Evaluation of Sternum Closure Techniques Using Finite Element Analysis

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Utvärdering av stängningstekniker för sternum med hjälp av finita elementmetoden

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Abstract

In an open thoracic surgery the surgeon dissociate the sternum, the breastbone, into two halves to be able to perform the operation. At the end of the surgery a standard technique is used which to close the sternum. The technique is based on steel wires that are wrapped around the halves of the sternum to close it. This technique is the most cost effective technique available on the market today but is still not optimal because it can cause infection, wound rupture and pain for the patient.

The goal with this master thesis was to, with the help of finite element method, to find out which closure technique is the best one to close the sternum and to provide suggestions for improvement. This was done with respect to the aspects of how large the displacement between the sternum halves is and how much the stresses generated by the implants affect the sternum.

Using literature studies and interviews three techniques were chosen to be simulated; the standard technique, Zipfix and Sternal Talon. Their implants consisted of stainless steel, PEEK and titanium respectively and the materials were simulated with every technique. In the lower part of the sternum it is a greater displacement between the two halves after simulation than in the rest of the sternum. An improvement was hence to simulate Zipfix and Sternal Talon with an extra steel wire in the lower part.

Zipfix with the implants of titanium and the standard technique with the implants of stainless steel provided the best results with respect to the two aspects. The two improvements produced smaller displacement but the stresses were higher.
Sammanfattning

Vid öppen thoraxkirurgi öppnar kirurgen sternum, bröstbenet, i två halvor för att kunna utföra operationen. När operationen är genomförd används en standardteknik som bygger på att använda stålstrådar för att försluta de två sternumhalvorna. Denna teknik är den mest kostnadseffektiva som finns på marknaden idag, men är trots detta inte optimal då den kan ge upphov till infektioner, sårrupturer och smärta för patienten.

Målet med detta examensarbete var att, med hjälp av finita elementmetoder, ta reda på vilken förslutningsmetod som är bäst samt att ge förbättringsförslag. Detta skedde utifrån aspekterna hur stor förskjutning som uppstår mellan sternumhalvorna samt hur stor spänning implantaten påverkar sternum med.

Med hjälp av litteraturstudier och intervjuer valdes tre metoder ut för att simuleras; standardtekniken, Zipfix och Sternal Talon. Dessa implantat bestod av rostfritt stål, PEEK respektive titan och varje teknik simulerades med varje material. I sternums nedre del uppstod efter simulering större förskjutning av sternumhalvorna än i resterande av sternum. Ett förbättringsförslag var därför att simulera Zipfix och Sternal Talon med en extra stålstråd i nedre delen av sternum.

Zipfix med implantat av titan och standardtekniken med implantat av rostfritt stål gav bäst resultat utifrån de två nämnda aspekterna. De två förbättringsförslagen gav mindre förskjutning men spänningen blev dock högre.
Foreword

This work is a 30 credits thesis within the Master of Science in Medical Engineering at the Royal Institute of Technology. The thesis is conducted at STH, the School of Technology and Health, and is about the study and development of the best closure technique to close the sternum after an open heart surgery.

The thesis is aimed for people who are interested in doing the same or similar investigations as in this project and for they who also want to continue to develop this study even further. Surgeons and buyers at the hospital are also target groups. With respect to them and other people, who may be unfamiliar with Finite Element Methods and with knowledge in simulations, the thesis is tried to be easy to follow and understandable.

Acknowledgement

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1. Introduction

During a cardiothoracic surgery the surgeon has to saw through the sternum, also called breast bone, and dissociate the sternum into two halves with a retractor to get an overview of the heart and lungs. When the sternum shall be put back in place the surgeon fixates the two halves to each other to enable healing (Plass et al. 2007, p. 1210-1212). To manage this wires of stainless steel are mostly used today and have been used for over fifty years (Grapow et al, 2012, p. 1-5). This closure technique is called the standard technique through this thesis.

Since then a lot has happened with the patient’s health and lifestyle. The patient has gone from relatively healthy to one with serious heart problems. Because of the change of the patient’s health condition, it is important that the current products on the market also develop in parallel with this. Patients with heart problems are often old, overweight, have diabetes, malnutrition etc. These factors affect the bone architecture, the composition of cortical and cancellous bone, and the bone healing process (Grapow et al, 2012, p. 1-5).

The closure technique with steel wire is the standard technique and is an effective, easy, inexpensive and safe closure technique for patients with strong bones but when the bone is weaker problems could arise. Problems like wound infections, dehiscence and no healing of bone are common (Grapow et al, 2012, p. 1-5). The steel wires can even rupture, as shown in Figure 1 (Matthias Corbascio, 2012, interview April 23rd). To meet the needs of the closure of the sternum several new closure techniques have been developed. However, among today’s surgeons there is no consensus on which closure technique is the most suitable one to use (Dasika, Trumble and Magovern 2003, p. 1618-1621). There are many requirements to be fulfilled for a sternal closure technique to be considered as well. Hospitals ask for it to be the most cost effective closure technique as possible. The surgeon wants it to be simple, fast and safe. It is also very important to have a fast reentry to the thoracic cavity if it starts bleeding or if other complications occur after the operation (Hawit 2012, p. 1-9). The patient wants a fast and painless closure technique that heals fast to make it possible to go back to normal life as soon as possible.

The idea to the project arose when the authors attended as spectators during a heart surgery at Karolinska University Hospital (KS) in Sweden. The surgeon Matthias Corbascio informed the authors what was happening during the surgery. During the surgery it was mentioned that a major problem in thoracic surgery is that there is no optimal way to close the sternum.
2. Goal of the Project

The goal of the project was, with help of finite element method, to find out which closure technique of the ones investigated is the most suitable for closing sternum after a thoracic surgery. The goal was also to try to give suggestions for improvements of the simulated closure techniques.
3. Limitations

Three closure techniques, of those available on the market today, were chosen to be simulated. This restriction was necessary due to lack of time and was made after a thorough investigation of many techniques on the market to choose the most used techniques in thoracic surgeries today and the ones that had the most potential for further development and become reasonable alternatives for closing the sternum.

In all the simulations in this project the aspects of how the implants and their material behavior are affected are not considered. What is considered is how sternum is affected during inhalation by implants that are holding the two sternum halves together. Therefore a simplification of the material model is made and only the elastic part of the material is used.
4. Background

Ever since the Greeks, 400 BC, there is evidence on the performance of cardiac surgery. During the 100th century details of a human heart was described by Galen of Pergamon with a full explanation by Andreas Versalius in 1534. William Harvey discovered the blood circulation and arteries and veins in the 17th century. The first successful heart surgery on a living human being was performed in 1896 (Baldwin, Elefteriades and Kopf, p. 313-314). In 1897 Milton was the first person to fixate the sternum with wires to close a median sternotomy (Centofanti et al. 2002, p. 943-945; Plass et al. 2007, p. 1210-1212). It has been widely used since 1957 when Julian et al made it popularized and today it is the most common closure technique for sternal closure (Hawit 2012, p. 1-9).

4.1 Anatomy of the Chest

In a human’s chest there is a flat bone, called sternum, which is located in the middle anterior to the chest. The chest, together with the sternum, provides protection and support to the internal organs (Tortora, G.J and Grabowski. S.R, 2003, p. 211). The sternum is containing both calcium and collagen connective tissue. These two will prevent the body from bone fractures, calcium provides strength to the bone while collagen provides elasticity. The bone is composed of an outer and an inner structure. The outer part consists of a strong and dense bone tissue called cortical bone. The inner part consists of cancellous bone (Osteoporosdoktor, 2012). In the chest there are twelve pairs of ribs, seven of these pairs are attached to the sternum (Tortora, G.J and Grabowski. S.R, 2003, p. 211). The shape of the sternum looks like the capital letter T and the average length of the sternum is 15 cm long. Sternum is divided into three parts; Manubrium, the Body and Xiphoid Process, see Figure 2 (Tortora, G.J and Grabowski. S.R, 2003, p. 211).

1. The Manubrium is the upper part of the sternum and has a triangular shape (Martini and Nath 2009, p. 241-242). As seen in Figure 2, Manubrium is widest at the top and then it becomes narrower at the point where the Manubrium meets the next part of the sternum; called the Body (Tortora, G.J and Grabowski. S.R, 2003, p. 211).

2. The Body is the middle segment of the sternum and also the longest part of it. As seen in Figure 2, the broadest part of the body is at the bottom when the body goes into the next part of the sternum, called the Xiphoid Process (Tortora, G.J and Grabowski. S.R, 2003, p. 211).

3. The Xiphoid Process is both the lowest and the smallest part of the sternum, see Figure 2 (Martini and Nath 2009, 241-242). It consists of hyaline cartilage during infancy and in early age it is not entirely fixed to the rest of the body. But through age it becomes fixed (Tortora, G.J and Grabowski. S.R, p. 2003, 211). Some muscles are attached to the Xiphoid Process, namely the diaphragm and the rectus abdominis muscles (Martini and Nath, 2009, p. 241-242). The respiration makes the lower thorax move a greater distance than upper thorax which makes forces at the Xiphoid Process greater than on the rest of the sternum. The smaller dimensions of the Xiphoid Process in comparison to the manubrium may also contribute to the greater distance (Martini and Nath, 2009, p. 241-242). The Xiphoid Process is the most sensitive part in the
sternum. This was proved by a test made by Dasika, Trumble and Magovern (2003, 1618-1621). It was also shown in the test that the Manubrium is the most stable part of the sternum.

![Diagram of chest anatomy](image)

**Fig 2. Schematic picture of the anatomy of the chest (Gray’s Anatomy, 2013).**

### 4.2 Sternotomy in Thoracic Surgery

To be able to perform a thoracic surgery and to obtain sufficient latitude in order to carry out the surgery, the surgeon performs a median sternotomy. It means that a vertical incision is made in the middle of the sternum from Manubrium in the top to the Xiphoid Process at the bottom with an oscillating saw. In this way the sternum is divided into two parts which are separated with a retractor to enable the surgery between these two halves (Popularmechanics, 2012, slide 1-5). This gives the surgeon a good mediastinal exposure (Casha et al. 2001, p. 249-253; Hawit 2012, p. 1-9). After sternotomy there is always a risk of sternal separation or infection. Hence, it is very important to have a closure technique that provides a stable sternal closure (Casha et al. 2001, p. 249-253).

According to Serry et al (referenced in Goodman et al, 1983, p. 225) complications that can occur 1-2 weeks after median sternotomy surgeries include:

- Sternal separation
- Blood or serum coming out of the sternotomy
- Inflammation in the area between the lungs (mediastinum)
- Wound and subcutaneous infection
After the surgery the surgeon closes the two halves of the sternum. The most common way to close the sternum today is with the standard technique using stainless steel wires. Every surgeon has their own way of doing this (if there is no prescription at the hospital). According to Matthias Corbascio (2012, interview, April 23rd) the most common closure technique is to do a combination of single transsternal and single peristernal techniques called alternating trans- and peristernal technique (See Fig. 4C) (Losanoff et al. 2004, p. 203-209). Transsternal means through the sternal body (See Fig. 4A) and peristernal indicates that the wires are placed around the entire sternum (See Fig. 4B) (Hawit 2012, p. 1-9).

The advantages with the standard technique are that it is safe, fast and inexpensive. The disadvantages are that closure techniques with these wires sometimes lead to dehiscence, wound infection and healing problem for the bone (Plass et al. 2007, p. 1210-1212). This is mostly due to the wires cutting into the bone, Figure 3, especially for patients with osteoporosis (Hawit 2012, p. 1-9). Osteoporosis means that the bone mineral density is lower than it should be, which results in higher risk of fracture.

It is of importance for the closure technique to be safe and durable. The technique should minimize the pain and help the patient to come back to normal life as soon as possible. The hospital is also eager to provide safe techniques to make it possible for the patient to leave the hospital shortly after an operation. The cost of a reoperation is 15 000 – 20 000 SEK. Typically, the patient has an average hospital stay of 7 days after a heart surgery, which would give an average cost of 250 000 SEK. If the patient need a reoperation the care time can reach 35 – 40 days and give a higher cost of 700 000 SEK instead (Jonsson H., email interview, 2012).

4.3 Closure techniques

The following are various closure techniques available on the market today which are trying to match the requirements from the patient, the surgeon and the hospital.
Wire Techniques

Standard Technique
The most common way to close the sternum is to use the alternating trans- and peristernal closure technique (Fig. 4C). This technique is used throughout the Western world. It has so far been shown to be the best closure technique because it is simple and easy to open up the sternum again in case of any postoperative bleeding. The technique is also inexpensive, four steel wires cost 1200 SEK (Jonsson H., Mail interview, 2012). However, the technique has two drawbacks. 2-3 percent of all thoracic operated patients using the standard technique must replace the wires due to pain or wire breakdown. The wire can also easily cut into an osteoporotic bone (Richard Ingemansson 2012, interview, May 3th).

Figure of Eight
Figure of Eight is also a closure technique with wires and can both be performed with a peristernal and a pericostal technique (between the ribs), see Figure 4, D and E. Peristernal is preferred, but both closure techniques should be used with caution because large parts of the sternum are opened if a wire breaks (Losanoff et al. 2004, p. 203-209).

Comparison of the Standard Technique and Figure of Eight
In the paper that Losanoff et al wrote in 2004 (p. 203-209) human cadaveric sternum models were used to compare different stainless steel wiring closure techniques and their closure strength and stability. The closure techniques that were biomechanically tested and compared with each other are shown in Figure 4. Robicsek (see Fig. 4F) is a closure technique that is using bilateral pericostal steel wires and around these steelwires five peristernal steel wires are placed. The closure techniques were ranked from 1 (best) to 6 (poorest). A distance between the two sternum halves occurred for all techniques, due to wires cutting through the bone, the distance occurred first in the Xiphoid Process. Peristernal single wires and alternating peristernal and transsternal single wires are the two closure techniques that were superior in closure stiffness and small displacement and resulting in a ranking of 1. The
pericostal figure-of-eight wires had a high failure rate and subsequently got a ranking of 4. In this test, a ranking of 4 was to be considered as the worst performing technique. The peristernal figure-of-eight wires got a ranking of 2 and Robicsek and single transsternal wires both got a ranking of 3. Robicsek is the best closure technique if the patient has osteoporotic bone or has to do a sternal reclosure.

**Staples**

Zurbrügg et al (2000, p. 1957-1958) have improved the standard technique to avoid the wires from cutting through the bone, which in that case would result in tension loss, gap formation and infection. The technique is shown in Figure 5. The staples, which consist of the same material as the wires, prevent the wires from cutting in the bone because of their greater area of contact and thus reduce the risk of deep wound infections. The tests made in the article mentioned showed that 93.1 percent of the staples were placed in the right position. This technique is based on the standard technique with addition of staples to prevent one of the disadvantages with the standard closure technique, namely cutting through the bone. The performance is simple to learn and the technique is basically as cheap as the standard technique.

**Clips**

Centofanti et al presented 2002 (p. 943-945) a new technique for closure of the sternum using clips. The material in the clips is called NITINOL (Nickel Titanium Naval Ordinance Laboratory) and consists of nickel and titanium. The clips are implanted in the sternum. The clips are made in a special form to fit in the sternal closure and should be 7-8 mm smaller than the intercostal spaces (the space between the ribs). The clips are cooled with ice before being placed in the patient to make the clips flexible to ease them into place in the intercostal spaces in the patient’s chest. When the clips are in place they are heated with water to make them hard and stable. The test in the article had 100 patients and no dehiscence, infections or sternal-related bleeding were reported. NITINOL is more stable, less corrosive and more biocompatible than the steel wires in the standard technique and the risk of bleeding is lower. The clips are thicker than the wires which results in a lower risk of cutting through bone. It is fast and easy to implant and to remove. Unfortunately this closure technique is expensive (Richard Ingemansson, 2012, interview, May 3rd).

**Zipfix**

During the interview with Matthias Corbascio, (2012, interview April 23rd), a closure technique that is used at Karolinska University Hospital, Sweden, to close the sternum was
mentioned. This closure technique is called Zipfix which has an implant that is similar to cable ties, Figure 6. This implant is made of PEEK (Poly Ether Ether Ketone) which is biocompatible. The closure technique uses cable ties wrapped around the opened sternum with help of a needle (Synthes, 2012). The number of cable ties varies, but usually five cable ties that are placed around the sternum (Matthias Corbascio, 2012, interview April 23rd). The needle is then removed, the cable ties are tightened and any redundant flaps are cut off. This feature has several advantages; it is easy to handle, it is MR safe when the needle is removed and it also reduces the risk of bone cut-through (Synthes, 2012). The reduced risk for bone cut-through is because the implants have a relatively large contact width, 4.2 mm. With steel wire the first powerful cough could result in that the steel wire cut through the sternum. This risk is reduced with Zipfix since the cable ties are broader than those used in the closure technique with steel wire. The contact area between sternum and cable ties is then greater than the contact area between sternum and steel wire, which results in a lower pressure on the sternum. The implants are wrapped around the sternum in the intercostal area, making the risk of bleeding smaller than the standard technique in which the wire could cut through the sternum transternally (Grapow et al, p. 2012, 1-5). According to Matthias Corbascio, Zipfix is a very good closure technique when it works and it has been used several times at the Karolinska University Hospital but in some cases, the locking part of these cable ties have released too early. This has resulted in reoperations to correct the error (Synthes, 2012). Zipfix provides a lower displacement compared to the standard technique which implies that the number of reoperations also could be reduced if Zipfix is used. It was actually shown at Karolinska University Hospital, Sweden, that the reoperations decreased when using Zipfix instead of the standard technique. The change was studied over a six month period and the total number of reoperations went from ten reoperations for steel wires to two reoperations for Zipfix implants.

According to Claes Rythammar (2012, Mail Interview, October 17th) Zipfix implants are three times higher resistance to bone cut-through in osteoporotic bone than steel wires. If a loading of 300 N is applied to both implants, Zipfix implants are capable of seven times more loading cycles than steel wires. And in dynamic strength testing of a sternotomy closure, like in this project, 5 Zipfix implants provide a 4 times higher strength than 8 single steel wires. Also in static tests Zipfix are stronger than steel wires.

However, the technique is rather expensive, 2500 SEK for five Zipfix bands is needed for one patient (Jonsson H., Mail interview, 2012). Another problem with Zipfix is that it is a risk of the lock being released too early, before the sternum has had time to heal properly (Matthias Corbascio 2012, interview, April 23rd).

![Fig 6. Zipfix](image-url)
Sternal Talon

Sternal Talon is a new technique used to close the sternum after a sternotomy. Sternal Talon implants, consisting of titanium, are built on a ratchet mechanism which tightens the parts of the implants that are placed on both sides of the sternum. To clamp Sternal Talon around the sternum a screw is used on the front part (See Fig. 7) (Rapid Sternal Closure, 2012). This screw can also be used when an emergent re-opening is necessary (Levin et al, 2010, p. 1995-1999). There are two models of this implant, single and double Sternal Talon. Single Sternal Talon has a locking mechanism with two legs which is tightened around the sternum. Double Sternal Talon has four legs which are tightened with two legs on each side around the sternum (Rapid Sternal Closure, 2012). The price for one single model is 9095 SEK and 10 500 SEK for one double model (Levin et al, 2010, p. 1995-1999; FOREX Bank, 2013). Normally, three units of the implant are put on the sternum; two double and a single, or three double. The width of the implant is selected among the sizes S, M, L or XL, and the depth can be 11 mm, 14 mm, 17 mm or 20 mm. Before choosing the size it is necessary to measure the width and thickness of the sternum (Rapid Sternal Closure, 2012).

Adhesive – Enhanced Sternal Closure

In an article Fedak et al (2011, p. 1444-1450) compared the standard technique with an adhesive-enhanced technique. In the adhesive-enhanced technique Kryptonite bone adhesive, which is bio-compatible, was used between the two sternum halves. The article focused on complications that arise from the two closure techniques. Coughing caused less pain for patients with adhesive-enhanced technique than for the standard technique. The patients with adhesive -enhanced closure needed lower use of narcotic analgesic the first week because the patients had less pain and could return to a quality life faster. The main disadvantage with this technique is that it complicates the re–opening in case of reoperations because it takes longer time than to cut the steel wires (Matthias Corbascio, 2012, interview April 23rd).

Posthorax Support Vest

A Posthorax Support Vest from the company Posthorax is a designed vest to be used around thorax after a cardiac surgery, see Figure 8. The Karolinska University in Sweden, among other hospitals, offers this vest to the patients. It should be worn in 6 weeks to stabilize the sternum and to facilitate the healing process. This vest can be seen as gypsum. It helps to prevent complications that otherwise often could arise from the friction of the two sternal halves. The thoracic vest reduces the risk of...
deep infections by up to 80 percent, combined with the standard technique. This can shorten the post-hospital stay and it can also be used regardless of closure techniques. The vest costs 1000 SEK but it is possible to reuse it for the next patient (Matthias Corbascio, interview, April 23rd). However, that is not the case in Sweden today.

4.4 Finite Element Method

The finite element method (FEM), that is used today, was developed during the 1950’s and 60’s. It has evolved with the development of computers. The use of computers simplifies the work because FEM solutions require a lot of hand calculations otherwise. There have been developments even after the 1960’s; developments from large computers to smaller computers and the computing capacity has become much faster. Because of this development it has become much easier to use FEM but the user is still required to have knowledge of the basic principles in FEM to be able to use it. Today FEM is used widespread in several areas; crash analysis, fatigue, flows, biomechanics and in many other areas (Finita elementmetoden, Nilsson, B., 2012).

FEM is a method where large and complex systems are split into smaller systems that are easier to solve and that together help solving the complex system. Known solutions for smaller problems are applied to the elements, the small parts of the complex system. In this way different analyses of the whole system can be made, for instance how displacement affects the model in stress analyses (Liu, G.R., Quek, S.S., 2003, p. 1-2).

Advanced linear or non-linear differential equations in a system can be solved with FEM (Dynasupport – FAQ, 2013). The system can either be static or dynamic. Static means that the system’s forces are in equilibrium and the net force is therefore zero. Dynamic means that the system’s forces and motions are studied. Acceleration is the time-derivative of the object’s movement and is dependent on both mass and force. Inertia is the result of the system’s mass related to the force over time. A greater mass will increase the system’s inertia, causing the acceleration to decrease if the amount of force is unaltered (Colorado University, 2013). A common mistake is to make dynamic problems static to simplify calculations. By using dynamic FEM instead, the solution becomes a better approximation of the real situation since the problem itself is of a dynamic nature, rather than a static one. (Li Cheng Yang et al., 2010).

Finite element models consist of points in a coordinate system called nodes. Between the nodes elements are defined. Beam elements are defined between two nodes. In the same way the shell elements are formed by three or four nodes and solid elements are formed by eight.
nodes, all shown in Figure 9 (Dynasupport – Elements, 2012). Together the elements create a so-called finite element mesh (Faleskog, J., 2012).

FEM is used in several parts of construction processes of engineering systems to modulate and simulate how the new system should be developed. In a construction process (for an example of a construction process, see Fig. 10), FEM is involved in the physical, mathematical and numerical aspects of modeling and in the simulations of numerical methods. FEM is also useful when the results are to be analyzed to check if the system is good or if it needs to be revised (Faleskog, J., 2012; Liu, G.R., Quek, S.S., 2003, p. 1-2)

LSTC (Livermore Software Technology Corporation, Livermore, CA, USA) has developed the program LS-DYNA (LSTC, 2012). LS-DYNA is a dynamic finite element program that is used for analyzing nonlinear dynamic response from three-dimensional structures (Dynamore, 2012). An example where LS-DYNA was used is the landing of NASA’s Mars pathfinder that used airbags etcetera to be able to enable landing (LS-DYNA products, 2013).

4.5 THUMS - Total Human Model for Safety

THUMS is a model that has been developed by Toyota Motor Corporation and Toyota Central R & D Labs. The model of a human body is designed for crash simulations to help auto manufacturers to better understand injury mechanisms for the development of safety and new solutions. The model is realistic since it describes the human in detail with the same material properties as in human bodies (LSTC – THUMS, 2012).

4.6 Solid Mechanics

The simulations that are made in this project are linear elastic, thus parameters for linear elasticity are only used in the simulations. For linear elastic material models the parameters E-Modulus, density and Poisson’s ratio are needed. Also the coefficient of friction was needed in this project. According to Lundh (2000) some commonly used parameters are defined as followed:

Density is a term that indicates the mass per volume of a substance (Encyclopedia Britannica, 2012).

Stress, $\sigma$, is the force in the material coming from the outer force and that is acting on the cross sectional area, i.e. $\sigma = \text{force} / \text{area}$. The unit is Pascal (Pa) but is often used in MPa.
Strain, \( \varepsilon \), is the deformation \( \delta \) of an object when force is acting on it in relation to its original length \( L \), i.e. \( \varepsilon = \delta / L \).

E-modulus, \( E \), describes the elastic properties of a material when it is stretched or compressed. E-modulus may therefore be described as the ratio between the stress \( (\sigma) \) and the strain \( (\varepsilon) \), \( E = \frac{\sigma}{\varepsilon} \). This equation is also called Hooke’s law (Encyclopedia Britannica, 2012; Karolinska Institutet, 2012).

The displacement is when a body is moving a distance without necessarily being deformed.

Poisson’s ratio, \( \nu \), is a material constant that is a measure of deformation in one direction when a material is stretched and the thickness of the body is reduced in another direction. The reduction of thickness is proportional to the strain in the first direction.

The coefficient of friction, \( \mu \), is a coefficient that indicates how much friction there is between two objects. Friction is a force that prevents object from moving because of the contact to another object (Encyclopedia Britannica, 2013).

von Mises stress is the most common method to calculate the equivalent stress with respect to stresses in all directions.

### 4.7 Implants

Medical implants are devices or tissues that are placed inside or on the surface of the body (FDA, 2012). The implants have to remain there for at least 30 days (Science Partner – Implants, 2012). Their main purpose is to stabilize or enhance various functions in the body (SIS, 2012). The implants can remain in the body until they are no longer needed or can stay there permanently, depending on the type of implants and the situations (FDA, 2012). There are two kinds of implants; active implant and inactive implant. The active implants have an integrated power supply and are not dependent of the gravitational energy or the energy from the human, while for the inactive implants it is the opposite (Science Partner – Implants, 2012). The implants which are used in these simulations are examples of inactive implants. These implants hold together the two sternum halves and are intended to stay there permanently to meet the patient’s needs. The implants do not have an integrated power supply.

### 4.8 Biocompatibility

When introducing an implant into the body, it is important that the implant is biocompatible, otherwise the body will not accept the new implant. A biocompatible material has the necessary properties to work in a biological tissue (Encyclopedia Britannica, 2012). It is also important that all side effects that occur, in the tissue and material interface, must be as small as possible. The implant should therefore interact as much as possible as a natural material. There are many factors that affect an implant’s biocompatibility e.g. implant size, shape, charge and composition (Corrosion doctors, 2012). To meet the requirements and to fulfill the
biocompatible requirements there are standards for the biocompatibility of materials used in medical devices in EU and the U.S. The purposes of the standards are to reduce the negative effects on human health caused by faulty materials in the product as much as possible (Science partner – Biocompatibility, 2012).

**4.9 Materials Used in Closure Techniques**

In the project’s simulations the following materials are used.

**Stainless Steel**

Stainless steel is an alloy that consists of at least 11.5 percent chromium and 50 percent iron (sv.vt.edu, 2013). Its characteristic is that it is not corrosive, because of the chromium oxide surface (Encyclopedia Britannica, 2012). If the surface is scratched or damaged it will repair itself with help of oxygen from the surrounding area. Stainless steel is environmental friendly, can be used in many ways such as steel wires and have a long lifetime (wisegeek.org, 2012). The most common type of stainless steel is called austenitic which is very flexible because it contains up to 35 percent nickel (Encyclopedia Britannica, 2012).

**PEEK**

PEEK stands for Poly Ether Ether Ketone (Encyclopedia Britannica, 2013). It is a semi-crystalline thermoplastic (Raha il Parvaiz et al, 2010). Its advantages are that it has a high strength and is chemical resistant. The material has also high thermal strength. Another advantage with PEEK is that it can be seen in X-ray pictures, in which e.g. an implant’s position can be studied (Encyclopedia Britannica, 2013). It is also wear resistant (Raha il Parvaiz et al, 2010). PEEK is biocompatible (Roeder, R.K. and Conrad, L. T. 2013). Although, it has high material costs (csuchico.edu, 2013).

**Titanium**

Titanium is a lightweight and strong metal with a density of 4500 kg/m³, melting point 1660°C and boiling point 3287°C. The weight of titanium is only half of the steel’s. It constitutes 0.44 percent of the Earth’s crust (Encyclopedia Britannica, 2012). It is the 9th most common element in the crust. Titanium is biocompatible and therefore a good material to use in medical equipment and implants. The oxide film on the surface make titanium resistant to erosion and organic and inorganic chemicals and gases. Titanium has a low E-Modulus compared to other metals and is non-magnetic and non-toxic (International Titanium Association, 2012). Unfortunately titanium is expensive in comparison to the other materials mentioned (Lapovok, R. et al, 2012).
5. Methods

To achieve the project’s goals a literature study was done to get a thorough investigation of which closure techniques that are available on the market today. This was done to be able to choose the most important techniques to simulate. The study was also performed to find information about the different implant properties. With help of written and oral interviews more information could be added. Reliable models of the chosen implants were created and a comparison between a real sternum and the modeled one was done. The different techniques were simulated in order to measure the displacement between the two sternum halves and to see how stresses on the sternum were generated by the implants.

5.1 Interviews

The background in the thesis is mostly based on information from written interviews with relevant and well-informed persons. Also one oral interview was done with Matthias Corbascio, Cardiothoracic surgeon. In order to get a thesis with the widest perspective possible, people with different skills and professions were interviewed. Interview questions were designed specifically to each interviewed person to get as much information as possible from the interview. The questions, for the written interviews, were asked through email and were clearly expressed to prevent any misunderstanding. Primarily, the questions were focused on technology and economics. The questions from the interviews can be found in Appendix 1 and 2. The interviewed persons were:

Matthias Corbascio is a Cardiothoracic Surgeon at Karolinska University Hospital (KS) in Sweden. Two interviews were made with Corbascio, one oral and one written. The purpose of the interviews was to get more basic information about the Zipfix implants, information about what kind of forces that are affecting on the sternum, from which company KS buys their products and to get in touch with someone who can answer financial questions.

Hans Jonsson is a M.D and Ph.D at Cardiothoracic Surgery and Anesthesiology (KS) in Sweden. Jonsson has good knowledge in the finance at KS and therefore gave valuable answers regarding financial matters like hospital charges for the actual surgery, costs regarding hospital stay for a patient and about product costs.

Claes Rytthammar is responsible for the thorax department at the company Synthes AB, Sweden. The company is manufacturing implants and therefore the questions focused on the products that were relevant to the closure techniques simulated in this project. Synthes AB had a lot of useful information about Zipfix.

Cristoph Maurath is working at Livermore Software Technology Corporation (LSTC). The interview with Maurath gave valuable information about the sternum model used in the project’s simulations. The information was useful to understand the difference between a real human sternum and the one that was simulated, and therefore also helpful to understand the limitations of the simulations.
Richard Ingemansson is an Associated Professor and Senior Consultant in Cardiac Surgery at Skåne’s University, Sweden. The purpose with this interview was to get more information about the closure of the sternum and to get ideas on how problems related to that can be reduced.

5.2 Literature Study

A literature study was done to get information about the current situation of the closure techniques and which techniques that are available today. The study was mainly based on scientific articles from PubMed.

Three appropriate closure techniques were chosen to be simulated from the literature study. After this selection the next step was to study these three closure techniques very carefully. If the models are created as lifelike as possible the simulations could, in turn, generate realistic results. In order to study these three closure techniques more closely, it required various parameters to have in mind: material properties and constants and also THUMS.

Material Properties and Constants

In order to create models of the implants for simulations, an extensive research was needed to find out which material the implants consist of today. Also the material properties, hence the material constants, for these materials were investigated. The research was mainly done on PubMed to get updated scientific information about the closure techniques and implants.

In order to connect the material properties to the models, material constants were required to be defined. The constants needed for the linear elastic materials in this project are E-modulus, density and Poisson’s ratio. Also the coefficient of friction is needed. Tensile tests with real sternums have been performed in earlier studies, e.g. in the article that Losanoff et al wrote in 2004, with some of these implants and materials and hence, these constants. In this project the simulations done are similar to these tests and hence the same material constants can be used for this project.

THUMS

The sternum model used in this project is a part of THUMS which is a full body model. This means that it is not a model developed and focused only for sternum but for a body. However, the sternum model has material models of cortical and cancellous bone reflecting the reality (Maurath, C., 2012, Interview October 31th).

To achieve results from the simulations in the project with the models of the implants it is important that the sternum that is used during the simulations is sufficiently realistic with respect to design and characteristics. This was done by exploring how a real sternum looks like and what it consists of. To find out these details about the sternum model that was used during the simulations, a person working for THUMS was contacted. A comparison was then made between the real sternum and the model to be able to say that the model was approved for being used in further simulations.
5.3 Modeling and Simulation

In the THUMS model implant models were created so that the several closure techniques could be simulated to achieve the goals of the project.

Three closure techniques, of the ones mentioned in the background, were chosen to be specialized in and to be simulated. These were chosen particularly with respect to ordinariness and prospects. The chosen ones were: standard technique, Zipfix and Sternal Talon. Two suggested improvements of these techniques were developed where one of them was in combination of a steel wire and Sternal Talon and a steel wire and Zipfix were combined in the other technique. In total 3 different techniques and 2 improvements of the techniques were simulated. Three materials were then used; stainless steel, PEEK and titanium, because of the closure techniques that were chosen.

**Sternum and Ribs**

The sternum model that was used in the simulations was taken from the model THUMS that has been developed by Toyota. In the model the cancellous bone is treated as solid elements and the cortical bone as shell elements. The element size of the model is 3-5 mm as seen in Figure 11 (Dynamore – Element size, 2013). The material model was chosen to linear elastic. The first step was to divide the sternum into two halves. Contact surfaces were then created between the two halves to get contact area between them when putting the halves next to each other. A contact area was needed to prevent the halves from cutting into each other during simulation.

A small part of the ribs was added to the sternum model. During breathing a gap is after a sternotomy normally created between the two sternum halves in the y-direction. The nodes on the sternum where the ribs are attached were fixed in both x- and z-direction, allowing the sternum to move only in y-direction. The fixation causes stresses on the sternum, of which more information could be found in Appendix 3. The fixation was done to make the simulations as similar as possible to the tests in the article by Losanoff et al (2004). When the sternum halves had been separated and the ribs were added, the different implants could be applied to the model.
Standard Technique

To emulate this closure technique, beam elements were placed like a thread around the sternum between the ribs. The alternating trans- and peristernal technique was used as the standard technique (Fig. 12). A contact surface was also created between the sternum and the beam elements. The transsternal steel wires are penetrating the sternum, making a hole in the sternum. Some beam nodes are shared with sternum nodes to make the steel wires not to cut through the sternum but to stay in the hole. To make the steel wires to not move in the z-direction a fixation was made in that direction to simulate the real case. Linear elastic material with material constants of stainless steel was used for the beam elements with the dimensions 1 mm in cross section.

![Fig 12. Sternum model with steel wire implant model, front and back](image)

Zipfix

This implant consists of two square shell elements, together 4.2 mm wide, and is wrapped around the sternum and placed between the ribs (see Fig. 13). The shell elements were also made in the same element size as the elements in the THUMS model. This was done to get the size of the shell elements to fit the rest of the sternum model better during simulation. A contact surface was created between the sternum and the implant. To not move in the z-direction the Zipfix implants were tied to the sternum like glue. A linear elastic material with material constants of PEEK was used for the shell elements.
Zipfix with One Transsternal Steel Wire

From the Zipfix technique this new suggestion was developed (see Fig. 14). It is a combination of the Zipfix model with implants of titanium and one transsternal steel wire of stainless steel from the standard technique. This extra steel wire was placed in the lower part of the sternum to prevent large deformations in that area which otherwise are very common.
**Sternal Talon**

This implant is made of square shell elements placed like birds’ feet around the sternum and the claws between the ribs to simulate the Sternal Talon implants (see Fig. 15). The shell elements have the thickness of 3 mm as the thickness of a Sternal Talon implant. A linear elastic material with material constants of titanium was used for the shell elements. Like in the other techniques, a contact surface was created between the sternum and the implant.

![Fig 15. Sternum model with the Sternal Talon implant model, front and back](image)

**Sternal Talon with One Transsternal Steel Wire**

This improvement of Sternal Talon (see Fig. 16) uses the implants from the Sternal Talon technique with implants of titanium but with one addition. As in the technique Zipfix with Transsternal Steel Wire a steel wire of stainless steel was placed transsternally in the lower part of the sternum. This modification was also done to reduce the displacement in the lower part of the sternum.
Preparation of the Simulation

To choose parameters for the simulations in this project the simulation setup and parameters such as load were made as similar to the tests in the article that Losanoff et al wrote in 2004. Losanoff et al performed test with real human sternum cadaver and not models or animal cadaver hence making the test more similar to the actual movements in the human body. The nodes where the ribs are attached to the sternum were loaded. From the article 800 N was chosen as the amount of force and the number of loaded nodes was counted to 99 of the total amount of nodes in the sternum model. The load per node was then calculated to force / amount of nodes = 800 / 99 ≈ 8 N/node.

The time of simulations was selected to 2 seconds to simulate an inhalation. To make the implants not to move more than in a real human body, friction was applied between the implants and the sternum. The implants were placed and adjusted to be as close to sternum as possible.
Table of Material Constants

The Table 1 below shows the material and their constants used in the models.

Table 1. Material table with material constants

<table>
<thead>
<tr>
<th>Material</th>
<th>E-modulus (GPa)</th>
<th>Density (kg/m³)</th>
<th>Poisson’s ratio, ν</th>
<th>Coefficient of Friction, μ</th>
</tr>
</thead>
<tbody>
<tr>
<td>316L Surgical Stainless Steel¹</td>
<td>193</td>
<td>8000</td>
<td>0.27</td>
<td>0.37</td>
</tr>
<tr>
<td>PEEK²</td>
<td>4.21</td>
<td>1285</td>
<td>0.39</td>
<td>0.34</td>
</tr>
<tr>
<td>Titanium³</td>
<td>108</td>
<td>4540</td>
<td>0.22</td>
<td>0.37</td>
</tr>
<tr>
<td>Cortical bone⁴</td>
<td>13</td>
<td>2000</td>
<td>0.30</td>
<td>0.58</td>
</tr>
<tr>
<td>Cancellous bone⁵</td>
<td>0.40</td>
<td>862</td>
<td>0.45</td>
<td>0.58</td>
</tr>
</tbody>
</table>

2. Fitch et al. 2010, p. 3768-3777
3. Handbok och formelsamling i Hållfasthetslära, KTH, 2010; Cordey et al, 2000, p. 21-28
4. LSTC – THUMS, Toyota; World Scientific, 2012
5. LSTC – THUMS, Toyota; World Scientific, 2012

Simulation

Processor type AMD64 was used in the LS-DYNA simulations and the version of LS-DYNA was Is971s R6.0.0. Simulations with stainless steel, PEEK and titanium were performed for each implant, one at a time, to be able to examine the impacts the implants and materials have on sternum. The results were then analyzed and improvements was developed from these analyzes. Every closure technique was simulated with the three materials and with the improvements a number of 11 simulations in total were performed.

In the simulations two aspects evaluated. One aspect was to measure the displacement between the sternum halves in the middle and lower part of sternum. This was done to see how much the two halves moved from each other despite the implants trying to hold them together. The other aspect was to see how much stress the implants generate on the sternum.

5.4 Selection of Simulated Closure Techniques

The reasons why the closure techniques and the improvements of the techniques were selected for simulations in this project are explained below.

Standard Technique

This closure technique was chosen to be simulated because it is the standard technique that has been used for years. It was an important part in the project to simulate this closure technique because it is essential to compare it with other “newer” closure techniques. This was to see whether it was the best one or if it could be replaced as the standard technique on
the market by any of the other closure techniques being compared with. The comparison with the standard technique can also show which improvements that can be made and be to inspired to develop even better closure techniques.

**Zipfix**

Zipfix was chosen to be simulated because it showed in earlier investigations, to be more advantageous than the standard technique. Hence, an investigation in this project was done to see if the results from these earlier studies were correct and if this technique could out-conquer the two other closure techniques that also were simulated. Even here the risk of cut-through is supposed to be lower than that of the standard technique and that was important to investigate, as well as the displacement to see whether this technique is a good alternative to the standard technique or not.

**Zipfix with One Transsternal Steel Wire**

A major problem after sternotomy is that the lower part of the sternum often has a greater displacement than the rest of the sternum. To try to overcome this problem the improvement Zipfix with One Transsternal Steel Wire of the technique Sternal Talon was created and simulated. With this technique the maximum value of displacement did not have to be so large and hence not cause so much pain for the patient. The disadvantage with this closure technique is that a steel wire is used which could generate stresses on the sternum, hence there is a risk of cut-through.

**Sternal Talon**

There are several advantages with these implants that make this technique worth simulating. Sternal Talon has a great range of sizes which makes it easy to adapt to individuals. It is also a rigid and secure implant which is placed in position to not allow the sternum halves to move away from each other in any direction causing painful friction. It also reduces the problem with cut-through in the bone because of its large contact area to the bone. Another advantage is that it is less invasive compared to the standard technique because it can be secured on the outer side of the sternum. Therefore it is easy to do a re-opening. This closure technique differs from the other closure techniques as it mainly targets at high-risk patients due to the high expense of the titanium (Levin et al, 2010, p. 1995-1999).

**Sternal Talon with One Transsternal Steel Wire**

As in the improvement Zipfix with One Transsternal Steel Wire this extra steel wire can reduce the displacement in the lower part of the sternum also in the technique Sternal Talon. Therefore this technique was developed and simulated to see if the displacement in the lower part becomes smaller than in the Sternal Talon technique.
5.5 Selection of Materials

The three chosen closure techniques to be simulated consist of three different materials respectively. Therefore, the materials chosen to simulate was then stainless steel, PEEK and titanium. The strongest argument for the selection of these three materials was because the materials are already being used in these techniques today. The materials are all also biocompatible and hence possible to be placed in the body of a patient.

Stainless Steel

This material is stainless which means no corrosion. It is a cheap material that often makes the implant cheaper compared to the other materials. Stainless steel is unfortunately much heavier than for example titanium which can result in that larger implants such as Sternal Talon become too heavy for the patient if using stainless steel. In this project stainless steel 316L is used because it is the type of steel alloy that often is used in medical implants and equipment.

PEEK

PEEK is a thermoplastic and hence very low weight and can handle high temperatures. PEEK has high strength and can be captured in an X-ray even if it is not a metal. This is convenient because the surgeon can check if the implants are still in place.

It was confirmed that PEEK was biocompatible in the end of the 1980s. In situations where the material has been used it has been shown from clinical studies that there is a good level of biological response. It has also been stated that PEEK is biocompatible at an independent laboratory in Germany. There is a lot of well documented studies that confirms that PEEK is a safe implant material (Rytthammar, C., 2012, interview October 17th).

Titanium

Titanium is a low weight material which makes it possible to be used in larger implants without making the implant too heavy which can lead to inconvenience for the patient. The main drawback is that titanium is expensive which makes it undesirable on the market compared to cheaper alternatives.

There are obvious advantages and disadvantages with the materials. Therefore, the three modeled techniques were simulated with all three materials, to investigate if the technique could achieve an equivalent or improved technical result compared to its ordinary material. This change does not make it a new technique but use the base of the technique to develop a better one. The analysis of these simulations, when the material is changed, should be done from an economic, environmental and biocompatible perspective. The cost is today an important factor which affects the development of new implants because it often limits the use of them due to too expensive material options.
6. Results

From the simulations in LS-DYNA the displacements in the middle and lower part of the sternum were measured at the end of the simulations and are collected in Table 2 below. Also the stresses in the cortical and cancellous parts of every technique with the different materials are presented. In total 11 simulations were done in this project.

Table 2. Result of displacement in the middle and lower part of the sternum for every closure technique and material

<table>
<thead>
<tr>
<th>Closure Technique</th>
<th>Material</th>
<th>Displacement in the middle of the sternum (mm)</th>
<th>Displacement in the lower part of the sternum (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard technique</td>
<td>Stainless Steel</td>
<td>0.28</td>
<td>0.78</td>
</tr>
<tr>
<td></td>
<td>Titanium</td>
<td>0.38</td>
<td>0.85</td>
</tr>
<tr>
<td></td>
<td>PEEK</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Zipfix</td>
<td>Stainless Steel</td>
<td>0.06</td>
<td>1.60</td>
</tr>
<tr>
<td></td>
<td>Titanium</td>
<td>0.14</td>
<td>1.45</td>
</tr>
<tr>
<td></td>
<td>PEEK</td>
<td>0.51</td>
<td>2.41</td>
</tr>
<tr>
<td>Zipfix with one transsternal steel wire</td>
<td>Titanium</td>
<td>0.09</td>
<td>1.12</td>
</tr>
<tr>
<td></td>
<td>Stainless steel</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sternal Talon</td>
<td>Stainless Steel</td>
<td>0.33</td>
<td>1.70</td>
</tr>
<tr>
<td></td>
<td>Titanium</td>
<td>0.46</td>
<td>1.96</td>
</tr>
<tr>
<td></td>
<td>PEEK</td>
<td>3.45</td>
<td>6.35</td>
</tr>
<tr>
<td>Sternal Talon with one transsternal steel wire</td>
<td>Titanium</td>
<td>0.44</td>
<td>1.69</td>
</tr>
<tr>
<td></td>
<td>Stainless steel</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The X in Table 2 means that no result could be obtained for the standard technique with PEEK. In this study the smallest displacement in the middle of the sternum was shown in the simulations with stainless steel in the closure technique Zipfix. The smallest displacement in the lower part was shown in the simulations with stainless steel in the standard technique.

The von Mises stresses are shown in Figure 17 and 18 for both cortical and cancellous bone. For every closure technique the highest stresses occur in the lower sternum and lowest stresses occur in the Manubrium. The stresses are prominent on the same places on the both bone layers of the sternum. The same levels of stress for cortical and cancellous bone are used through the thesis. More results of stresses can be found in Appendix 4. Figure 18 shows the improvements Zipfix with One Transsternal Steel Wire and Sternal Talon with One Transsternal Steel Wire with Zipfix implants and Sternal Talon implants of titanium and the extra steel wire of stainless steel.
Fig 17. Stresses generated by the implants on the cortical bone with the original material using A) Standard technique B) Zipfix C) Sternal Talon. Fringe levels in MPa for cortical bone are also shown. Stresses generated by the implants on the cancellous bone with the original material using D) Standard technique E) Zipfix F) Sternal Talon. Fringe levels in MPa for cancellous bone are also shown.

Fig 18. Stresses generated by the Zipfix with One Transsternal Steel Wire on the A) Cortical bone B) Cancellous bone. Stresses generated by the Sternal Talon with One Transsternal Steel Wire on the C) Cortical bone D) Cancellous bone. Fringe levels are as in Fig 17.
The discussion is based on the result from the simulated closure techniques, especially with respect to the displacement between the two sternum halves and the generated stresses from the implants. A comparison is also provided between the closure techniques. Future work and reasons for errors will also be discussed.

7.1 Closure Techniques

The discussion in this section is about the simulated techniques based on the displacement from Table 2 and the stresses from Figure 17 and 18. For Figure 19-23, see Appendix 4.

Standard Technique

Table 2 shows that the smallest displacement in the standard technique, both in the middle and in the lower part of sternum, was given by the material stainless steel. When simulating the standard technique with the material titanium it was shown that the titanium implants generated a greater displacement comparing to stainless steel. This was expected because titanium has a lower E-Modulus, therefore it generates a greater strain, hence greater displacement. The implants with PEEK did not give reasonable results. This is because the implants could not hold the two sternum halves together during the simulation. The problem with the material PEEK in the simulations in this project will be further discussed in this section.

As seen in Figure 17, A and D, the implants of stainless steel generate most stresses on the lower part of the sternum compared to the rest of the sternum. The two transsternal steel wires generate high stresses on sternum, especially the one placed in the lower part. This is because more ribs are attached to the lower part of sternum and the transsternal steel wire counteract these high forces by generate larger stresses on the sternum. The stresses from the peristernal steel wires, especially in the upper part, are quite small compared to the stresses that the transsternal steel wires are generating. Stresses generated by implants of stainless steel and titanium are similar. This, together with the result from the displacement and the fact that titanium is more expensive than stainless steel, gives reason to choose stainless steel before titanium for this technique.

Zipfix

PEEK is the original material for the Zipfix implants but results in the largest displacement in this technique, both in the middle and lower part of sternum (see Table 2). Both the implants of stainless steel and titanium generated one of the smallest displacements in this study.

The stresses are though high in the implants of stainless steel, see Figure 20 B and E. A reason for the high stresses in the implants of stainless steel can be due to the high E-Modulus which makes the implants stiffer hence hold the two sternum halves stronger together. A comparison between the implants of PEEK (see Fig. 20 A, D) and titanium (see Fig. 20 C, F) shows that the stresses are distributed over a larger area with the implants of titanium. With
the implants of PEEK the stresses are more focused on small spots. The distribution of stresses in the implants of titanium could reduce the risk of cut-through and hence the risk of infection. Therefore titanium is preferred as a material in the Zipfix implants.

When creating the implant for Zipfix the idea was to do a similar model of the real technique. For that reason the implants were attached to sternum as close to it as possible, but sternum’s surface is not completely flat. This resulted in that the first part of the simulations consisted of stretching the implant without inducing any strain and hence some of the displacement is due to this action. To better mimic the reality a pre-strain could be added to the implants before the load is applied to the sternum. This is a better idea because the implants are tightened when the technique is used in real life. In that way the simulations could generate a decreased displacement and therefore probably even better results in displacement.

**Zipfix with One Transsternal Steel Wire**

After Zipfix was simulated, suggestions for improvements of this technique arose. One suggestion was to place an extra transsternal steel wire of the material stainless steel in the lower part of sternum to decrease the displacement in that area. As could be seen from Table 2, the displacement in the lower part was decreased compared to the original Zipfix, which was expected.

The largest stresses that arose because of this extra transsternal steel wire (see Fig. 18 A, B) was on the same location as were seen in the original zipfix. But these new stresses from the transsternal steel wire were distributed over a larger area.

The lower displacement that arose with the improvement of this technique is not low enough to outcompete the disadvantages with the stresses appeared due to the transsternal wire. This is the reason why this suggestion of closing the sternum is not considered further when choosing the best closure technique.

**Sternal Talon**

Sternal Talon with implants of stainless steel gives the lowest values in displacement, both in the middle and lower part of sternum, compared to implants of titanium and PEEK, as can be seen in Table 2. Unfortunately stainless steel is much heavier than the other two materials and due to Sternal Talon implant’s large size it can cause problem. This means that the material stainless steel is not possible to use for this technique. Also here the simulations with the material PEEK did not give any reasonable results. Titanium is therefore more suitable to use for this technique even if the displacement was greater for this material than for stainless steel and has much higher costs.

Of the three titanium implants that are placed on sternum the one placed on the lower part are generating most stresses on the sternum (Fig. 17 C, F). Stresses on the middle and the upper part are small compared to the lower part. This is an expected result because of the greater amount of ribs attached to the lower part than to the rest of the sternum which results in greater stress. Implants with PEEK (Fig. 21 C, F) shows lower stress level in cortical bone
compared with implants of stainless steel (Fig. 21 B, E). As mention above the properties of PEEK make the displacement remarkably large in comparison to every other simulated technique.

**Sternal Talon with One Transsternal Steel Wire**

This improvement, to place a transsternal steel wire in the lower part of sternum, was done for the same reason as in Zipfix with One Transsternal Steel Wire, i.e. to decrease the displacement in the lower part of the sternum. When simulating this approach it was shown, in Table 2, that the displacement in the middle of the sternum was about the same compared to the Sternal Talon. With this improvement the displacement was decreased compared to Sternal Talon which was expected. With this extra transsternal steel wire the lower part, which is most sensitive and most exposed to pressure, may be more robust in this way. The extra transsternal steel wire will probably not increase the costs that much because stainless steel are not that expensive comparing to titanium and it is not that much of stainless steel that is needed.

Because of the extra transsternal steel wire placed in the lower part of sternum the stresses are moving toward the middle of the sternum (see Fig. 18 C, D) instead of on the edges of sternum like in the Sternal Talon technique (see Fig. 17 C, F). The upper part in the cancellous bone in the Sternal Talon implants shows higher stresses than for the cancellous bone in the upper part of the Sternal Talon with One Steel Wire. This extra steel wire makes the load more distributed over several implants and hence the stresses are more distributed on the sternum. Because of this reason and the smaller displacement than the original Sternal Talon this improvement is more preferred to use.

**Stresses on the Cortical and the Cancellous Bone**

One important aspect to have in mind when discussing the stresses generated by the implants, is that there are different amount of stresses generated by the implants on the different bone layers in the sternum. In Figure 17 it can be seen that stresses are much greater on the cortical bone than on the cancellous bone, regardless which closure technique that are simulated. Even though the cortical bone is protecting the cancellous bone there are stresses that affect the cancellous bone as well. This can result in large hole in the sternum because the cancellous bone is soft. These large holes can for example result in high risk for infection.

**7.2 Comparison between the Best Simulations from Every Closure Techniques**

The best simulations from the three closure techniques based on the discussions above are standard technique with implants of stainless steel, Zipfix with implants of titanium and Sternal Talon (titanium) with One Transsternal Steel Wire (stainless steel). In order to find the best closure technique a comparison between these three was therefore necessary and a compromise in terms of displacement and stress was needed. The closure technique with the smallest displacement is not necessarily the one that generates the lowest stress.
Sternal Talon with One Transsternal Steel Wire showed a significant larger displacement than both the standard technique with implants of stainless steel and Zipfix with implants of titanium. Comparing the stresses generated by the different implants with each other it could also be shown that all the stresses were relatively similar. For this reason both standard technique with implants of stainless steel and Zipfix with implant of titanium are better alternative than Sternal Talon with One Transsternal Steel Wire. Therefore the Sternal Talon with One Transsternal Steel Wire can be excluded for further investigation in this discussion.

Both the standard technique with implants of stainless steel and the Zipfix implants of titanium show small displacement in both the middle and lower part of sternum. Zipfix with titanium shows a smaller displacement in the middle of sternum while the standard technique with stainless steel shows a smaller displacement in the lower part.

When comparing these two techniques with respect to the stresses it is shown that the stresses are more focused in the lower part of the sternum with the standard technique with implants of stainless steel while the use of Zipfix with implants of titanium the stress level is lower and more distributed over the whole area of the sternum. This gives reason to believe that Zipfix with implants of titanium is a better technique to close the sternum with. This is because a more distributed stress can result in less cut-through and hence less risk of infection and pain for the patient.

### 7.3 Analysis of Material

When trying to combine the techniques with other materials than in the original implants it was shown in some cases that the other materials were not suitable for the technique. For example when simulating Sternal Talon neither stainless steel nor PEEK was suitable as material in the implant. To find a new suitable material the optimal material constants were identified by comparing the material constants of the materials in the techniques with the corresponding results in the simulations. This comparison resulted in that a preferred material should have low density while in the same time have a high E-Modulus. This material should with these properties make the implant stiffer, more robust and in the same time be low weight. If all these requirements are met the sternum will be stable and the weight will not affect the patient necessarily. Another aspect is that it should be cheap to meet the requirements from the hospitals.

With the material PEEK there was some problem to get reasonable results. In both the Standard Technique and Sternal Talon the material PEEK showed unrealistic results in form of too large displacement. When comparing material constants of PEEK with Stainless Steel and Titanium it shows that PEEK has a much lower E-Modulus. According to Hooke’s law a lower E-Modulus gives a greater elongation in the material, since the stress is constant. Therefore the material PEEK is not as good as the other two materials to keep the two sternum halves together which make it a good reason to exclude it as a good material for steel wire and sternal talon. The parameters used in the simulations are linear elastic. PEEK is a nonlinear material and a simplified version of PEEK was used in the simulations since the
aspect of the implant material was not what was investigated but how the implants affect the sternum. This was a too simplified limitation to assume and could be a reason why the simulations with this material did not get proper results.

### 7.4 Environmental Aspects

When forming new techniques and looking for better alternatives on the market the environmental aspect is important. It is impossible not to affect the environment in a negative way when manufacturing implants, for example when materials are received from nature, but actions can be taken to reduce the effects. When considering changing material, as discussed in the section above, environment is an important aspect to consider when deciding to change the material. In general when using the different closure techniques one action could be to reuse the devices that are not disposable. For example the Posthorax Vest can easily be reused by patients if the hygiene aspect is considered. This could reduce the production of the Posthorax Vest which in turn could reduce the load on the environment and still help many patients. Also if the techniques become better and no reoperations are necessary, the material usage will be reduced and hence make it more environmentally friendly.

### 7.5 Reasons for Errors

The comparison between a real sternum and the model used during the simulations was done in order to get realistic results from the simulations. From the comparison it could be shown that the model has in general a similar structure as a real sternum and the result from the simulations can therefore be considered as reliable in this aspect. A potential problem could be that the ribs are attached to sternum differently from each other compared to a real sternum. For those implants that are using the intercostal space this will therefore affect the implants position on the sternum. The location of the sternum’s ribs in the sternum model being used during the simulations could affect the results and give some discrepancies.

After the closure techniques were simulated it arose that the stress level on the sternum were very high in some areas. One reason for that could be that the implants are placed too close to the sternum which generates high stresses on the sternum.

In an attempt to mimic the tests described in the article by Losanoff et al (2004) as much as possible the force were attached on the ribs on each short side of the sternum with a load of 800 N in the same direction as the ribs pull the sternum (y-direction). Forcing the sternum only to move in the y-direction causes stresses in the sternum. These stresses are affecting the measurement of the stresses that arises from the implants which were to be observed in this project. The sternum that are used in the simulations are the same for all the simulations and so is the force direction when separating the sternum halves which make the stresses that appear from these fixations the same for every simulation. In that way it is possible to compare the simulated techniques with each other to see which one is the best considering the influences of the stresses that can lead to cut-through. It is also possible to see in every simulation where the stresses on the sternum are the highest. How much stresses that are generated only from the fixation of the force in x and z direction is shown in Appendix 3.
7.6 Economy

The economics is a very important issue when a material and technique are being selected. Even if the properties are promising the likelihood of using the material or technique do not have to be high because it is also depending on the price. The hospital will not buy something expensive if there are a cheaper alternative that still works. The advantages must be significant to compensate for the high costs.

The steel wire implants are the cheapest ones in this comparison, about one-seventh of the price of one Sternal Talon implant. The low cost is a good reason for using this technique. The Zipfix implants are a bit more expensive than the steel wire technique but cheaper than the Sternal Talon technique, which is the most expensive technique in this comparison.

The cost of an operation is inevitable for all the techniques but is still an important expenditure to take into account when summarizing the costs for each technique. Because the operation is such a huge cost a technique that often needs reoperations is not a preferable choice in addition to all the complications that can happen during an operation and the extra suffering for the patient. There are various reasons for reoperation e.g. bleeding or rupture of the implants and depending on the patient’s condition the numbers of hospital days varies. This affects the total cost of what the patient will cause health care. The Zipfix with implants of titanium are a more expensive technique than the standard method but has probably fewer complications if looking at the aspects displacement and stress. The total costs of Zipfix with implants of titanium could therefore be about the same when also having reoperations and hospital stay in mind.

7.7 Future Work

Due to the limit of time in this project some priorities had to be made. During the project several ideas for the future arose and are referred to future work. An interesting investigation could be to see whether a better locking system can be developed in the Zipfix technique. This could be done by coming up with different locking proposals and simulating them to see the durability. For instance if a plastic-friendly and biocompatible glue is applied to the lock junction in order to make it more durable so that it does not release. Another suggestion is to use diathermia to melt the lock junction since diathermia is available during a heart surgery because that is the way the skin is split to reach the sternum. In that way the locking junction could be better and hopefully reduces the risk for reoperation. The Zipfix technique is quite expensive, about 2500 SEK for the five bands. The proposed locking technique hopefully reduces the risk of reoperation which otherwise could be a great cost to the hospital and the total cost for this technique would then not be so high.
8. Conclusion

The goal with this project was to investigate which closure technique that is the best one on the market today and to improve it. This was done by simulating the techniques and improvements with respect to displacement between the two sternum halves and stresses generated due to implants acting on the sternum.

The simulations show that both Zipfix with implants of titanium and the standard technique with implants of stainless steel are the two best closure techniques. By combining either of the suggested closure techniques, with the Posthorax Support Vest even better results could be achieved.

The suggested improvements to the closure techniques Zipfix and Sternal Talon resulted in smaller displacement but due to higher stresses these improved techniques were not usable.
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Appendix 1

Questions Used in Oral Interview

Matthias Corbascio, Cardiothoracic Surgeon

1. Do you know when they started using wires to close the sternum? How did they do before that?
2. How common is the method?
3. What are the advantages and disadvantages with wires/cerclage, according to you?
4. Is it expensive? What is the reason for using it although it is not ultimate?
5. Could you tell us more about Zipfix (cable-ties)? Was it just you who used the method? Why did you start and stop using them? What made them release too early?
6. Have you tried any more methods/techniques? Advantages/disadvantages with them?
7. Which materials are the most ultimate materials for the body but also sustainable?
8. Could you tell us some more about the anatomy of the sternum? It consists of three parts? How come a needle can run through a bone? Is just that part more cancellous?
9. Would large staples work to implant instead of wires? Like they do in for example hip operations?
10. Would you appreciate if a new technique was developed that worked better than the standard method or was “good enough”? 
Appendix 2

Questions Used in Written Interviews

Matthias Corbascio, Cardiothoracic Surgeon

1. From where (e.g. behind the sternum from the lungs) is pressure applied to sternum? What forces is acting on sternum in different movements? E.g. coughing or breathing.
2. Do you know how great the forces that affect sternum are or do you perhaps have a table on it? Maybe it is affected by for example the body weight.
3. We also have some financial issues about reoperations, material costs etcetera. Do you know any at KS that we can contact regarding this?
4. Do you know which companies you are buying your products from? For instance who you are buying stainless steel wires or Zipfix from? Or who we can contact to get information about this?
5. Who decide the medical technology rules regarding which material that is good enough to use in the body (biocompatibility)? Is there anyone on KS working with this that we can contact?
6. A relatively new closure technique on the market is named Sternal Talon. Do you use it at KS and if so, is it good? If you are not using it, why not/ do you know any disadvantages with that technique? Do you know any other hospital in Sweden that is using that closure technique?

Hans Jonsson, M.D and Ph.D at Cardiothoracic Surgery and Anesthesiology

1. How much does a reoperation cost? By reoperation we mean that you have to open up the chest again after a heart surgery due to acute bleedings and complications when closing the sternum after the heart surgery.
2. When the chest is to be closed you often use steel wires. How much does this product cost?
3. We have also heard that the technique Zipfix is used at the Karolinska Hospital to close the chest. A cardiothoracic surgeon at that hospital estimated the cost to 2000 SEK for five Zipfix that are needed for one patient. Is there a more precise number on this or is this correct?

Claes Rytthammar, Responsible for the Thorax Department at the Company Synthes AB

1. As we have understood, there are different ”kinds” of PEEK. Which one do you use?
2. What mechanical properties of PEEK do you use when you are doing tests on Zipfix? For example E-Modulus, Poisson’s Ratio and Shear Modulus.
3. How much do Zipfix cost? (To be enough for one patient)
Cristoph Maurath, Working at LSTC
1. Which material properties are you using in the bone?
2. Do you take cancellous and cortical bones into account in your model?
3. What constants do you use in the sternum part? I am interested in Young’s modulus, Poisson’s ratio, density, shear modulus etcetera in the bone model of sternum.
4. Do you use elastic and/or nonelastic (plastic) properties?

Richard Ingemansson, an Associated Professor and Senior Consultant in Cardiac Surgery
1. Do you know when they started using wires to close the sternum? How did they do before that?
2. How common is the method?
3. What are the advantages and disadvantages with wires/cerclage, according to you?
4. Is it expensive? What is the reason for using it although it is not ultimate?
5. Do you know a method that is called Zip Fix? Please, tell us more about it. Good/bad? Cheap/expensive?
6. We heard that the cable-ties (Zip Fix) released too early. Do you know why?
7. Have you tried any more methods/techniques? Advantages/disadvantages with them?
8. What materials are the most ultimate materials for the body but also sustainable?
9. Could you tell us some more about the anatomy of the sternum? It consists of three parts? How come a needle can run through a bone? Is just that part more cancellous?
10. Would you appreciate if a new technique was developed that worked better than the standard method or was “good enough”?

We have suggestions for two new techniques on how to close the sternum in a better way than the current method. Please, tell us what you think!

**Suggestion number 1:** To use cable ties like Zipfix but reinforce the lock with for example a metal lock or more plastic in the lock. To avoid that the halves will rub against each other we suggest adhesive glue for bone with the name Kryptonite bone cement. This will also reduce the risk of infection.

**Suggestion number 2:** This device consists of a thin stainless steel plate. From the plate several legs are standing out. These legs are made of NITINOL, which is a material that is sensitive to temperature. At room temperature it is soft and flexible while at body temperature it solidifies. The plate is placed on the sternum and the legs are folded around the sternum, between the ribs, so that the halves get support of the plate (that has the same dimensions as the sternum).

The two suggestions are complemented by the Posthorax Support Vest.
Appendix 3

Stresses Caused by Fixation of the Sternum

The stresses that arise from the fixation of the sternum in x and z direction are shown in the picture below. The levels are in the unit MPa. This is done to prevent moment from acting on the sternum and thus cause these stresses. Since these stresses are applied in the same way on the sternum and hence are equal in all simulations a comparison can still be made to see which technique that has the highest and lowest stresses even though these stresses are not specifically calculated.
Figures from the Stress Results

Standard Technique

Fig 19. Stresses generated by the standard technique implants on the cortical bone with the material A) Stainless steel B) Titanium. Fringe levels in MPa for cortical bone are also shown. Stresses generated by the standard technique implants on the cancellous bone with the material C) Stainless steel D) Titanium. Fringe levels in MPa for cancellous bone are also shown.
Fig 20. Stresses generated by the Zipfix implants on the cortical bone with the material A) PEEK B) Stainless steel C) Titanium. Fringe levels in MPa for cortical bone are also shown.

Stresses generated by the Zipfix implants on the cancellous bone with the material D) PEEK E) Stainless steel F) Titanium. Fringe levels in MPa for cancellous bone are also shown.
Fig 21. Stresses generated by the Sternal Talon implants on the cortical bone with the material A) Titanium B) Stainless steel C) PEEK. Fringe levels in MPa for cortical bone are also shown.
Stresses generated by the Sternal Talon implants on the cancellous bone with the material D) Titanium E) Stainless steel F) PEEK. Fringe levels in MPa for cancellous bone are also shown.
Fig 22. Stresses generated by the Zipfix with One Transsternal Steel Wire on the A) Cortical bone B) Cancellous bone. C) Fringe levels for cortical bone. D) Fringe levels for cancellous bone.

Fig 23. Stresses generated by the Sternal Talon with One Transsternal Steel Wire on the A) Cortical bone B) Cancellous bone. C) Fringe levels for cortical bone. D) Fringe levels for cancellous bone.