s health and thoracic swelling to be monitored with the improved quality of care. Finally, the uniquely designed cantilever will maintain heating on the patient and this will prevent temperature related health concerns. The adjustable setup will allow the treatment to be customized to the care of the patient and the preferences of the surgeon. The quick-release clips will also allow health-care staff to respond quickly if the child is in distress or cardiac arrest. Overall, this project has conceptualized, proposed, built and tested a prototype medical device which could help to improve the care of tight syndrome newborns in a variety of different ways.
10 Conclusion

This manuscript has presented the design process of a mechanical tensioner unit for supporting the chest-wall of postoperative newborns after open-heart surgery. This review began by describing the current standard of care in these patients and the known limitations. A specific problem and hypothesis for the design were then stated, and the objectives defined. Next, the CS technique and the affected patients were studied through a single-center, retrospective chart-review and an interview-based survey of health-care workers familiar with CS. These results were then discussed and used to inform a set of concrete design requirements for the CSU. Next, a conceptual design process was undertaken by considering both commercially available alternatives and the permissible geometric approaches around the Dräger bed. Once an overall design structure was selected, the unit was then broken into a set of subsystems. First, the framing of the CSU was developed along with its fixation to the Dräger bed for support. The deflections in the structure were then measured. Next, the wire guide system for tensioning the traction lines was designed. This included creating a pulley-based compensator, finding a non-backdrivable input and a selecting a measurement system. The tensile transmission across the device was then tested experimentally. Finally, the cantilevered head was designed which included mechanical beam modelling, material selection, and quick-release clip conceptualization. This beam was then evaluated against both heat transfer and radiolucency requirements. Overall, a CSU prototype was developed, built and tested in order to overcome limitations in the current CS technique. While there are still outstanding functionality challenges, this prototype is a strong first towards resolving limitations in current CS.

10.1 Recap of the Problem

Children born with congenital heart defects often require immediate, or near immediate, reconstructive heart surgery in order to save their lives. Consequently, a median sternotomy is needed to access the thoracic cavity to perform the repair. The sternum is then typically closed at the end of the procedure but complications can arise at this stage. During this procedure, fluid, swelling, surgical edema and the nature of the operation may expand the size of the thoracic organs. Attempted closure will then compress the heart and lungs and restrict their healthy motion. This can impede proper functioning and create hemodynamic instability, respiratory instability, tamponade, low CO or even heart failure. Therefore, the chest wall is left open for a few days up to a few weeks post operatively in a DSC until the edema can dissipate. Sometimes, the unsupported chest wall may roll back into the chest or the cartilaginous side-walls may flatten. Both of these actions can re-compress the heart and create similar complications to those noted during failed closure attempts. Overall, these issues are collectively termed tight syndrome and the HSC developed the CS technique to mitigate these complications in the most critically-ill patients. CS is a critical-care approach whereby anterior traction is applied to the patient’s chest via a series of sutures. Despite positive initial qualitative results, the current method has several limitations.
Firstly, CS is a crudely designed approach. The traction wire are fastened intercostally on the patient to the overhead grate of the heat lamp. This aesthetic may further exacerbate parental anxieties during a sensitive time. Also, by connecting to the heat lamp grate, this method introduces risks to the patient by relying structurally on a component not designed to be load bearing. Further, the nature of connecting wires to the heat-lamp completely prevents the possibility of taking X-ray images of the patient without de-suspending and re-suspending them. This process can be traumatic to an already fragile patient, but the X-rays may be necessary to track the patient’s clinical status. The current methodology is also completely unstandardized and qualitative. The approach lacks quantified tension or a consistent methodology for implementation. The problem at hand is to develop a mechanism based device that can overcome these aforementioned limitations in the CS technique.

10.2 Main Findings

The nature of the design process means that results were established at several key stages of the device development. First-off, the survey results indicated that the perceived limitations of the current CS technique, and the desired functionalities int he CSU, were consistent with the initial hypothesis. Further, these interviews were used to establish design requirements covering the suture placement, the tensile magnitude, the accessibility needs, the quick-release function, the sterilizability, the radioluency, the stiffness, and the heating and light conductivity. Next, the results from the chart-review gave evidence that CS patients have longer stays with more treatments than DSC and IC patients. The results also indicated that the CS patients are more fragile to complication and thus a more ill group overall. In following, the conceptual design phase generated several potential options for the CSU structure and a Pugh matrix was used to decide that a foot-based cantilever would be the best approach.

The device itself was tested across four different requirements. First, the deflection in the tool under loading was shown to be under the established design requirement. However, discrepancies between the analytical, numerical and experimental results suggested that the bearing may be rolling more than anticipated. Secondly, tensile transmission across the device was shown to be quite poor. In order to overcome this limitation, it was determined that bearing pulleys need to be installed at identified points along the wire guide system. Thirdly, the heat transfer across the CSU was assessed. Both analytical and experimental results showed that the effect of the presence of the CSU would not significantly impact the ability of the radiant warmer to heat the child. Finally, the radioluency of the tool was determined using a Beer-Lambert model with a predictable range of electromagnetic wavelengths. The result indicated that the tool should not impede X-ray imaging but that further experimental validation is also required.
10.3 Comparison with Literature

The nature of this design project means that many of the results of a newly developed tool will not compare directly to literature. However, certain points are worthwhile to consider as extensions of previously published work. The design requirements and CS limitations established in the survey are very consistent with the issues indicated in DSC papers. This includes the difficulties with the thorax flattening, the importance of nurse accessibility and value of imaging. Furthermore, the length of stay, types of conditions and treatments of tight syndrome patients were consistent between literature and the chart review presented here. In terms of mechanical considerations, the component selection and modelling were largely consistent between the results here and prior publications. The non-backdrivable input was able to hold tension as noted in patents. Further, the heat transfer model was largely consistent with the experimental results when it was understood that it discounts convection. Further, the modelling of the X-ray transmission was consistent with the design expectation that thermoplastics will be radiolucent. Overall, both clinically and technically, the published information surrounding CS were consistent with the outcomes in this project.

10.4 Perceived Contributions to the Field

This section is an enumerated list of this project’s aspects which may be valuable in the fields of chest suspension or surgical tool design. This listing is presented in following:

1. The first collection and analysis of clinical data relating to CS patients, from a retrospective chart-review, regarding their conditions, treatments and outcomes.
2. A compiled list of established design requirements for any technique attempting to replace or improve upon CS.
3. A spatial deliberation on designing devices within the constraints of a neonatal radiant heater.
4. The design of a framing unit for support, rigidity and stability around neonatal intensive care.
5. The design of a pulley-based compensator for balancing both tensile loadings and wire length changes across a circuit of cabling.
6. The mechanical analysis of an offset planetary gear system for application as a bidirectional, continuous and non-backdrivable tensioner input.
7. A multivariate design analysis for material selection in a cantilever beam within the CCCU.
8. The conceptualization and choice of quick-release clips for chest traction lines.
10. The design, construction and evaluation of a prototype medical device for supporting CS in newborn patients.
10.5 Outstanding Challenges and Future Research Directions

Although the cardiac suspension project has included and produced several successes, there remain limitations which should be addressed in the next steps. Primary of these is resolving the issues with tensile transmission. One of the primary goals of the CSU is to provide quantified tension in the traction lines. Therefore, it is essential to have an accurate recording in the spring but this is impossible with the current friction losses. Therefore, frictionless bearing pulleys must be installed at the key points along the wire guide system. This will allow the wire to slide over these points without catching. Once the setup is altered, the tensile transmission should be retested so as to validate the device. At this point, tensile transmission during vertical motion of the head should also be tested to evaluate the functionality of the compensator. The ability of the tension to hold over time to ensure the device’s effectiveness as a non-backdrivable system. Also, the device requires an experimental validation of its radiolucency. These tests should include a quantified dosimetry tested and a subjective evaluation by clinicians. These steps are important to ensure that the device is compatible with X-ray imaging. Finally, the tool should undergo usability testing with the critical-care nurses and surgeons. These tests should include:

I A testing of the setup process of the CSU involving both the surgeons and the nurses. This experiment should both time the setup and assess if staff have any issues with the procedure.

II A scenario of adjusting the tension with the nursing staff. This should address both the subjective ease-of-use of the system and the accuracy with which the nurses can correct the tension.

III A mock trial of taking X-rays through the CSU. The device would need to be lowered and re-raised without disturbing the traction tension. The difficulty and feasibility of this undertaking would be assessed with nursing and X-ray imaging staff.

IV A simulation of an emergency patient event where the tool needs to be rapidly removed. This experiment would involve timing the nurses and identifying any inconvenient or difficult parts of this task.

Once the device is both functional and usable, failure trialing should also be conducted so that an overall FoS can be determined for the tool. This testing will also allow the tool to be used with a high degree of confidence that it does not place the patient in any risk. All of these steps will need to be addressed before the tool is applied clinically. Completing the work noted here will allow the CSU to turn from research project into a clinically meaningful tool.
References


Appendix A - Extended Results from the Retrospective Chart Review

Table 8: Survival per Group

<table>
<thead>
<tr>
<th>Group of Interest</th>
<th>All Patients</th>
<th>Immediate Closure</th>
<th>Delayed Sternal Closure</th>
<th>Cardiac Suspension</th>
</tr>
</thead>
<tbody>
<tr>
<td>Survival</td>
<td>91.4%</td>
<td>97.9%</td>
<td>90.4%</td>
<td>75%</td>
</tr>
</tbody>
</table>

Figure 38: Histogram of Total Number of Operations over Different Groups (Bin Size: 1 operation)

Figure 39: Histogram of Total Length of CCCU Stay over Different Groups (Bin Size: 7 days or 1 week)
Figure 40: Histogram of Total Cardiac Arrest Time over Different Groups (Bin Size: 5 minutes)

Figure 41: Histogram of Days of Open-Chest Time over Different Groups (Bin Size: 3 days)

Figure 42: Barchart of the Highest Received RACHS Score of Patients in Different Groups
Figure 43: Barchart of the Probability of Diagnosis for Different Groups

Figure 44: Barchart of the Probability of Procedure for Different Groups
Appendix B - Full Results from the Healthcare Practitioner Survey Interviews

Professionals Interviewed

- Glen Van Arsdell (GVA) - Cardiovascular Surgeon, Head of Cardiovascular Surgery (SickKids)
- Chris Caldarone (CC) - Cardiovascular Surgeon, Surgeon-in-Chief (SickKids)
- Claire Watt (CW) - Intensive-Care Nurse Practitioner, Cardiac Corset Inventor
- Brenda Drouillard (BD) - ICU Registered Nurse, Cardiac Corset Inventor

Experience

How many years have you been involved in cardiac suspension?

GVA - About 20 years. Since the late 90s.
CC - 13 years
CW - 14 years
BD - 5 to 7 years

Do you support the technique? Apprehensions?

GVA – Yes, but its a barbaric approach.
CC - Generally support in extreme cases. No functional apprehension.
CW - Concerns with aesthetic, the dräger bed, and the consistency (the lack of measurement).
   Side-note: A Tegaderm dressing is currently used to cover the DSC.
BD - Aesthetic concerns, only comfortable as a last resort after DSC

Notes on Indicators

- Cardiac suspension indicators are a gray area.
- Ultimately the surgeon’s decision based on a judgment call.
- Suspension is removed intermittently if a cardiac arrest event occurs.
- There is potential application in all congenital corrective surgeries, but it is most common in neonates.
Table 9: Indicators noted in electing for a Delayed Sternal Closure or Cardiac Suspension

<table>
<thead>
<tr>
<th>Indicator</th>
<th>GVA</th>
<th>CC</th>
<th>CW</th>
<th>BD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Norwood Stage I</td>
<td>Generally</td>
<td>Generally</td>
<td>Surgeon’s discretion</td>
<td>Yes</td>
</tr>
<tr>
<td>ECMO Placement</td>
<td>Usually</td>
<td>No</td>
<td>Surgeon’s discretion</td>
<td>No</td>
</tr>
<tr>
<td>Hemodynamic Instabilities</td>
<td>Most Important</td>
<td>Yes</td>
<td>Key Indicator</td>
<td>Almost always</td>
</tr>
<tr>
<td>Respiratory Instabilities</td>
<td>Common for CS</td>
<td>DSC</td>
<td>-</td>
<td>Yes</td>
</tr>
<tr>
<td>Persistent Bleeding</td>
<td>No</td>
<td>DSC only</td>
<td>-</td>
<td>No</td>
</tr>
<tr>
<td>Cardiac Edema</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Tamponade</td>
<td>Yes. Blood or tissue tamponade.</td>
<td>Upon opening or reopening</td>
<td>-</td>
<td>No</td>
</tr>
<tr>
<td>Cardiac Failure</td>
<td>Yes</td>
<td>DSC</td>
<td>Yes</td>
<td>Less common</td>
</tr>
<tr>
<td>Atrial-Septal Shunt</td>
<td>Typical procedure</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>VSD</td>
<td>Common</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>ASD</td>
<td>Yes</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Desaturation</td>
<td>Yes</td>
<td>-</td>
<td>Post-complication</td>
<td>-</td>
</tr>
<tr>
<td>Long Bypass Time</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Swelling in the Chest</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes, must dehydrate</td>
</tr>
<tr>
<td>Low CO</td>
<td>-</td>
<td>-</td>
<td>Common</td>
<td>-</td>
</tr>
<tr>
<td>Chest tube compression</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>Original reason was to avoid compressing the tube</td>
</tr>
</tbody>
</table>
How many patients are suspended each year?

GVA - About 100 are DSC, about 33 are CS.
CC - Somewhere in the 10s are suspended, about a third of all DSC.
CW - Unsure, recommends 'Treatments and Care' records, around 30 sounds reasonable.
BD - About 20 patients.

Most common surgery requiring cardiac suspension?

GVA - Generally any neonatal congenital corrections.
CC - Complex cases.
CW - Don't know. Surgeons decision. Very case-by-case basis.
BD - Don't know.

When is the decision for these techniques typically made?

GVA - Typically upon attempted closure, but the can be decided prophylactically in the OR.
CC - DSC is upon opening or reopening. CS is after the OR.
CW - Upon closure or once closed and you're getting bad vital numbers.
BD - Typically the DSC is in the OR. The CS will often be made in the ICU.

Design Requirements

How many wires are needed?

GVA - Commonly one in the lower-left corner. Two or four in fragile cases (can last weeks).
CC - Always two.
CW - Two or four.
BD - Typically two.

What is the range of orientation that is required?

GVA - Only partial angling. At most 20°.
CC - Mostly Straight.
CW - Overhead center-middle is a good. Mostly straight up. The previous model is sufficient.
BD - No very much angle, almost always straight up.
<table>
<thead>
<tr>
<th>Function</th>
<th>GVA</th>
<th>CC</th>
<th>CW</th>
<th>BD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Access to the Patient’s Sides</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes. Both Sides</td>
</tr>
<tr>
<td>Height Adjustable (45cm to 60cm) [9]</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes. Note adjustable bed.</td>
</tr>
<tr>
<td>X-Ray Imaging Compatible</td>
<td>Yes, radiolucent.</td>
<td>Yes</td>
<td>Radiolucent</td>
<td>Radiolucent</td>
</tr>
<tr>
<td>Sterilizable/Cleanable</td>
<td>Sterilizable</td>
<td>Easily cleanable</td>
<td>Sterilizable nice feature</td>
<td>Cleanable</td>
</tr>
<tr>
<td>Easily transportable</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes, for between beds</td>
</tr>
<tr>
<td>Quick-Release (&lt;5s)</td>
<td>Yes, ideally &lt;3s</td>
<td>Yes</td>
<td>5s should be sufficient</td>
<td>Should be sufficient</td>
</tr>
<tr>
<td>Heat and light transmittance (90%)</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes. Particulariy heat</td>
</tr>
<tr>
<td>Hard tray under mattress</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Data Monitoring</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>–</td>
</tr>
</tbody>
</table>
## New Functions

Table 11: Initial Opinions on New Potential Functionalities of the CSU

<table>
<thead>
<tr>
<th>Function</th>
<th>GVA</th>
<th>CC</th>
<th>CW</th>
<th>BD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensor for Wire Tension</td>
<td>Yes. Very beneficial</td>
<td>Yes. Main Goal</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Automated Tension</td>
<td>Yes, ideally.</td>
<td>No</td>
<td>–</td>
<td>No, maybe for the surgeons</td>
</tr>
<tr>
<td>Orientation Recorder</td>
<td>Marginal</td>
<td>Yes</td>
<td>–</td>
<td>Yes</td>
</tr>
<tr>
<td>Automated Orientation</td>
<td>Gold standard but not necessary</td>
<td>No</td>
<td>–</td>
<td>No</td>
</tr>
<tr>
<td>Closure Likelihood Prediction</td>
<td>Cool and academic</td>
<td>Later on</td>
<td>As a research aside</td>
<td>Maybe for surgeons</td>
</tr>
<tr>
<td>Standardized Suture Placement</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>Yes</td>
</tr>
<tr>
<td>Compatibility with the Corset</td>
<td>–</td>
<td>–</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>
Appendix C - Common Suspension Cases

This section explains the common methodologies for implementing cardiac suspension. The figure illustrates the three main cases and then further details are offered for each case in-following. The large ovals represent the patient, and black ovals represent the sternal wound.

![Figure 45: Cardiac suspension implementation cases.](image)

**Case 1**
- One Suture, typically in the bottom left quadrant.
- Used for specifically reducing pressure or a tube occlusion.
- The original and most common implementation.
- Used on relatively stable patients. Closure typically occurs after two to three days.

**Case 2**
- Two sutures for lateral separation while undergoing DSC.
- Used in intermediate cases.
- Often these cases last about a week but there can be significant variation.
- Some practitioners use this method almost exclusively.

**Case 3**
- Four sutures are applied, one in each quadrant, to distribute loading on the chest.
- Used in the most fragile cases where the patient has significant swelling.
- Can last for two to three weeks before a closure attempt.
Appendix D - Technical Drawings of the CSU

Figure 46: Technical Drawing of the Cantilevered Head Structure (Clamping dimensions are shown in gold)
Figure 47: Adjustable Finger Structure from the Wire Guide System
Figure 48: The Top Attachment of the Dynamic Spine with the Entry Turns
Figure 49: The Bottom Attachment of the Dynamic Spine with the Compensator Turns
Figure 50: The Top Attachment of the Static Spine with the Spring Holder
Figure 51: The Bottom Attachment of the Static Spine containing the Peg Box
Figure 52: The Fixation Pins to the Dräger Babytherm Bed
Appendix E - Publications from MHSc work


II L. J. MacLean, J. Andrysek, and V. Forte, "Design of a Mechanical Tensioner Unit for Chest Suspension in Postoperative Cardiac Neonates". IBBME Annual Research Conference. Toronto, On, Canada. 29 May 2018. (Poster)

III L. J. MacLean, J. Andrysek, and V. Forte, "Cardiac Suspension for Mitigating Tight Syndrome in Postoperative Newborns: Design of a Mechanical Tensioner Device". Institute of Biomaterials and Biomedical Engineering Seminar Series. Toronto, On, Canada. 15 Nov 2017. (Oral)


VI L. J. MacLean, V. Forte, G. van Arsdell, "The Cardiac Suspension Project: A Retrospective, Single Centre Chart Review". Cardiac Science Review Seminar. The Hospital for Sick Children, Toronto, On, Canada. 5 Apr 2017. (Oral)
