Tampere University

JUHA HAUTALAHTI

Sternal Stability after Cardiac Surgery

Assessments by vibration transmittance and symptoms suggestive of postoperative sternal instability

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Assessments by vibration transmittance and symptoms suggestive of postoperative sternal instability

ACADEMIC DISSERTATION
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To Aura, Venla and Outi

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Juha Hautalahti

Abstract

Sternotomy is the standard exposure in cardiac surgery. The healing of sternotomy is disrupted in 0.3–5% of cases, leading to pain, disability and wound infections. Deep sternal wound infection is the most feared complication and is mainly preceded by instability of the sternotomy. This is difficult and expensive to treat, and, despite advances in treatment, it still carries a considerable risk of death.

Sternal instability progresses gradually, usually within a few days. Awareness of the abnormality would enable measures to stabilize the sternum by using a support vest or by surgical re-fixation before the more advanced phase with infection has begun.

Currently sternal stability is evaluated by manual compression, which is a subjective method and difficult to standardize. Computed tomography (CT) is the most useful imaging modality but yields indirect information on sternal stability. A method for the objective evaluation of sternal stability after median sternotomy would therefore be called for.

Mechanical vibration is widely used in engineering to evaluate the integrity of an object and has been applied to evaluate the integrity of long bones and also the stability of orthopaedic or dental implants.

Our aim was to test the applicability of mechanical forced vibration transmittance for postoperative sternotomy stability assessment and hence a vibration transmittance -based device (Sternal Vibration Device, SVD) was designed and built for the purposes of the study by the engineers in our research group. The device emits low frequency vibration, which travels through the sternotomy junction and is recorded by a special sensor. Instability of the sternotomy reduces the transmission of mechanical vibration energy.

This study on sternotomy stability assessments demonstrates a series of experiments conducted in research laboratory facilities, in clinical studies on patients recovering from open heart surgery and again in experimental settings with cadavers. We also examined patients having symptoms suggestive of sternal instability late after cardiac surgery. According to the findings of these studies the sternal vibration device seems applicable.

It differentiates between solid and discontinuous objects (bone), detects rising vibration transmission as the normal sternotomy healing process progresses and can differentiate between tight and loose sternotomy closure. The last part of the study permits the conclusion that symptoms suggestive of instability late after the sternotomy are mainly not caused by mechanical aetiology.

Tiivistelmä

Sternotomia eli rintalastan halkaisu on tavallisin avaus sydänkirurgiassa. Leikkauksen lopussa halkaistun rintalastan puoliskot kiinnitetään yhteen tavallisimmin teräslankalenkein ja pehmytkudokset suljetaan ompelemalla. Löyhä rintalastaliitos on häiriintyneen paranemisen keskeinen löydös. Se aiheuttaa kipuja, hidastaa toimintakyvyn palautumista leikkauksen jälkeen ja altistaa haavainfektiolle, joiden hoito on vaativaa, kallista ja joihin liittyy merkittävää kuolleisuutta. Rintalastaliitoksen paraneminen häiriintyy 0,3–5 %:lla potilaista.

Rintalastaliitos löystyy vähitellen muutamien päivien aikana. Sen toteaminen ja hoito varhaisvaiheessa estäisi todennäköisesti osan vaikeimmista infektiokomplikaatioista sekä kivun kroonistumisen, mikäli rintalasta stabiloitaisiin ulkoisella tukiliivillä tai kiinnitysleikkauksella.

Tällä hetkellä sternotomian tukevuutta arvioidaan käsin tunnustelemalla, mitä voidaan pitää varsin epäherkkänä ja epäluotettavana menetelmänä. Kuvantamistutkimuksista tietokonetomografia on käyttökelpoisin, mutta se antaa vain välillistä tietoa liitoksen mekaanisesta tukevuudesta eikä tunnista varhaisvaiheen löyhyyttä riittävän tarkasti. Näin ollen tarvittaisiin tarkempi menetelmä rintalastaliitoksen tukevuuden arviointiin.

Mekaanisen värähtelyenergian etenemisen havainnointia käytetään laajalti tekniikan alalla kappaleiden eheyden määrittelyyn sekä jonkin verran ortopedisten ja hammaslääketieteellisten implanttien kiinnittymisen mittaamiseen.

Tämän tutkimuksen tavoitteena on ollut selvittää mekaanisen värähtelyn etenemisen mittaamisen soveltuvuutta sydänkirurgian jälkeisen rintalastaliitoksen tukevuuden arviointiin. Tutkimusryhmäämme kuuluvat insinöörit ovat suunnitelleet ja rakentaneet mittauslaitteiston tutkimuksia varten. Laite tuottaa matalataajuuksista värähtelyä rintalastan viereen ja rintalastaliitoksen yli kulkeutunutta värähtelyä mitataan erityisellä anturilla. Luuliitoksessa oleva löyhyys vaimentaa sen läpi kulkevaa värähtelyä.

Mittausmenetelmän soveltuvuutta on testattu kokeellisissa laboratorio-olosuhteissa, kliinisessä tutkimuksessa avosydänleikkauksesta toipuvilla potilailla sekä kokeellisessa

tutkimuksessa vainajilla, joiden rintalastaliitokset suljettiin tiukasti ja löyhästi. Tutkimusten perusteella voidaan todeta, että laite erottelee ehyen ja katkaistun kappaleen, toteaa rintalastaliitoksen tukevoituvan normaalin paranemisprosessin edetessä ja kykenee erottamaan tiukasti suljetun rintalastaliitoksen löyhästi suljetusta liitoksesta. Tutkimuksen neljännessä osatyössä tutkittiin rintalastaliitoksen löyhyyteen viittaavista oireista kärsiviä potilaita keskimäärin kolmen vuoden kuluttua leikkauksesta ja todettiin, etteivät oireet selity rintalastaliitoksen mekaanisella epävakaudella.

Original publications

I Joutsen A, Hautalahti J, Jaatinen E, Goebeler S, Paldanius A, Viik J, Laurikka J, Hyttinen J. (2019). A device for measuring sternal bone connectivity using vibration analysis techniques. Proceedings of the Institution of Mechanical Engineers, Part H: Journal of Engineering in Medicine. (Accepted for publication).

II Hautalahti, J., Beev, N., Hyttinen, J., Tarkka, M., & Laurikka, J. (2012). Postoperative sternal stability assessed by vibration: A preliminary study. The Annals of Thoracic Surgery, 94(1), 260–264.

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IV Hautalahti, J., Rinta-Kiikka, I., Tarkka, M., & Laurikka, J. (2017). Symptoms of Sternal Nonunion Late after Cardiac Surgery. The Thoracic and Cardiovascular Surgeon, 65(4), 325–331.

Abbreviations

CT	computed tomography
kPa	kilopascal
MEMS	micro-electronic mechanical system
MRI	magnetic resonance imaging
N	Newton
PC	personal computer
PLA	polylactic acid
PSD	power-spectral density
SVD	Sternal Vibration Device
US	ultrasound
QUS	quantitative ultrasound
3D	three-dimensional

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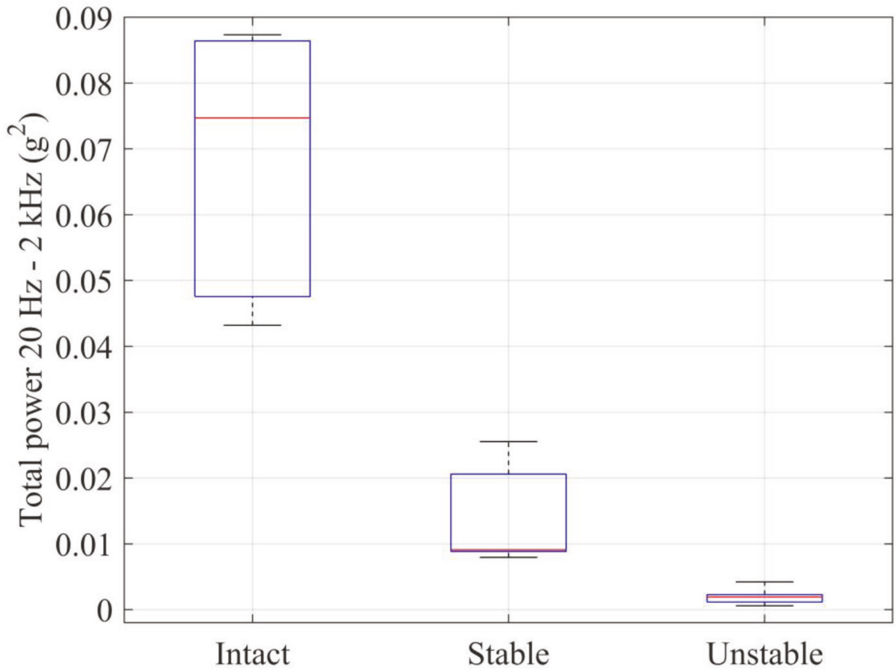

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1 Introduction

Sternotomy is the surgical division of the sternum to gain access to the organs inside the thorax for corrective surgery. The technique was described by Milton in 1897 but after Julian's publication on the subject in 1957 it became the standard exposure in human cardiac surgery (Julian, Lopez-Belio, Dye, Javid, & Grove, 1957). Now, over 60 years later, it is still the most common exposure in cardiothoracic surgery, offering a straightforward route for various procedures. The annual estimated number of sternotomies currently, for example, in the USA is over 500,000 (Allen et al., 2017; Jacobs et al., 2013; Writing Group Members et al., 2016) and about 3,400 in Finland

The incised sternum is routinely fixed using surgical steel wires which support the sternum and allow the bone to regenerate during the healing process. Stability of the sternum is essential for normal recovery after sternotomy (Losanoff, Richman, & Jones, 2002; Robicsek, Fokin, Cook, & Bhatia, 2000). Postoperative sternal instability occurs in 0.9–1.9% of patients (Doherty et al., 2014; Fu et al., 2016) and may lead to pain, disability and wound infection. Sternal instability is often associated with deep sternal wound infection (Fowler et al., 2003), but a sterile form of instability, i.e. dehiscence, is also known (Olbrecht et al., 2006). The exact percentage of deep sternal wound infections with concurrent sternal instability have not been reported in the literature so far; these complications are most often categorized as a single complication (Fu et al., 2016). Mediastinitis, deep sternal wound infection, is the gravest complication of sternotomy and is associated with mortality in 10% to 25% of cases (Sjogren, Malmsjo, Gustafsson, & Ingemansson, 2006). The incidence of mediastinitis varies from 0.5% to 5.0% (Fu et al., 2016). If the complication progresses to mediastinitis, the costs are vastly increased, up to 50,000 USD tripling the average hospital costs of cardiac surgical patients due to the need for prolonged hospitalization and multiple surgical procedures (Graf et al., 2011).

Awareness of the suboptimal stability of the sternotomy wound make it possible to take measures from conservative monitoring and advice to daily routine activities to support the sternum mechanically, either by using supportive thorax vests (Gorlitzer et al., 2013) or by surgical re-fixation before sternal fragmentation and infection. The pre-emptive approach to sternal stabilization has been recommended in the literature (Jacobson et al., 2015; Robicsek et al., 2000).

The current clinical practice of sternotomy stability evaluation is based on bimanual palpation (Francel, 2004) and static computed tomography imaging (Li & Fishman, 2003; Restrepo et al., 2009), which are inadequate in the detection of the early phases of instability after sternotomy. Hence a more precise method for sternotomy stability assessment would be of value. Besides imaging, a clinically applicable method for sternotomy stability assessments must be non-invasive.

Potential non-invasive biomechanical methods include vibration transmittance analysis, quantitative ultrasound, telemetric implants and radiostereometric analysis. The use of quantitative ultrasound for sternotomy assessment is excluded due to the damping effects of the covering soft tissue layer (Augat et al., 2014a). Telemetric implants for fracture healing assessments are currently available only for long bones and the experiences so far are relatively limited (Claes & Cunningham, 2009; Seide et al., 2012). Radiostereometric analysis requiring implantation of metallic landmarks on each side of the sternotomy and the need for specialized imaging techniques makes it cumbersome for sternotomy evaluation in clinical work (Madanat, Makinen, Moritz, Mattila, & Aro, 2005). However, Vestergaard et al. have recently published the first report on its use for sternal stability assessments (Vestergaard, Soballe, Hasenkam, & Stilling, 2018). Vibration transmittance analysis, on the other hand, has been widely used in engineering in the analysis of the integrity of machines and structures. In medicine vibration has been used for diagnosing bone fracture, monitoring fracture healing, assessing bone density and bone implant stability (Cunningham, 2004; Lippmann, 1932; Nokes, 1999; Pastrav, Jaecques, Jonkers, Perre, & Mulier, 2009; Sennerby & Meredith, 2008; Siffert & Kaufman, 1996). In light of the foregoing we conducted Studies I-III, in which we developed and tested the applicability of a new mechanical vibration transmission-based method for postoperative sternal stability assessment method (Sternal Vibration Device, SVD) using bench testing, cadaver measurements and clinical studies.

The problems associated with sternotomy are unfortunately not confined to the early period after surgery. The incidence of chronic pain years after sternotomy has been reported to be approximately 23–56% (Kalso, Mennander, Tasmuth, & Nilsson, 2001; Meyerson, J., Thelin, Gordh, & Karlsten, 2001; Eisenberg, Pultorak, Pud, & Bar-El, 2001; Taillefer et al., 2006; Lahtinen, Kokki, & Hynynen, 2006). Failed sternal reunion has been associated with increased pain intensity in the later postoperative period (Papadopoulos et al., 2013). The possible role of sternal instability in the late symptoms after sternotomy is not well researched. This motivated us to conduct Study IV, in which we examined patients having symptoms suggestive of sternal instability three years after surgery.

2 Review of the Literature

2.1 Anatomy of the sternum

The sternum is a tripartite 15 to 20 cm long bone in the anterior midline of the chest, made of cancellous bone with haematopoietic marrow. It consists of two main parts, the manubrium and the body, which are connected by a secondary cartilaginous joint that contributes to the movement of the ribs and normally ossifies in adulthood. The most cranial part, the manubrium, is about 5 cm wide in its upper half and 2.5 to 3.0 cm wide in its lower half. It receives the sternal ends of the clavicles in a shallow concave facet. The widest portion of the manubrium has bilateral costal incisurae that articulate with the first costal cartilage to form a primary cartilaginous joint. The second costal cartilage articulates with both the lower lateral ends of the manubrium and the body of the sternum, forming separate synovial joints. Sternocleidomastoid, sternohyoid and sternothyroid muscles attach the manubrium superiorly and pectoralis major muscle anterolaterally as seen in Figure 1 (Meyerson & Harpole, 2009; Shahani, 2005).

Due to the steeper slanting of the body of the sternum compared to the manubrium the articulation of these bones forms the sternal angle or the angle of Louis, Figure 2. The body is slightly more than twice the length of the manubrium. The articular facets for ribs two to seven lie along the lateral border of the body of the sternum. These make single synovial joints with the costal cartilages. The lateral border provides attachment to the anterior intercostal membrane and the internal intercostal muscles while the pectoralis major rises anteriorly. Weak sternopericardial ligaments pass into the fibrous pericardium. The cartilaginous xiphoid may be bifid or perforated, of 2 to 3 cm in length and usually ossifies in the fourth decade of life. The costoxiphoid ligaments prevent its displacement during diaphragmatic contractions (Meyerson & Harpole, 2009; Shahani, 2005).

The sternum is supplied by internal thoracic arteries and veins arising respectively from the subclavian arteries and veins. These vessels are part of the anastomotic chain that links the subclavian artery and brachiocephalic veins to the external iliac vessels. Internal thoracic vessels are also connected to the intercostal vessels, which are connected to the descending aorta and azygos system of veins (Meyerson & Harpole, 2009; Shahani, 2005).

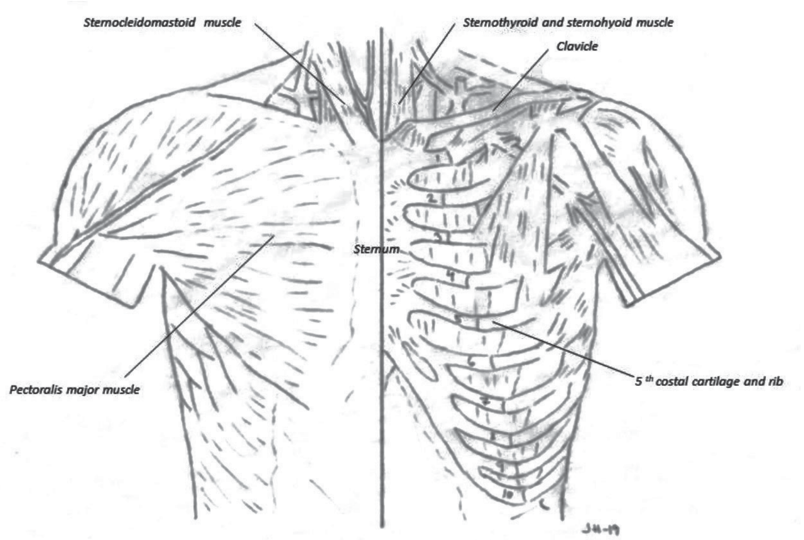

Figure 1. Anterior chest wall

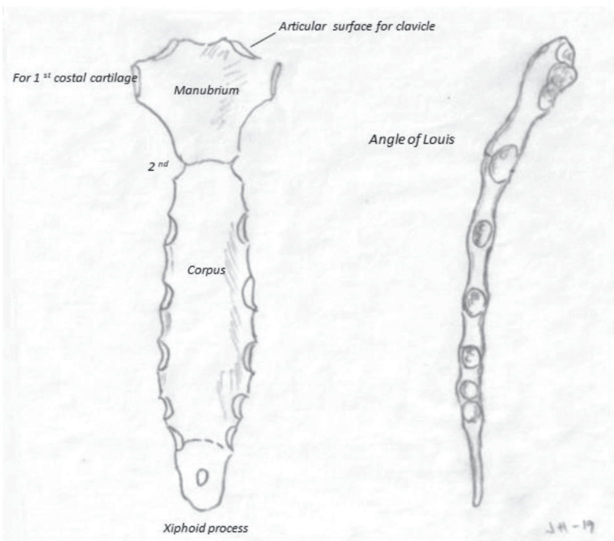

Figure 2. Sternum

2.2 Sternotomy

In sternotomy, the skin is incised from the jugular notch to just below the xiphoid process. The subcutaneous tissues and presternal fascia are incised to expose the periosteum of the sternum. The sternum is divided longitudinally either by a hammered sternum chisel or by a powered oscillating surgical saw in the anatomical midline, which is recommended to be marked by cautery before division to ensure reliable closure at the end of the operation (Robicsek et al., 2000). Haemostasis is made to the sternal edges using cautery, but its use should be limited to a minimum to prevent tissue necrosis (Losanoff, Jones, & Richman, 2002). The sternal edges are protected by sterile dressings and a sternal spreader is inserted. A spreader with wide blades distributing the spreading force along most of the sternal length is recommended to avoid sternal fracture and fragmentation. The thymic fat pad is divided up to the brachiocephalic vein. The pericardium is opened anteriorly to expose the heart.

At the end of the operation the haemostasis at the cardiac suture lines is inspected and secured. Drainage tubes are left in place, usually behind the heart in the posterior pericardium and in the anterior mediastinum. The pericardium is usually left open. The sternal halves are typically attached with six or more steel wires which are pulled and twisted tightly and cut short to make a strong connection between the sternal halves. The wire ends are bent to lie flat over the sternum. Presternal fascia, subdermal subcutis and skin are closed using absorbable sutures. The wound is cleaned and covered with sterile surgical dressings (Mill, Anderson, & Cohn, 2012).

2.3 Bone healing after sternotomy

2.3.1 Basic biology

Bone has the potential for regeneration throughout life. Regenerated bone has properties almost equal to the pre-fracture situation (Giannoudis, Einhorn, & Marsh, 2007). There are two different mechanisms of bone formation: Primary, direct or intramembranous and secondary, indirect or endochondral ossification. In the first process the cells of the compacted mesenchymal tissue differentiate into osteoblasts and form bone tissue directly. This entails absolute contact of the fragments and almost complete stability and minimization of the interfragmentary strains, rather compressive strain which can be achieved by rigid internal fixation (Egol, Kubiak, Fulkerson, Kummer, & Koval, 2004; Kwong & Harris, 2008). This process is rare. In the second process bone formation involves the formation of cartilaginous primordium, which then endures calcification and invasion by vessels, resulting in the formation of new bone by multipotent stem cells. Most often bone healing involves both intramembranous and endochondral ossification. The four essential elements for bone regeneration are growth factors, scaffolds, mesenchymal stem cells and mechanical stability (Giannoudis et al., 2007; Oryan, Monazzah, & Bigham-Sadegh, 2015).

The healing of osteotomy or fracture can be divided into three phases. The first phase is the inflammatory phase lasting for three to seven days after the injury (Oryan et al., 2015). The coagulation system is activated (Haverstock & Mandracchia, 1998), vasoactive and inflammatory mediators are elevated at the site of the injury (Mountziaris & Mikos, 2008). These mediators have chemotactic effects on other inflammatory cells. Macrophages phagocytize necrotic areas and release signalling factors which are responsible for the migration, recruitment and proliferation of mesenchymal stem cells and their differentiation (LaStayo, Winters, & Hardy, 2003). Primitive callus is developed, which reduces the uncontrolled mobility at the fracture site. Injury affects lymphocyte immune mechanisms leading to generalized immunosuppression, which increases susceptibility to infection. The lymphocytes are adversely affected by stress hormones, inflammatory cytokines and nitric oxide (Schaffer & Barbul, 1998). Macrophages in the inflammatory phase have a role in directing the differentiation of chondrocytes and regulating vascularization (Cho-Chung, 2006). The second, reparative or proliferative phase starts on the fourth day after the injury and lasts for up to several months. Organization of the fracture haematoma is seen. Angiogenesis and soft callus formation by chondrocytes are seen in the early phase (Pilitsis, Lucas, & Rengachary, 2002). Weak woven bone replaces the cartilage through endochondral bone formation resulting in the formation of hard callus (Haverstock & Mandracchia, 1998). Full vascularization is needed for bone formation and this is aided by numerous growth factors (Albrektsson & Johansson, 2001). The third, remodelling phase is reached months to years after surgery (Pilitsis et al., 2002). This phase involves the formation and mineralization of the callus and its replacement by mineralized bone. The bone is sculpted back to its original shape, size and biomechanical competency (Thomson, 2003). The irregular woven bone is resorbed by osteoclasts and converted into lamellar bone by osteoblasts. Lamellae are aligned in a direction parallel to the longitudinal axis of the greatest force and adequate loading is required to promote osteogenesis and direct the optimal geometric configuration of osteons (LaStayo at al., 2003; Mavcic & Antolic, 2012; Oryan et al., 2015).

There is no precise definition of when a fracture is healed. Usually bone healing is understood as the restoration of the bone's biomechanical function (Augat et al., 2014a). Radiographic findings do not correlate with biomechanical findings (Sano, Uhthoff, Backman, & Yeadon, 1999). The criteria for healed sternotomy are moreover imprecise and the time needed for the restoration of the sternum's ability to withstand physiological forces is not accurately known.

2.3.2 Stability – prerequisite for bone healing

Mechanical stability is essential for the formation of a callus that bridges the fracture site allowing loads to be transmitted across the fracture line. Stability is needed for the maturation phase of the lamellar bone. The current concept of biologic fixation has replaced the former AO system of fracture and osteotomy stabilization. The key elements of biologic fixation are relative stability, maximal respect of the soft tissue envelope and the vascularity around the fracture site. Relative stability means minimizing the interfragmentary gap size and keeping the interfragmentary strain below 10% (Augat et al., 1998; Giannoudis et al., 2007).

Strain is defined as the relative change in fracture gap. In other words, strain is a measure of deformation representing the displacement between particles in the body relative to a reference length. Bone strains mediate an adaptive remodelling response of the bone cell population. Stability determines the amount of strain at the fracture site and strain determines the type of healing that can occur at the fracture site. Primary bone healing occurs at strains less than 2%; secondary bone healing occurs when strain remains between 2% and 10%. Bone cannot be formed when strain is greater than 10% (Egol et al., 2004).

However, the optimal mechanical environment for fracture or osteotomy healing is controversial (Claes & Cunningham, 2009). Very rigid fixation prolongs the healing time and may cause osteopenia due to excessive protection from stress and/or due to decreased bone blood perfusion (Mavcic & Antolic, 2012; Bottlang et al., 2017). Based on in vivo and in vitro experiments, if secondary bone healing is the goal, movement of fragments along the axes is beneficial for the formation of soft callus. The amplitude of movements of fragments should be kept small, in the range of 0.2–1 mm and the fracture gap should be smaller than 2 mm. Later, the formation of hard callus is compromised by vigorous mechanical stimulation. Thus, motion should also be limited in the final phase of fracture consolidation (Jagodzinski & Krettek, 2007). In addition to the optimal mechanical strain, the frequency of strain application and the amount of repetition cycles on the site of the fracture or osteotomy is also critical. Higher frequency of mechanical strain application or larger number of repetition cycles result in increased bone mass at the healing fracture site, but only up to certain limit values beyond which no additional benefit is observed (Mavcic & Antolic, 2012). An interesting finding outlining the importance of certain degrees of motion is that femur fractures treated with titanium plates had 75% more callus than fractures treated with stiffer stainless-steel plates and greater callus formed in the region where interfragmentary motion was greatest (Lujan et al., 2010). A recent study reported that dynamic stabilization with active plates delivers significantly stronger healing than does conventional compression plating (Bottlang et al., 2017).

In the recent literature there is strong but indirect evidence that stability is also essential for successful bone healing after sternotomy (Robicsek et al., 2000; Fowler et al., 2003; Losanoff, Jones, & Richman, 2002; Meeks, Lozekoot, Verstraeten, Nelis, & Maessen, 2013). According to a study by Raman and co-workers it seems that locked plate sternotomy closure enhances healing better than wire closure (Raman et al., 2012). Theoretically, locked plating ensures strain enabling optimal secondary bone healing (Egol et al., 2004). However, the optimal mechanical environment of sternotomy is not known.

2.3.3 Role of sternal blood supply

The internal thoracic arteries and veins supply the sternum and median thoracic wall. The healing of sternotomy and soft tissues may be compromised if an internal thoracic artery is harvested for coronary artery bypass grafting. Internal thoracic artery harvesting compromises tissue perfusion in its proximity (Seyfer, Shriver, Miller, & Graeber, 1988; Fokin, Robicsek, Fokin, & Anderson, 2004) and may lead to wound complications, especially in the lower half of the sternum. There is an anatomical explanation for this phenomenon. Namely, the collateral arterial network is poorer in the lower half of the sternum than in the upper one (Berdajs, Zund, Turina, & Genoni, 2006; de Jesus & Acland, 1995). The role of internal thoracic artery graft harvesting technique (skeletonized versus pedicled) has also been actively studied and it seems advisable to save the collateral network (De Paulis et al., 2005). The arterial collateral network of internal thoracic arteries may also be disturbed by the sternal steel wires (de Jesus & Acland, 1995). If this potentially detrimental effect of the peristernally applied sternal closure steel wires to the sternal vascular network is considered, the clinically observed trend having most of the sternal wound complications in the lower half has two potential causes: disturbed perfusion and biomechanics, which is discussed in more detail in next chapter.

Due to the beneficial long-term patency and survival rates compared to vein grafts, especially to the left coronary artery system, bilateral internal thoracic arteries are recommended for patients undergoing coronary artery bypass grafting and having a predicted survival rate longer than ten years (Aldea et al., 2016; Neumann et al., 2019). The possible effect of bilateral internal thoracic artery harvesting on sternal healing and infection risk is of crucial clinical relevance. It has been studied actively but remains a controversial issue. Based on non-randomized studies the use of bilateral over single internal thoracic artery grafting has been associated with an increase in sternal dehiscence and an increased rate of mediastinitis in obese, diabetic and elderly patients (Toumpoulis, Theakos, & Dunning, 2007; Hemo et al., 2013; Elmistekawy et a., 2012). However, recent meta-analyses have reported minimized sternal wound risks of using bilateral ITA if skeletonized instead of pedicled technique is used for graft harvesting (Deo et al., 2013; Zhou, Zhu, Nie, & Zheng, 2019).

2.4 Biomechanics of sternotomy

2.4.1 Natural forces

In the early postoperative period, the only cohesive force to counteract sternal separation is the holding of closure steel wires. There are several different forces with disruptive action on the sternotomy. Lateral traction is produced when the chest expands during inspiration or transverse extension or abduction of the arms. The pectoralis muscles exert pull in opposite lateral directions. Lateral traction tends to spread the sternal halves apart thus being the main mechanical force leading to sternal instability. Upward movement of the arms has an axial as well as a lateral directed vector. The inspiratory expansion has an anterior-posterior bending component pivoted at the sternotomy suture line. Activation of the anterior abdominal wall muscles exerts an axial as well as a diagonal force on the sternal region and costae (McGregor, Trumble, & Magovern, 1999; Robicsek et al., 2000).

Valsalva forces are produced by inspiration, coughing or sneezing. Valsalva forces may produce dynamic and transient stress which may loosen the sternal fixation. Coughing places significant strain on the sternal closure site. End inspiratory intrathoracic pressure rises to 300 mmHg (i.e. 40 kPa). It increases during coughing creating lateral stress on the sternum. The lower half of the sternum is more prone to distraction. The forces may be as high as 150 kg across the sternum (Casha, Yang, Kay, Saleh, & Cooper, 1999; Dasika, Trumble, & Magovern, 2003; McGregor et al., 1999). Estimations of the magnitude of force exerted on an adult sternum due to intrathoracic pressure have been calculated using the Law of Laplace. According to this the tension (T) across the sternal midline equals the product of chest radius (R), chest length (L) and pressure (P) in chest ($T=RLP\approx 0.15$ m* 0.25 m *40 kPa≈1500N) (Casha, Yang, & Cooper, 1999).

Factors of importance for the holding of steel wires are strength, location and numbers of wires, as well as the tightness of the applied stress (force/area) exerted. The tighter the wires are twisted and the narrower they are, the more likely it is that they will cut through the bone (Robicsek et al., 2000).

2.4.2 Experimental findings

McGregor and co-workers conducted an important biomechanical study in 1999. Using cadaver sternums and seven single steel wire closures they found that the first step in sternal instability is the cutting of the steel wires into the bone and that the lower part of the sternum was weaker than the upper part. The force needed to achieve distraction in a lateral direction was smallest compared to anterior-posterior or cranio-caudal direction (McGregor et al., 1999).

Experimental fatigue testing on a six-wire sternotomy has shown that a lateral force of 10 kg per wire or 589 N causes the wire to cut through bone (Casha et al., 2001) while a force of 20 kg per wire or 1176 N would result in the untwisting of stainless-steel no. 5 wires (Casha et al., 1999) with either mode of failure leading to sternotomy dehiscence. Casha and co-workers measured chest wall forces on 40 kPa coughing using a finite element analysis. They compared normal ellipsoid chest model to barrel chest mimicking chronic obstructive pulmonary disease. They found that lateral chest wall forces were significantly higher in the barrel shaped chest (660 N vs. 827 N). They observed a significant relationship between circumferential rib load and rib level. The distracting circumferential rib forces on a 40 kPa cough were greater towards the lower part of the sternum and exceeding the wire cut-through force at the 5th–7th costal level when six single sternal steel wires were used for sternotomy closure. Adding just one extra wire to the lower end of the sternum strengthened the closure significantly. These workers suggested that there are three mechanisms leading to greater distraction at the lower end of the sternum. Firstly, the circumferential forces are greater at the lower level as the model predicts that chest wall tension is proportional to the tangential radius at the relative chest level. Secondly, there is a concentration of forces in the lower part of the sternum due to the proximity of the attachment of the 5th, 6th and 7th costal cartilages on the sternum. Thirdly, the 7th rib carries additional forces from the 8th, 9th and 10th ribs through the costal margin (Casha et al., 2014).

Wangsgard and co-workers assessed the fatigue performance of three sternotomy closure techniques mimicking the loads focused at sternotomy during the normal healing process of six weeks. They used polyurethane foam sternal models and applied cyclic loading in a uniaxial direction (lateral distraction and longitudinal shear). They found the stainless-steel cable the most resistant to failure compared to Pectofix Dynamic Sternal Fixation plates or figure-of-eight steel wire closure (Wangsgard, Cohen, & Griffin, 2008).

Biomechanical experimental studies on cadaver and polyurethane sternal models have demonstrated the superior stability of plate and screw fixation over steel wire fixation (Ozaki, Buchman, Iannettoni, & Frankenburg, 1998; Pai et al., 2005).

2.4.3 Implications regarding physical restrictions after sternotomy

Patients are normally instructed on activity restrictions in an attempt to prevent sternal complications after sternotomy. Most often these include restrictions on upper limb and trunk movements as well as lifting heavy objects for 8 to 12 weeks following surgery (Brocki, Thorup, & Andreasen, 2010). The role of restrictions on physical activity after sternotomy is clinically interesting and relevant but insufficiently understood. Due to the high forces exerted on the sternum during sneezing as compared to bench press-up exercise, the restrictions on physical activities after sternotomy have been questioned (Adams et al., 2014). A randomized trial in 2018 compared usual restrictive sternal precautions to less restrictive precautions (i.e. pain and discomfort as the safe limits for upper limb use in daily activities). The study groups experienced similar effects on physical recovery, pain and quality of life during the follow-up of six weeks indicating that restrictions may not be necessary (Katijjahbe et al., 2018). A recent meta-analysis concluded that resistance training, in isolation or when combined with aerobic training, may lead to greater improvements in physical and functional recovery following cardiac surgery via median sternotomy (Pengelly et al., 2019). A recent observational study showed that motion between the sternal halves could not be detected using ultrasound one week, six weeks or three months postoperatively unless the patients coughed or made conventionally prohibited movements (i.e. elevated upper limbs uni- or bilaterally) during ultrasound evaluation (Balachandran et al., 2019). Further studies are needed on this issue.

2.5 Sternal fixation methods

2.5.1 Steel wires

The incised sternum is usually fixed using surgical steel wires. Steel wire closure is an easy and inexpensive method and can be done rapidly. The steel wires support the sternum and allow the bone to regenerate during the healing process.

The standard way to close the sternum is to put two wires through the manubrium (i.e. transsternally) and four or five wires around the body (corpus) of the sternum (i.e. peristernally). Transsternal passage can be used for the whole sternum. The peristernal route seems to lead to stronger sternal closure (Casha et al., 2001; Losanoff et al., 2004). The wires can be put lateral to the sternocostal joint in case of fracture in the intercostal part of the sternum.

Numerous different steel wire configurations have been described in the literature (Losanoff et al., 2002). The most used methods are single wire loops, wires in figure-of-eight configuration and double wires. According to the most recent literature, there is no clear difference between sternotomy closures done by single wire loops or by figures-of-eight. When figures-of-eight are used, at least four are recommended (Almdahl, Halvorsen, Veel, & Rynning, 2013; Casha et al., 1999; Khasati, Sivaprakasam, & Dunning, 2004; Kiessling et al., 2005; Ramzisham et al., 2009; Tekumit, Cenal, Tataroglu, Uzun, & Akinci, 2009). Rationally, the number of single loops correlates with avoidance of sternal complications: according to the literature, at least seven to eight single loops should be used for proper sternal closure (Friberg, Dahlin, Soderquist, Kallman, & Svedjeholm, 2006; Kamiya et al., 2012; Shaikhrezai, Robertson, Anderson, Slight, & Brackenbury, 2012). According to one cadaver study and one clinical study double wire closure is superior to single loops (Kiessling et al., 2005; Losanoff, Basson, Gruber, Huff, & Hsieh, 2007).

Steel wires can be used longitudinally to reinforce the lateral part of the sternum (Robicsek sternal weave). The prophylactic effect of this method for reducing sternal complications among high-risk patients has been somewhat controversial (Aykut, Celik, & Acikel, 2011; Molina, Lew, & Hyland, 2004; Schimmer et al., 2008).

2.5.2 Bands

Different kinds of bands have been tested and used for sternotomy closure. According to bench tests they are inferior to standard steel wires in terms of stability (Casha et al., 1999), but seem to be less prone to cut through the bone (Casha et al., 2001). The clinical evidence supporting the use of sternal bands is limited (Grapow, Melly, Eckstein, & Reuthebuch, 2012; Stelly, Rodning, & Stelly, 2015; Marasco et al., 2018).

2.5.3 Plates and screws

In general, plating decreases motion at the osteotomy site, thereby reducing postoperative pain and improving the rate of primary bone healing compared to that of steel wire fixation. Plate and screw fixation have almost completely replaced wire fixation in orthopaedic, craniomaxillofacial, otolaryngologic, oral and neurologic surgery (Ozaki et al., 1998). Sternotomy closure using plates and screws correlates with better healing than with standard steel wire fixation (Allen et al., 2017; Chase, Franklin, Guest, & Barker, 1999; Mitra et al., 2004; Raman et al., 2012; Sargent, Seyfer, Hollinger, Hinson, & Graeber, 1991; Song, Lohman, Renucci, Jeevanandam, & Raman, 2004) or modified parasternal reinforced wire closure (i.e. the Robicsek technique) (Park, Kuo, Young, & Wong, 2017). A recent meta-analysis concluded that plate and screw fixation may lead to reduced sternal complications, improved perioperative survival and decreased length of hospital stay in patients at high risk for such events (Tam et al., 2018).

Plating is thought to impair sternal perfusion less than steel wire closure. Plate fixation accelerates sternal bone healing evaluated by computed tomography at 3 and 6 months postoperatively compared to standard wire closure. It also reduces postoperative pain, which has been interpreted as an outcome of better stability (Raman et al., 2012). According to a recent study by Allen and co-workers, sternotomy closure with plate fixation resulted in no additional costs compared to wire fixation at 6 months after surgery but resulted in better sternal healing and fewer sternal complications (Allen et al., 2017).

2.5.4 Bone cement and bioglass

Various bioadhesive materials can be utilized in surgical applications. Bone cement is widely used in dental surgery and orthopaedics for implant fixation (Alhalawani & Towler, 2013). Calcium phosphate cement has been used to control bleeding after sternotomy in osteoporotic sternums (Muehrcke, Shimp, & Aponte-Lopez, 2009). A triglyseride based porous adhesive cement (Kryptonite bone cement) has been proven to enhance sternotomy wire fixation (Bayramoglu et al., 2013; Fedak et al., 2010). The use of cements in sternal fixation may have potential in the future but more research work is needed to prove the concept (Alhalawani & Towler, 2013).

Bioglasses are surface reactive glass-ceramic biomaterials. For example, tantalum-containing bioglass seems promising for sternal fixation in addition to traditional steel wires since it is bio-inert offering favourable biological environment for adhesion, growth and differentiation of human cells. In addition, it has shown antibacterial and antifungal properties making it very interesting for sternotomy fixation (Alhalawani, Mehrvar, Stone, Waldman, & Towler, 2017). According to a recent biomechanical study bioglass-enhanced sternal fixation was more resistant to cyclic tensile loading than steel wire fixation (Mehrvar et al., 2019). However, more evidence is needed to determine the role of bioadhesive materials in sternotomy closure.

2.6 Disrupted healing after sternotomy

2.6.1 Instability: dehiscence and nonunion

Sternotomy junction needs to be mechanically stable. Postoperative sternal instability is described as motion between sternal halves following median sternotomy. Sternal instability up to six weeks after the operation is defined as dehiscence (El Oakley & Wright, 1996; Robicsek et al., 2000). Sternal nonunion is a case of instability in which the two halves remain partially or completely separated more than six weeks after surgery. Usually the lower third of the sternum is affected (Robicsek et al., 2000). In the orthopaedic literature, nonunion of a fracture is defined as the cessation of both the periosteal and endosteal healing process after three months. The fracture shows no visibly progressive signs of healing. There is a gap between the fragment ends and motion between the fragments. Radiographically nonunion is characterized by sclerosis and rounding of fragment edges. It can be hypertrophic or atrophic (Randolph & Vogler, 1985).

The loosening of sternotomy usually progresses over a few days as the patient moves and coughs. At the early sequelae of sternal instability, the separated sternal edges rub against each other causing pain and clicking. This causes pain in patients lying on their sides. Respiratory pain, especially expiratory pain, is typical for sternal instability (Francel, 2004). The fixation steel wires cut deeper into the bone as the instability increases. The sternum may fracture or be cut into several pieces, which, again, may become infected by the skin bacteria if the skin and soft tissues are also separated by the motion. Respiratory failure may develop due to a vicious cycle of pain, tachypnoea, hypoventilation, atelectasis and pneumonia (Boiselle, Mansilla, White, & Fisher, 2001; Meeks et al., 2013; Robicsek et al., 2000).

The estimated incidence of poststernotomy instability is from 0.6 to 2.8% (Bryan, Lamarra, Angelini, West, & Breckenridge, 1992; Doherty et al., 2014; Harjula & Jarvinen, 1983; Olbrecht et al., 2006). Risk factors for sternal wound instability include diabetes, chronic obstructive pulmonary disease, obesity, smoking, older age, immunosuppressive state, renal failure, osteoporosis, re-sternotomy due to bleeding, and prolonged cardiopulmonary bypass (Losanoff et al., 2002; Robicsek et al., 2000) as well as paramedian sternotomy (Jacobson et al., 2015; Zeitani et al., 2006; Zeitani et al., 2008). The use of bone wax for sternal haemostasis may predispose to sternal complications due to the insoluble nature of the bone wax, its inability to be metabolized or resorbed, and its indefinite persistence at the site of application. The published adverse effects of bone wax include inhibition of osteogenesis, infection, foreign body granulomata, local inflammation, and pain (Nelson, Buxton, Luu, & Rissing 1990; Wellisz, Armstrong, Cambridge, & Fisher, 2006). A human cadaveric study showed impaired sternal healing manifesting in chronic inflammation persisting as long as 10 years after application (Sudmann, Bang, & Sudmann, 2006). Due to the side effects of bone wax substitutive mechanical haemostatic agents have been investigated. One of the most widely used of these is Ostene™, which is made of water-soluble copolymers. It is relatively inexpensive and easy to use. In a study by Vestergaard and colleagues, it seemed not to inhibit sternal bone healing in porcine model as compared to bone wax (Vestergaard et al., 2015).

Unstable sternum in the early postoperative period is a risk factor for mediastinitis i.e. deep sternal wound infection (Fowler et al., 2003; Losanoff et al., 2002). Sternal instability most often precedes infection (Meeks et al., 2013) but the question of whether instability or infection is the primary underlying problem in sternotomy complications is unresolved (Losanoff et al., 2002).

In the later postoperative period nonunion manifests as chronic discomfort, clicking and a sensation of abnormal motion (Robicsek et al., 2000). The refixation of unstable sternotomy follows the same principles as secondary closure after wound infection and is discussed in the next paragraph.

2.6.2 Infection

The reported incidence of deep sternotomy wound infection ranges from 0.3% to 5%. It is a major cause of morbidity and mortality of 10–25%, and even up to 35% following cardiac surgery (El Oakley & Wright, 1996; Hillis et al., 2011; Satta, Lahtinen, Raisanen, Salmela, & Juvonen, 1998; Sjogren et al., 2006). The risk factors for sternal wound infection are practically the same as for sternal instability mentioned in the previous paragraph.

It is estimated that most poststernotomy infections involve the superficial tissues not affecting the bone or mediastinal space. In these cases, sternotomy is stable. However, these cases may lead to sternal instability due to the infection process impending bone healing. Sternal instability with signs of infection usually signifies a deep sternal wound infection (Francel, 2004).

According to the U.S. Centers for Disease Control and Prevention guidelines deep sternal wound infection, i.e. mediastinitis, is defined based on at least one of the following:

a) an organism isolated from cultures of mediastinal tissue or fluid; b) evidence of mediastinitis seen during a surgical operation or histopathologic examination; or c) one of the following: chest pain, sternal instability and temperature >38°C, together with purulent discharge from the mediastinum, an organism isolated from blood culture or mediastinal area drainage, or mediastinal widening on x-ray examination (Horan, Andrus, & Dudeck, 2008).

Cardiac surgical patients have impaired immune responses due to cardiopulmonary bypass and may suffer from other predisposing factors, such as diabetes mellitus or tobacco smoking. They also have increased number of potential ports of entry for bacterial pathogens which causes a substantial infection risk to this patient population. The role of sternal instability in relation to the infective process is debatable. Exact percentages of deep sternal wound infection with concurrent sternal instability are not available in the literature so far as these complications are most often categorized as a single complication (Fu et al., 2016). Inadequate mediastinal drainage leading to culture medium to bacterial growth has been suggested as a cause of infection. Most postoperative mediastinitis cases show evidence of infection within 14 days. The symptoms of wound infection include increased wound pain, tenderness, swelling, redness and discharge. There may be clicking of sternal edges. Fever, chills and poorer general condition may be signs of the septic course of the infection (El Oakley & Wright, 1996).

Postoperative infection triples (Graf et al., 2011) or quadruples (Taylor et al., 1990) the costs of surgical treatment depending on the analysis. The excess costs of mediastinitis after coronary artery bypass graft surgery amounted to over 31,000 USD per patient in 2001 (Jenney, Harrington, Russo, & Spelman, 2001).

There are several effective measures to prevent sternal wound infection. Intravenous antibiotic prophylaxis initiated before surgery reduces the postoperative rates of infections and in turn associated morbidity and mortality (Kreter & Woods, 1992). Other means for infection prevention in cardiac surgery include meticulous pinpoint haemostasis, proper sternum fixation, avoidance of excessive use of bone wax, strict aseptic technique and skeletonization of the internal thoracic arteries instead of pedicled harvesting technique (Sa et al., 2013). Local antibiotic products have also been used for infection prevention in various surgical applications. These implants deliver high concentrations of antibiotic locally within the wound, thereby preventing the systemic adverse effects and at the same time lowering the risk of acquired bacterial resistance to antibiotics (Raja, 2012). Implantable gentamicin-collagen sponges have been tested and shown to decrease wound infections in patients undergoing abdominal, vascular and breast surgery (de Bruin, Gosselink, & van den Harst, 2012; Costa Almeida, Reis, Carvalho, & Costa Almeida, 2014; Yetim, Ozkan, Dervisoglu, Erzurumlu, & Canbolant, 2010). According to a recent meta-analysis including four randomized controlled studies and ten observational studies, altogether 22,135 patients, implantable gentamicin-collagen sponge significantly reduced the risk of sternal wound infection after cardiac surgery by nearly 40% but did not reduce mortality.

The extent of infection reduction may be attenuated in patients receiving bilateral internal thoracic artery grafts (Kowalewski et al., 2015). In addition to gentamicin, vancomycin and bacitracin have been tested in sternal wound infection prophylaxis with promising results. In a recent study, cardiac surgical patients treated with topical vancomycin applied as a slurry to the cut edges of the sternum (1075 patients) were less likely to develop superficial and deep sternal wound infection compared with a matched control group (2190 patients) (Lazar, Ketchedijan, Haime, Karlson, & Cabral, 2014). Another study including 2,455 patients reported a 6-fold reduction in the risk of mediastinitis after cardiac surgery in patients in whom bacitracin ointment was applied to the sternotomy incision after closure (MacIver, Stewart, Frederiksen, Fullerton, and Horvath, 2006).

Conservative treatment of sternal wound infection consists of antibiotic therapy and possible drainage of the wound. The failure rate of conservative treatment is as high as 40% (De Feo et al., 2001) and can be used only in cases of superficial sternal wound infection.

Surgical wound revision, application of continuous antibiotic irrigation tubes combined with immediate sternotomy closure was described by Shumacker in 1963 (Shumacker & Mandelbaum, 1963). The advantage of this method is the immediate stability of the anterior chest after the surgery and in successful cases the length of hospital stay is short compared to other treatment modalities. Due to the high infection recurrence rate immediate primary closure is not used in current practice (Fleck et al., 2004).

Radical excision of infected sternum combined with omentoplasty and immediate wound closure was described in 1976 (Lee, Schimert, Shaktin, & Seigel, 1976). The advantages of omentum are easy handling and plasticity, immunologic and angiogenic activity and its ability to remove secretions (Graeber & McClelland, 2004). The disadvantages of omental flap include the possibility of infection spreading to the abdominal cavity, the risk of hernias and disturbance of the duodenal passage (Francel, 2004; Ghazi, Carlson, & Losken, 2008).

The use of muscle flaps in the treatment on mediastinitis was described in 1980 (Jurkiewicz, Bostwick, Hester, Bishop, & Craver, 1980). Prior to flap closure the infection must be eradicated. Muscle flaps bring well perfused vital tissue to cover the wound. Pectoralis major and rectus abdominis are most often used muscle flaps. Muscle flaps also play a role in the mechanical stabilization of sternotomy. By detaching the pectoralis muscles and suturing the two muscles together the laterally distracting force is reversed, making the force they exert cohesive instead of disruptive (Robicsek & Hamilton, 1989). The use of muscle flaps has improved the results of mediastinitis treatment (Davison, Clemens, Armstrong, Newton, & Swartz, 2007; Francel, 2004).

Vacuum assisted closure has been used in the treatment of sternal wound infections since 1999 (Obdeijn, de Lange, Lichtendahl, & de Boer, 1999). Most often vacuum assisted closure acts as a bridge to recovery from infection and secondary sternal closure. In combination with muscle flap closure it is currently widely used for the treatment of sternal wound infection. Vacuum assisted closure increases wound perfusion, granulation formation and stabilizes the anterior thorax. It reduces the number of bacteria, secretions, swelling and pain in the wound region (Sjogren et al., 2006). Compared to conventional treatment (antibiotic irrigation; open packing) vacuum assisted closure has resulted in decreased mortality and shorter hospital stay (De Feo et al., 2001; Vos, Yilmaz, Sonker, Kelder, & Kloppenburg, 2012). The American College of Cardiology Foundation/American Heart Association (ACCF/AHA) guideline in 2011 gives class I recommendation for treating deep sternal wound infection with aggressive surgical debridement with vacuum assisted therapy as an effective adjunctive therapy and primary or secondary closure with muscle or omental flap (Hillis et al., 2011).

2.6.3 Prolonged pain

The reported incidence of chronic nonanginal poststernotomy pain is 11–56% one year after cardiac surgery (Eisenberg et al., 2001; Kalso et al., 2001; Kleiman, Sanders, Nemergut, & Huffmyer, 2017; Lahtinen et al., 2006; Taillefer et al., 2006). Depending on the definition it lasts over three months and presents as numbness, allodynia, palpation tenderness or constant pain (Kleiman et al., 2017). Factors that may aggravate poststernotomy pain include pressure on the site, clothes rubbing against the scar, movement, deep breathing, coughing, weather or temperature change and stress (Eisenberg et al., 2001).

The aetiology of chronic non-anginal post-sternotomy pain is not well understood. Suggested causes are osteomyelitis of the sternum, fracture or incomplete healing of bone, sternocostal chodritis (Weber & Peters, 1986), costal fracture (Greenwald, Baisden, & Symbas, 1983; Woodring, Royer, & Todd, 1985), injury of the brachial plexus (Sharma, Parmley, Sreeram, & Grocott, 2000; Vahl, Carl, Muller-Vahl, & Struck, 1991), entrapment of nerves due to sternal wire sutures (Defalque & Bromley, 1989; Eastridge, Mahfood, Walker, & Cole, 1991) or hypersensitivity reaction against the metal wire (Eastridge et al., 1991; Fine & Karwande, 1990; Norgaard, Andersen, Lavrsen, & Borgeskov, 2006). Dissection of the internal thoracic artery for coronary graft has earlier been suggested to increase the risk of chronic post-sternotomy pain (Cohen et al., 1993; Moore, Follette, & Berkoff, 1994; Vahl et al., 1991). Later studies have challenged the theory (Kalso et al., 2001; Meyerson, J. et al., 2001; Taillefer et al., 2006). Essential in the differential diagnosis of poststernotomy pain is exclusion of recurrent ischaemic angina, infection and sternal instability (Norgaard et al., 2006). Publications so far have not reported the sternal stability of symptomatic patients. Thus, it is possible that sternal instability plays a role in the aetiology of post-sternotomy pain.

Slowly emerging signs of sternotomy bone healing in computed tomography (Bitkover, Cederlund, Aberg, & Vaage, 1999; Raman et al., 2012) and frequently prolonged pain after sternotomy (Eisenberg et al., 2001; Kalso et al., 2001; Taillefer et al., 2006) suggests that optimal mechanical stability is not always achieved by standard steel wire closure.

2.7 Current methods for assessing sternotomy stability

In clinical practice the assessment of sternal stability is done by manual palpation. If imaging is needed, computed tomography is the modality of choice. However, these both have limitations in detecting early instability of sternotomy. The findings of palpation and CT are combined with the clinical state of the wound (e.g. redness, swelling, pain, discharge) and the condition of the patient (including haemodynamic status, body temperature, white blood cell count and the amount of c-reactive protein in the blood) to conclude the healing state of the sternotomy.

Plain radiography is no longer feasible in the current era of clinical imaging. So far ultrasound (US) has rarely been used for bone healing monitoring or sternotomy stability assessments, but it certainly has potential for both indications. Magnetic resonance imaging (MRI) and scintigraphy are rarely used for sternotomy evaluation.

2.7.1 Palpation

The diagnosis of sternotomy instability is based on palpation, which is a simple method and easily used in clinical everyday routine. Regional tenderness and motion between sternal halves are estimated by firm bimanual compression (Francel, 2004). Clicking sounds or sensations of grinding of the edges of the sternal bone during chest wall motion are typical signs of sternal instability. This kind of evaluation is subjective and prone to misinterpretations. The provocative force cannot be standardized. In the literature there is only one description for the classification of sternal instability by palpation. This five-point examination scale was created by a group of physiotherapists, but the concept is neither used in clinical practice nor is the paper indexed in any medical databases (El-Ansary, Adams, Toms, & Elkins, 2000).

2.7.2 Radiography

Imaging of a healing bone provides a non-invasive and instructive reproduction of a repair progress and the healing status of the bone. Interpretation of this reproduction is qualitative and provides an indirect and surrogate measure of the mechanical stability of the healing bone. The attenuation of X-rays in bone tissue depends heavily on the amount of mineral that must be penetrated by the X-ray beam. The increasing calcification of the fracture callus and the fracture gap during the progress of healing can therefore be observed by an increase in X-ray attenuation (Augat, Morgan, Lujan, MacGillivray, & Cheung, 2014b). Generally, the relationship between radiological signs of bone healing and the mechanical properties of the healing fracture are not clear (Watanabe, Nishizawa, Takenaka, Kobayashi, & Matsushita, 2009), but the formation of fracture callus visible on standard radiographs is of relevance to the fracture's mechanical environment (Augat et al., 2014b). There are several radiological scorings for the evaluation of bone defects on radiographs, but they have not been used for sternotomy evaluation. Scores are based on the bone formation occupying the defect, evaluation of bone union, bridging, length of fracture lines and existence of remodelling. Automated computerized algorithms analysing fracture callus in digital radiographs can be used to overcome the inter-physician variability of 20–25% of the method (Augat et al., 2014b; Oryan et al., 2015).

Plain radiographs in the anteroposterior or posteroanterior projection may detect air in the mediastinum suggesting mediastinitis and a sternal stripe, which reflects air between the separated sternal halves. Sternal wire displacement seen in chest radiographs has been reported to be helpful in patients with sternal dehiscence. Fractures and pseudoarthrosis may also be detected (Boiselle et al., 2001; Escovitz, Okulski, & Lapayowker, 1976; Vogel, Nagele, & Bleese, 1982). Radiographic signs of sternal dehiscence have been detectable even before the clinical diagnosis (Peivandi et al., 2006). However, the accuracy of the plain x-ray is low compared to computed tomography and it has practically disappeared from current clinical practice for the evaluation of sternal healing or the exclusion of sternal instability.

2.7.3 Computed tomography

Computed tomography (CT) is currently the most useful and informative imaging modality for assessing healing of sternotomy. It can reveal gaps and displacement of steel wires (Restrepo et al., 2009). However, because bone formation occurs slowly, it is far from being an optimal method for evaluating the healing of the sternotomy within the first months after surgery. According to Bitkover et al. none of the computed tomographic scans showed radiological signs of healing at three months after surgery (Bitkover et al., 1999). These findings are parallel with the experimental findings on the healing of beagle femoral osteotomies, i.e. there was no significant correlation between radiographic and biomechanical findings up to 16 weeks after the operation (Sano et al., 1999). Also, Raman et al. found that signs of sternal union are infrequent in CT scans three months after sternotomy (Raman et al., 2012). At six months, half of the symptom-free patients are healed completely according to CT. Compared to plain radiograph CT is better at revealing gaps between the sternal halves. Gaps of less than 3 mm are usually not associated with clinical instability (Bitkover et al., 1999). However, progressive widening of the incisional gap is indicative of instability.

Early sternal osteomyelitis is difficult to differentiate from minor sternal irregularities caused by the bone saw and anatomic variants. CT can show subtle erosions, periosteal reaction, sharply emarginated sclerosis and swelling in the adjacent soft tissues in sternal osteomyelitis. Sternal union should be complete one year after the procedure and thus it can be regarded as the current gold standard in evaluating sternal healing years after sternotomy (Li & Fishman, 2003).

The main concerns in using CT are radiation and costs. The average radiation dose of lung computed tomography in Finland in 2017 was 4 mSv, which is equivalent to 130 thorax PA plain radiographs or 16 months' background radiation (Radiation doses of radiographic examinations 2017). The most advanced CT technology using iterative reconstruction can reduce the radiation dose to as low as 1.4 mSv (den Harder et al., 2015). The radiation dose, especially when serial imaging is needed, must be kept in mind even if most adult cardiac surgical patients are elderly. The cost of native chest CT, for example in our institution, has come down to 164 Euros, which is nevertheless considerable. Lastly, when contemplating the phenomenon in question, early sternal instability, the static nature of CT is a drawback. Serial scanning within few days may give a vague indication of the instability, but then the costs and radiation dose are higher.

2.7.4 Ultrasound

US has obvious potential generally in fracture healing monitoring: it can reveal the initial stages of callus formation earlier than radiography; 3D ultrasound enhances image interpretation and can be combined with the position sensing device; the vascularity can be detected using power Doppler US. However, no large multicentre studies comparing ultrasound and radiography in fracture healing monitoring are currently available (Chachan, Tudu, & Sahu, 2015; Augat et al., 2014b). These features could also be useful in sternotomy healing assessments.

Ultrasound has been used to detect movement in the sternotomy junction in a couple of studies, but it is not utilised in clinical practice. El-Ansary and colleagues used US under mechanical loading in the evaluation of gross sternal instability years after surgery (El-Ansary, Waddington, & Adams, 2007). However, the actual benefit or extra information can be questioned when gross, i.e. even clinically obvious, sternal instability is examined by ultrasound. In 2017 a preliminary study on determining the reliability of ultrasound for measuring postoperative sternal micromotion was published (Balachandran et al., 2017). In 2019 the same Australian group published an observational study of 75 patients and this can be regarded as a proof-of-concept since the measured distances seemed to be very accurate (Balachandran et al., 2019). The concept is interesting and must be studied in more detail keeping in mind that extra manipulation of the healing soft tissues may increase the risk of infection.

2.7.5 MRI and scintigraphy

MRI is the modality of choice for evaluating for sternal osteomyelitis; it has higher reported sensitivity and specificity than other modalities. Scintigraphy may also be used for the evaluation of chronic osteomyelitis. However, due to the high costs, limited availability compared to computed tomography, excess of time needed and the artefacts that the sternal closure steel wires cause to the MRI images, they are seldom used in clinical practice for sternotomy stability assessments (Randall et al., 1993; Hota, Dass, Erkmen, Donuru, & Kumaran, 2018).

2.8 Potential biomechanical methods for assessing sternotomy stability

Non-invasive biomechanical methods may offer new solutions for clinical sternal stability evaluation and are discussed in more detail. Invasive techniques are naturally usable only in experimental settings.

2.8.1 Vibration

2.8.1.1 Principle

The mechanical properties of a medium can be evaluated by studying its dynamic properties. The stimulus applied to the medium may be a mechanical impulse or vibration causing a pressure wave propagation in the medium. Vibration is mechanical oscillation about a fixed reference point. The analysis of the transmitted pressure waves can be performed as analysis of the wave propagation or by resonant frequency analysis. The underlying principle is that the response to mechanical stimulus depends on the geometry of the studied object (shape and size), its material properties (e.g. density, stiffness,) and its boundary conditions (in the case of bones: soft tissues covering the studied bones, joints, cartilages, etc). Localized defects or discontinuities of the studied object affect the measured response (Augat et al., 2014a).

Externally applied low-power low-frequency mechanical vibration excitation is widely used for equipment fault detection in engineering, particularly in the experimental analysis of machines and structures. Vibration can also be used to obtain diagnostic information from bones non-invasively and in vivo. The natural frequencies at which long bones resonate are at the lower end of the audible spectrum (100–500 Hz) (Kaufman et al., 1990; Lippmann, 1932; Nokes, 1999; Siffert & Kaufman, 1996). The simplest way to evaluate the existence of bone fracture or its repair is acoustic registration (Lippmann, 1932; Moore, 2009). The intensity of the propagating sound wave decreases after a fracture and sounds dull and muffled in fractured bones compared to the intact contralateral bone. Both theoretical and experimental studies show a considerable shift of natural resonant frequencies towards lower bands in fractured bones (Kaufman et al., 1990). When the frequency response of the fractured bone coincides with that of the uninjured bone and approaches the natural frequency of intact bone, the patient can be considered to have achieved full healing (Augat et al., 2014a; Cunningham, 2004). Vibration has also been used to assess bone density and dental or orthopaedic implant stability (Bediz, Nevzat Ozguven, & Korkusuz, 2010; Nokes, 1999; Pastrav et al., 2009; Sennerby & Meredith, 2008).

2.8.1.2 Vibration modalities, actuators and sensors

There are several types of low-frequency excitation that can be used for automated analysis of mechanical systems. The input excitation determines the devices used, the specifics of the actuators and sensors, signal acquisition and processing methods, as well as the subsequent analysis chain. Placement of actuators and sensors is essential for measurements.

Mechanical excitation may be applied as a short duration impulse, for example by manual percussion, hammer or electromechanical tapper (Doemland, Jacobs, Spence, & Roberts, 1986; Folman, Goshen, Gepstein, Sevi, & Liberty, 1993; Sonstegard & Matthews, 1976). This is so-called free vibration excitation. The frequency input to a system can also be applied by sinusoidal excitation of varying frequency by signal generators that drive a mechanical stimulus over a wide frequency band (forced vibration excitation). The frequency can be modulated continuously or in steps. Many bone studies are based on the frequency sweep method (Doemland et al., 1986; Kaufman et al., 1990; Siffert & Kaufman, 1996). Electromagnetic shakers are the most commonly used actuators in vibration analysis. Another option is, for example, a modified loudspeaker (Augat et al., 2014a; Jurist, 1970a; Jurist, 1970b).

The electromechanical shaker is a coil-magnet actuator. It has a strong permanent magnet which is placed near a coil and is driven with electrical impulses. The varying magnetic field produced by the coil causes deflection to the magnet, which has enough mass to transmit this vibration to the bone by overcoming the damping effects of soft tissues. Vibration with the same frequency as the applied current is produced. Accelerometers or adequately tuned microphones are possible options for vibration sensors (Augat et al., 2014a). Accelerometers are less sensitive to background noise and external interference than microphones. Until the end of the 1990`s vibration transmittance studies were accomplished using pietzo-electric accelerometers (Folman et al., 1993; Siffert & Kaufman, 1996; Sonstegard & Matthews, 1976). Nowadays micro-electronic mechanical system (MEMS) accelerometers are used in vibration measurements due to the lower production costs, smaller size and natural interface to other microelectronics. There are nearly thirty different types of accelerometers available, of which pietzoresistive, capacitive, tunnelling current and resonant types are mainly used for vibration sensors. The pietzoresistive accelerometer is based on the changes in the resistance of the embedded piezoresistor; capacitive accelerometers measure changes in the capacitance (the ability of a body to store an electric charge) between a proof mass and a fixed conductive electrode separated by a narrow gap; a tunnelling current accelerometer uses the tunnelling effect to sense the displacement; and a resonant accelerometer is based on a frequency shift of a resonant beam (Gao & Li Zhan, 2004; Albarbar, Badri, Sinha, & Starr, 2009).

2.8.1.3 Signal processing, analysis and modelling

With the fixed vibration transmittance input excitation, i.e. power emitted by the vibration actuator, the detected power measured by the accelerometer acts as a measure of the mechanical integrity of the studied object. Raw vibration measurement data is largely filled with non-informative content. The valuable information must be extracted using algorithms and signal processing. Raw data is segmented, filtered and a transfer function is estimated from it. The features are then extracted to conduct transfer function analysis. Different descriptive parameters can be extracted from it (Manolakis, Ingle, & Kogon, 2005). A recorded impulse response can be studied in time or frequency domain. For example, Matlab (Mathworks, MA, USA) scientific computing environment can be used to process the signals. The power spectral density (PSD) of the signal can be calculated using Welch's method (Welch, 1967) with e.g. 4096-point discrete Fourier transform. Welch's method is used for estimating the power of a signal at different frequencies. It enables converting a signal from the time domain to the frequency domain. The frequency domain Fourier transform results can be used to compute a complex transfer function, which can be represented by its separate magnitude and phase components. For example, it enables the analysis of spectral power in certain bands of interest, averaged transfer admittance in narrow bands, resonant frequency or more complex variables (Fellinger et al., 1994; Siffert & Kaufman, 1996). Further processing can be based, for example, on artificial neural networks (Kaufman et al., 1990). Analysis based on resonant frequencies is called harmonic analysis (Augat et al., 2014a; Collier & Donarski, 1987a; Collier & Donarski, 1987b; Cunningham, 2004; Jurist, 1970a; Singh, Yadav, & Adya, 1989).

2.8.1.4 Challenges of vibration transmittance analysis

Vibrational techniques are relatively easy to perform but they have not been widely accepted or used for the assessment of the fracture healing (Augat et al., 2014a). The main problems of in vivo vibration measurements of bone arise from the effects of covering skin and soft tissues which cause damping and attenuation leading to high variability in the analysed signal. Moreover, achieving constant and good mechanical coupling of the measurement system to the studied bone is challenging even when long limb bones with thin soft tissue coverage are studied. Several approaches have been developed for minimizing the effects of soft tissues. Accelerometer preload has been considered to compensate the undesirable effects of soft tissues (Nokes, Fairclough, Mintowt-Czyz, Mackie, & Williams, 1984). Hypodermic needles have been used in experimental settings to enhance mechanical coupling (Sonstegard & Matthews, 1976), but naturally, this is an invasive approach not suitable for clinical use. Creating adequate mechanical coupling seems particularly critical when measuring sternotomy junction due to the amount of soft tissue covering the sternum and costal cartilages.

Normally the vibration signal of the injured and healing limb is compared to the intact contralateral limb of the same patient (Cunningham, 2004). This is not possible when measuring sternal instability. In addition, one cannot count on simultaneous reference data because there is so far no such database. Instead, recordings must be obtained from the intact sternum before the operation. Comparative serial measurements can then be performed at different stages of healing and conclusions of the healing status are drawn based on them.

2.8.2 Quantitative ultrasound

Non-imaging ultrasound methods are known as quantitative ultrasound (QUS). The basic principle of ultrasound analysis is the same as in lower frequency vibration transmittance analysis except that the frequency of the utilized sound is higher, above hearing level. The velocity of an ultrasound wave is affected by local material properties and the attenuation is largely influenced by structural properties. Quantitative ultrasound has potential in bone fracture repair detection (Augat et al., 2014a) and in the diagnosis of osteoporosis (Cunningham, 2004; Thomsen et al., 2015).

The propagation velocity of an ultrasound wave is easily determined by using two transducers, one being the US emitter and the other the US detector. Characteristically the US transducer emits a signal in the 0.2–2 MHz frequency domain. The ratio of the distance between the two transducers and the time of flight of the first incoming signal is the propagation velocity. The attenuation of the US signal can be determined by calculating the ratio of signal intensity of the first incoming signal by the intensity of the emitted signal. The transducers need to be placed as close as possible to the bone surface and need to be coupled to skin by ultrasound gel. As thick layers of soft tissues attenuate the US signal, the medial aspect of the tibia, for example, is ideally suited to perform measurements with the US technique (Augat et al., 2014a).

After the fracture the velocity of the US wave is significantly reduced. The US wave is partly reflected and dissipated at the fracture surfaces causing attenuation, which diminishes during the healing process. Changes in the US properties during fracture healing can be detected much earlier than changes observed by conventional radiography (Eyres, Bell, & Kanis, 1993).

Quantitative ultrasound is easy to use, the devices are readily available and the measurement values can be easily interpreted. However, the attenuation effect of the surrounding soft tissues limits its applicability to long bones with thin soft tissue coverage (Augat et al., 2014a) and so far, it is not widely used in clinical or research practice (Morshed, 2014). Hence it is not readily applicable for sternotomy stability assessments.

2.8.3 Telemetric implants

Telemetric implants provide the method for determining the local deformation at fracture site as a function of external loading by instrumented implants. They employ biocompatible strain gauges directly attached to the osteosynthesis plate (Seide et al., 2012). They measure the deformation of the implant being sensitive to the bending of the plate. They were used for the first time in 2012 with patients suffering femoral nonunion. Interestingly, there was mechanically effective healing several weeks before this was shown radiographically. The information can be used to increase weightbearing during the healing process and it could be used as load monitor during physiotherapy to avoid excessive loads. A limitation of this technology is, for example, the possible loosening of the fixator pins of the device (Claes & Cunningham, 2009). Telemetric implants do not appear suitable for sternotomy stability assessments due to the excess tissue preparation needed for proper transverse plate implantation. Adequate fixation is challenged by the relatively soft costal cartilages attaching the sternum which itself is too narrow to serve as a decent fixation for the telemetric implant.

2.8.4 Radiostereometric analysis

Radiostereometric analysis provides very accurate measurements of small relative three-dimensional displacements of body parts or implants in vivo. The method is based on the implantation of tantalum bead landmarks on each side of the bone fracture or osteotomy. Stereoradiographs using a calibration cage and special software are then used to determine the location of the markers three-dimensionally, thereby enabling the calculation of translations and rotations between different segments (Madanat et al., 2005). Radiostereometric analysis has been used to assess the effect of surgical treatment and different rehabilitation regimens on the stability of fractures. The method needs to be validated to clinical practice in more detail, but it has been acknowledged as a potential tool for fracture healing evaluation (Augat et al., 2014a). Vestergaard and colleagues recently published a report on its use for sternal stability assessments. They found radiostereometric analysis to be a precise and low-dose imaging modality and applicable for sternal stability evaluation in research work (Vestergaard et al., 2018). However, this concept does not seem applicable for sternal stability assessments in routine clinical practice.

3 Aims of the Study

The aim of the study was to investigate if the stability of human sternotomy can be evaluated by vibration transmission. The intention was to explore the applicability of sternal vibration transmission to describe the normal healing process after sternotomy in clinical series of patients recovering from cardiac surgery as well as to diagnose mechanical sternal instability in experimental conditions using a human cadaver model. In addition, we wanted to explore the correlation between the symptoms of instability and objective clinical and imaging findings in a clinical cohort of patients late after cardiac surgery.

The hypotheses were:

1. The Sternal Vibration Device differentiates between intact, split and bound objects.
2. The transmittance measured by the Sternal Vibration Device decreases due to sternotomy and increases as the healing process proceeds.
3. The transmittance measured by the Sternal Vibration Device is lower in sternotomy with a gap than in a tightly closed sternotomy.
4. Patients having sensations of movement or clicking at the sternotomy junction have mechanically unstable sternotomy junctions which can be verified using objective methods.

4 Materials and Methods

4.1 Sternal Vibration Device versions

A special measurement system, the Sternal Vibration Device (SVD), was designed and constructed for the purposes of this study by Nikolai Beev, M.Sc. in collaboration with Professor Jari Hyttinen at Tampere University of Technology. The SVD consists of a main board, a sensor module and a vibration actuator. The actuator and sensor were custom made. The main unit sends commands to the electromagnetic actuator to initiate the vibration sequence and simultaneously records the sensor data. The actuator houses a mechanical mass which is deflected using a magnetic field. The mass introduces a mechanical stimulus, which propagates through a chain of tissues and arrives at the sensor where the vibration is detected. The vibration propagates efficiently through solid tissues, whereas discontinuities, such as abnormal healing of the sternum may decrease the detected vibration. The first prototype provided a vibration stimulus sweep from 64 Hz to 1450 Hz. The data was collected on a portable computer for further processing off-line using routines implemented in Matlab (Mathworks, MA, USA) scientific computing environment. The first prototype was used in Study II which was chronologically the first study undertaken.

The second SVD version was used in Study IV, which was chronologically employed second. Due to the prototype nature of the first device some signs of wear were seen in the components and also some obvious development needs were also seen during Study II. These were actualised in the second SVD version which was battery-driven. It had an LCD display and was made feasible by a clinician without the need for the presence of an engineer during the measurement sessions. This version had USB port for data storage. Due to the unexpected result that all tested sternums were stable, the vibration transmittance data could not be used for instability assessments in the study.

The third SVD version, Figures 3 and 4, was used in Study III and finally in Study I since the second version of SVD was damaged in the laboratory tuning sessions after

Study IV. The third SVD-version provides vibration stimulus sweep from 20 Hz to 2000 Hz in about 3.7 seconds. The actuator was realized using a latching type solenoid, with a cylindrical magnet acting as the piston for the actuator. The actuator is driven by a separate microcontroller to ensure that the central processing unit has enough clock cycles to produce as clean frequency sweep as possible. The transmitted vibration is recorded by a spring-loaded accelerometer having 32 kPa pressure on the skin at 10 kHz sample rate. This version is also battery driven. The device components were chosen to make the equipment more user-friendly and easier to clean. All the electronic components used in the third version are off-the-shelf, thereby increasing the cost efficiency and facilitating the replacement of the components, if needed. The user interface was improved: LCD display and audible beeps guided the measurement set more precisely and numerous consecutive vibration sweeps were feasible. Recorded data was processed off-line on a PC after measurement sessions. Study I describing the detailed technical design, realisation and validation of the SVD was intentionally postponed until the completion of the patenting process and hence it was carried out last.

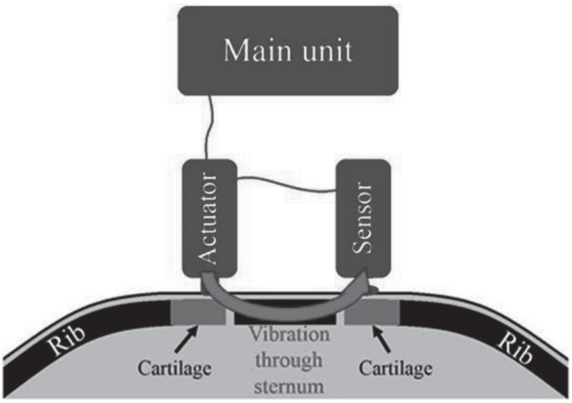

Figure 3. Schematic view of the third version of the SVD in use on human sternum. The red arrow illustrates the mechanical vibration impulse travelling in the sternal tissue (Reprinted from Publication III, Open Access).

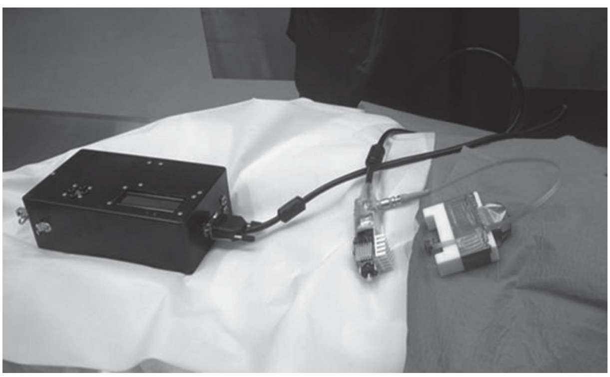

Figure 4. The 3rd version of SVD: main unit (left), the actuator (middle) and the sensor (right). A pen-shaped actuator and short wiring to the sensor provided easy handling of the unit during the measurements. (Reprinted from Publication III, Open Access).

4.2 Signal processing and analysis

Signal processing and analysis were performed according to the principles described in paragraph 2.8.1.3. In Study II the features of the data were extracted to conduct transfer function analysis and different descriptive parameters were derived from it, Figure 5.

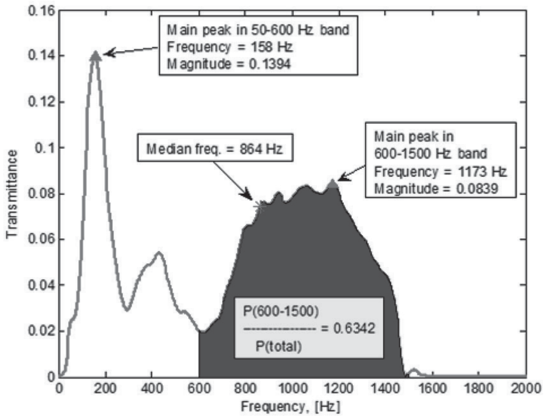

Figure 5. Descriptive parameters extracted from the estimated transfer function (Reprinted from The Annals of Thoracic Surgery, 2012 Jul;94(1):260-4. Hautalahti J, Beev N, Hyttinen J, Tarkka M, Laurikka J. Postoperative sternal stability assessed by vibration: a preliminary study. Copyright (2012). With permission from Elsevier).

In Study III the total vibration transmittance power at the whole tested band of 20–2000 Hz was calculated for each measurement repetition, averaged and plotted, Figure 6. Total power gave good separation between the sternotomy closure configurations and was used as a studied parameter.

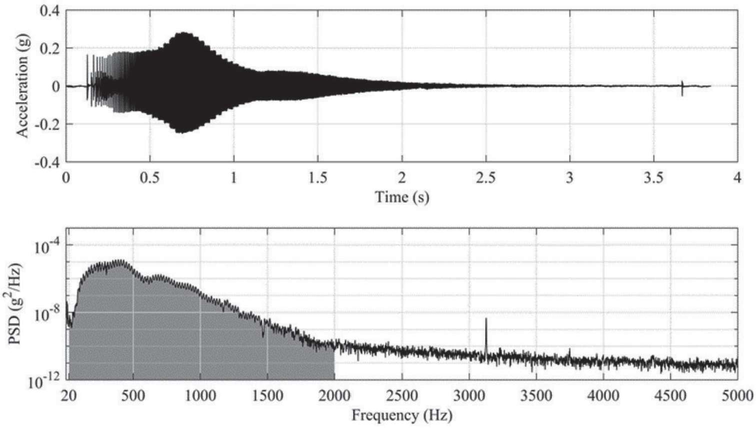

Figure 6. Above: Raw data from a typical vibration sweep that has been transmitted from the actuator, passed through the inspected tissues and picked up by the accelerometer sensor. Below: the same data as above transformed from time to frequency domain. The grey-shaded area under the curve is integrated to produce the total power in the 20–2000 Hz band. Y-axis shows the power spectral density (PSD) in the detected signal and X-axis shows the vibration frequency. (Reprinted from Publication III, Open Access).

4.3 Physical phantoms

Three physical phantoms were manufactured to simulate intact, split and steel wire fixed and split sternums. A 3D printed 20 mm x 5 mm x 200 mm PLA rod (PLA silver grey 2.85 mm filament by Ultimaker B.V., Geldermalsen, The Netherlands) modelled the rib-sternum-rib combination. The rods were embedded into 150 mm x 60 mm x 210 mm ballistic gel blocks (10% ballistic gelatin by Clear Ballistics, Fort Smith, AR, USA) to a depth of 5 mm, Figure 7. The actuator to sensor distance was 6 cm. Five repeated measurements were made on the physical phantoms and the median of their total powers calculated to assess the vibration transmittance.

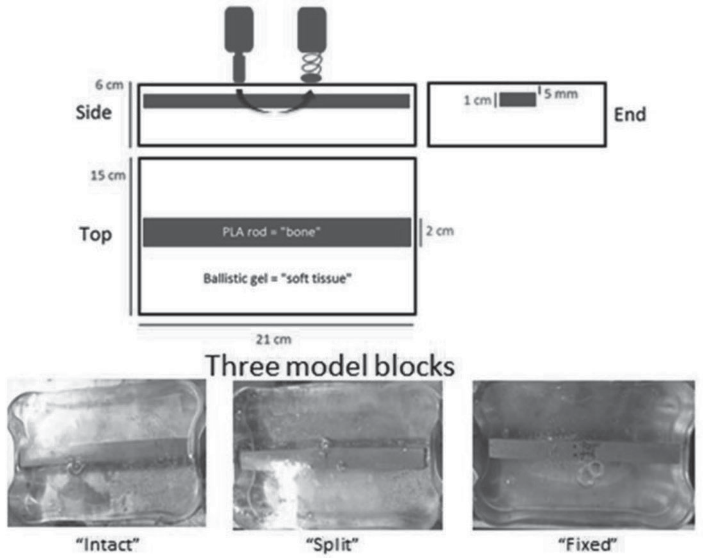

Figure 7. The physical phantoms consisted of 3D printed polylactic acid rods embedded in synthetic ballistic gel blocks. These modelled the vibration pathway through the sternum and adjacent ribs in three conditions: intact, split and steel wire fixed.

4.4 Patients

In Study I two human cadavers were measured in addition to bench tests needed for device and method testing. These two cadavers are not included in Study III.

The patients in Study II were 22 elective patients scheduled for open cardiac surgery via sternotomy. Patients having cardiac pacemakers or implantable cardiac defibrillators were excluded from the study for safety reasons. The patients were measured by the SVD preoperatively, right after the surgery (fourth postoperative day), three weeks and three months postoperatively, Figure 8. The sternotomies were closed using number 7 stainless steel wires in single or figures of eight configurations or using number 5 double steel wires. Pain was scored using a numerical rating scale score, clinical evaluation of the wound and detecting of signs of infection. In addition, ultrasound during manual compression was done three weeks and three months postoperatively.

Figure 8. In Study II the vibration was measured on top of the clavicles, at the level of the third and fifth costal cartilages. The accelerometer was attached with adhesive tape (A) and the electromagnetic actuator was held by hand (B).

Twelve adult cadavers were examined in Study III by vibration transmission in three different conditions: Intact sternum, tight sternotomy closure and loose sternotomy closure with 10 mm diastasis. Measurements were taken at the level of the second, third and fourth costal cartilages. Height, weight, age, sex, time elapsing post mortem, soft tissue thickness at measurement levels, sternal thickness at measurement levels and temperature were recorded in addition to vibration transmittance. Standard sternotomies were performed, and standard closure done with six stainless steel single wires (no. 7; Ethicon, NJ, USA). Soft tissue was sutured in two layers. Air in the cadaver sternotomy wound was supplanted by filling the wound with ultrasound gel (LiNA BLUESCAN Ultrasound transmission gel, LiNA Medical ApS, Glostrup, Denmark).

In Study IV a survey (figure 9) was mailed to 2,053 cardiac surgery patients operated on earlier at our institution. The patients' symptoms were elicited regarding sternal instability. A group of symptomatic individuals (21) as well as 1:1 age- and time-matched asymptomatic controls (21) were examined with sternal palpation, ultrasound during standardized sternal pressure provocation, computed tomography and the SVD.

CODE

Oirekyselykaavake / ETL R11062
Tutkimus: Krooninen rintakipu ja rintalastan luutumishäiriö sydänkirurgian jälkeen

Hyvä Vastaanottaja,

Vastatkaa ystävällisesti seuraaviin kysymyksiin joko merkitsemällä rasti (X) sopivaan vastausruutuun tai kirjoittamalla selvällä käsialalla vastauksenne siihen varattuun tilaan. Vastatkaa kuluneen vuorokauden keskimääräisen vointinne mukaisesti. Palauttakaa täytetty kaavake postitse oheisessa kirjekuoressa 4.11.2011 mennessä. Postimaksu on maksettu puolestanne.

1. Onko Teillä kipuja rintalastanne seudussa? 1☐ Kyllä 2☐ Ei

Jos vastasitte edelliseen kysymykseen "Ei", voitte siirtyä suoraan kysymykseen 17 vastaamatta kysymyksiin 2-16.

2. Ilmaantuiko kipunne sydänleikkauksen jälkeen? 1☐ Kyllä 2☐ Ei

3. Onko kipunne luonteeltaan erilaista kuin mahdollinen rintakipunne ennen sydänleikkausta? 1☐ Kyllä 2☐ Ei

4. Ilmaantuuko rintakipu, jos kiirehditte tai kuljette ylämäkeen? 1☐ Kyllä 2☐ Ei

5. Ilmaantuuko rintakipu, jos kävelette rauhallisella vauhdilla tasamaata? 1☐ Kyllä 2☐ Ei

6. Mitä teette, jos rintakipu ilmaantuu kävellessänne?
   1☐ pysähdyn
   2☐ hidastan vauhtia
   3☐ jatkan kävelyä normaalisti
   4☐ muuta, mitä? ____________________

7. Miten rintakivun käy, jos pysähdytte seisomaan?
   1☐ lievittyy 2☐ pysyy ennallaan 3☐ voimistuu

8. Kuinka pian pysähtymisen jälkeen mahdollinen kipuoireen muutos tulee?
   1☐ heti
   2☐ 1 minuutin kuluessa
   3☐ 10 minuutin kuluessa
   4☐ hitaammin
   5☐ ei muutosta

9. Missä kipunne tuntuu? (Valitkaa kaikki sopivat vaihtoehdot)
   1☐ rintakehän etuosassa keskellä
   1☐ rintakehän etuosassa vasemmalla
   1☐ rintakehän etuosassa oikealla
   1☐ ylämahassa
   1☐ kaulalle säteillen
   1☐ vasempaan käteen säteillen
   1☐ oikeaan käteen säteillen
   1☐ selkäpuolella

10. Onko kivun voimakkuus muuttunut ajan kuluessa? Miten?
   1☐ lievittynyt 2☐ pysynyt ennallaan 3☐ voimistunut

Kysymykset jatkuvat toisella sivulla!

11. Kuinka voimakas kipunne on asteikolla 0 - 10? (Valitkaa vain yksi vaihtoehto.)
(0 = ei lainkaan kipua, 10 = voimakkain kuviteltavissa oleva kipu)

	0	1	2	3	4	5	6	7	8	9	10
11.1. Levossa:	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
11.2. Yskiessä:	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
11.3. Liikkuessa:	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

12. Rajoittaako kipu päivittäisiä askareitanne? (Valitkaa oikea vaihtoehto.)

1☐ Ei 2☐ Hieman 3☐ Merkittävästi 4☐ Erittäin paljon

13. Vaikeuttaako kipu nukkumistanne?

1☐ Ei 2☐ Hieman 3☐ Merkittävästi 4☐ Erittäin paljon

14. Oletteko ollut lääkärin tutkimuksissa sydänleikkauksen
jälkeisen rintakipunne vuoksi? 1☐ Kyllä 2☐ Ei

14.1. Kertokaa tarkemmin, jos vastasitte "kyllä":

____

____

15. Käytättekö tällä hetkellä särkylääkkeitä rintakipunne vuoksi? 1☐ Kyllä 2☐ Ei

16. Onko rintakipuanne hoidettu jotenkin muuten? 1☐ Kyllä 2☐ Ei

16.1. Kertokaa miten, jos vastasitte edelliseen "kyllä":

____

17. Tehtiinkö rintalastaanne lisätoimenpiteitä sydänleikkauksen jälkeen? 1☐ Kyllä 2☐ Ei

17.1. Mikä toimenpide, missä sairaalassa, milloin? (Jos vastasitte "kyllä" kohtaan 17.)

____

____

18. Onko rintalastassanne tunnetta ylimääräisestä liikkeestä (naksumista, lonksumista)?

18.1. Levossa? 1☐ Kyllä 2☐ Ei

18.2. Yskiessä tai aivastaessa? 1☐ Kyllä 2☐ Ei

18.2. Liikkuessa? 1☐ Kyllä 2☐ Ei

19. Onko Teillä pysyvä sydämen tahdistin? 1☐ Kyllä 2☐ Ei

Kiitos avustanne!

Figure 9. Mailed survey on poststernotomy pain and symptoms referring to sternal instability used in Study IV. Front and back page.

4.5 Imaging hardware

Ultrasonography by Esaote My Lab 30 CV, equipped with LA 424 linear probe (10/15 MHz, depth 3/4 cm, gain 82%) was used in Study II for evaluating the sternotomy under manual provocation three weeks and three months after the operation.

Siemens Acuson S2000 ultrasound system with 14L5 linear probe (6–14 MHz) Siemens AG, Erlangen, Germany, was used in Study IV during standardized sternal pressure provocation in addition to computed tomography (Philips Achieva 64 slice scanner, Philips Healthcare, DA Best, The Netherlands) without contrast medium enhancement. The standardized sternal pressure provocation was implemented using a specially designed and manufactured bar simulating normal clinical palpation producing a force of 50 to 70 Newton to a round area with a diameter of 5 cm on top of a costal cartilage.

4.6 Statistics

Inspection of histograms in Studies I and II revealed that the parameter distributions were non-normal and the statistical summary of the results was given in non-parametric form, in which the median value and range are more meaningful than mean value and standard deviation. The non-normal parameter distributions were analysed using the Wilcoxon signed rank test including corrections for small sample numbers ($n<30$) for determining the changes in the transfer function parameters between the consecutive measurements. A p-value was considered significant at the 0.05 level.

Skewed data was transformed using logarithmic (ln) transformation of the original transmittance values which was utilized in Study III. In order to determine the ability of the vibration transmittance device to differentiate mechanical settings in the sternotomy regardless the costal level Generalized Linear Mixed Model with lme function was used. The mean response was modelled as a linear combination of the population characteristics shared by all individuals (fixed effects), and subject-specific effects unique to a particular individual constituted the random effects. Three different mechanical settings and three costal levels were modelled as fixed effects and number of repeated measurements for each cadaver constituted a potential source of variation and was included as random effects in the model (Fitzmaurice, Laird, & Ware, 2011). The generalized linear mixed model analyses were performed with Statistical Package R version 3.3.0 package lme4 (The R Foundation, www.r-project.org). All p-values were two-tailed. A p-value less than 0.05 was considered statistically significant. Spearman's rho was used for the detection and quantification of correlations between nonparametric scale variables.

Independent samples t-test was used for continuous normally distributed variables and Pearson's chi square test for cross-tabulated data and Fischer's exact test in comparisons in 2x2 tables (Study IV).

4.7 Ethical aspects

This study aims to improve patient care. The risks to and burden on the studied patients were considered less than the probable benefit to be achieved from this study. The patients in Studies II and IV received oral and written information about the methods and objectives of the study, signed the informed consent form and were free to withdraw from the study at any time. In Study III, the relatives of each study subject were contacted by the coroner and their consent sought before inclusion in the study.

There was infection risk of the sternotomy wound related to vibration measurements at postoperative day 4 in Study II. The risk was minimized by cleaning the wound with antiseptic alcohol solution and covering the skin with a sterile plastic dressing during the measurements.

The mechanical provocation of SVD on the studied patients was minimal and caused the patients no discomfort. The electrical safety of the SVD was considered thoroughly, especially for Study II and thus optical isolation for the device was conducted. The industry standards for medical devices were used as a guideline for the work. Design documentation referring to patient safety was submitted to the Finnish National Supervisory Authority for Welfare and Health (VALVIRA), which duly granted its approval for the clinical use of the system.

Study IV included CT scans, which were done only for scientific purposes. The risk caused by the added radiation was considered low when compared to the potential benefits of the study. Some of the CT-scanned and clinically evaluated patients had findings necessitating further medical actions. These patients were referred for appropriate supplementary medical examinations.

The study protocols of Studies II, III and IV were approved by the Institutional Ethics Committee. Approval numbers were ETL R09245, ETL R14131 and ETL R11062 respectively.

TAYS Heart Hospital Co. has a patent on the vibration transmittance device, as agreed upon by the inventors. (Patent numbers: USA: 9,788,726 B2; EU: 2717779; Canada: 2,837,121; Russia: 2601097). This is mentioned in the conflicts of interests sections of the publications. Despite the patenting we have been objective in our research work and reported the results as obtained. The funding of the projects has been from non-commercial sources and is duly reported in the publications.

The patient records were handled and stored according to Finnish law.

The results of our studies are published in peer reviewed journals and all the writers contributed to the articles. Citations in the papers as well as in this dissertation have been done according to the Uniform Requirements for Manuscripts Submitted to Biomedical Journals (International Committee of Medical Journal Editors, ICMJE).

The above-mentioned acts are in accordance with Finnish Advisory Board on Research Integrity (TENK), the Finnish law on medical research, the Declaration of Helsinki (World Medical Association, 2013) and The Nuremberg Code.

5 Results

5.1 Technical performance of the Sternal Vibration Device

In Study I the measurement device worked reliably and we obtained logical findings verifying its applicability in further clinical studies. The importance of the placement of the actuator and sensor perpendicularly on top of the measured solid object was noticed.

In Study II the device worked well and there were no major problems with the operation of the measurement system. No modifications concerning stimulation and data acquisition were made after the initial tuning, when the stimulation and measurement range was extended from 1000 to approximately 1500 Hz. Several minor problems with parts of the system occurred and were solved during the measurement sessions. The quality of the measured data was controlled on a laptop PC right after the single vibration sweep. If disturbances or suboptimal data quality were noticed, the measurement was repeated without delay. Of note is that only a single vibration sweep per setting was picked up.

In Study III the SVD seemed to work without errors. Signal analysis was not available during the measurements with the cadavers. Signal processing after the measurement sessions indicated that the data on two cases was not usable and consisted of artefact. The reason for this could not be traced to the device. Since 20 consecutive sweeps were recorded at each measurement setting, the actuator became warm and needed to be cooled by 1,1,1,2-tetrafluoroethane spray. In more detailed analysis of sweep sets signal fatigue could be seen towards the end of each set. Thus, the first five sweeps out of each series were chosen for more detailed data analysis. The sensor and actuator were ergonomic to handle due to their form factor and lightness. The sensor and actuator placements were easy after the correct positions on the tissues had been determined and marked. To hold the sensor and actuator by hand perpendicularly and steadily on the skin surface was fairly challenging during the 20 sweeps lasting approximately 1 minute and 15 seconds. To improve the operating ergonomics the subject should be placed on a table with adjustable height, which is often the case in the clinical environment. The SVD allowed measuring serial sweeps in a row by keeping the trigger activated. Each sweep start and end were marked by audible beeps, which made following the measurements easy. The device battery was charged before each measurement session and the charge sufficed easily for a complete session.

5.2 Physical phantom studies

Validation of the SVD, both the actuator and the sensor, was accomplished. The vibration sweep was linear in the frequency range of 20 to 2000 Hz tested and the power output was stable. The sensor calibration yielded expected and logical results.

In the physical phantoms the vibration transmittance behaved as expected: The transmittance was highest with the intact object, lower with the split and fixed object and lowest with the split object, as illustrated in Figure 10.

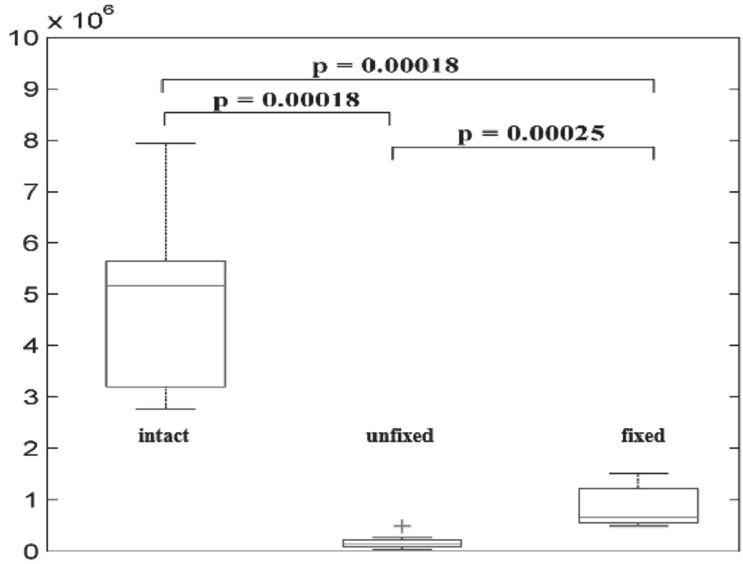

Figure 10. Total vibration transmittance in tested 20–2000 Hz band. Intact setting at left, split and unfixed in the middle, and split and fixed at right. 5 repeated measurements were done per condition.

5.3 Vibration transmittance of normally healing sternotomy

In the clinical series vibration transmittance cross the sternum decreased due to the sternotomy but increased as healing proceeded. Eight out of 22 patients were excluded from the study due to different reasons: The vibration spectral range was widened after the first patient's preoperative measurement and one patient withdrew from the experiment after the operation for reasons not related to this study. We recruited two patients with a clinically obvious sternal instability in the postoperative period. For one patient a permanent pacemaker was implanted postoperatively: For safety reasons a pacemaker was a contraindication for vibration transmittance assessments in the study protocol. One patient was on a district hospital ward at the time of the follow-up visit at three-week measurements, and two high-risk patients died before the last control.

Numerous parameters were extracted and analysed from the vibration transmittance transfer function: median frequency, frequency of the main peak in the 50–600 Hz band, frequency of the main peak in the 600–1500 Hz band, total transmittance (Ptotal), transmittance in the 600–1500 Hz band (P600–1500), transmittance in the 600–1500 Hz band divided by the total transmittance (P600–1500/Ptotal index), transmittance in the 600–1500 Hz band normalized using its preoperative value (P600–1500 index), spectral skewness, spectral kurtosis, cross-correlation coeffient and mean spectral coherence. The P600–1500 index was found to be most informative parameter and chosen for reporting even though the total transmittance also revealed similar results. It dropped due to the sternotomy and a reverse trend attributed to bone healing was seen postoperatively, as shown in Figure 11. No damping effect caused by soft tissues was seen in this series tested by comparing transmittance at three months to the patient's body mass index (P600–1500 index greater than 1 at three months and body mass index less than or above 28). However, no absolute transmitted vibration power versus body mass index was tested. The most cranial, i.e. interclavicular measurement position, yielded no usable data.

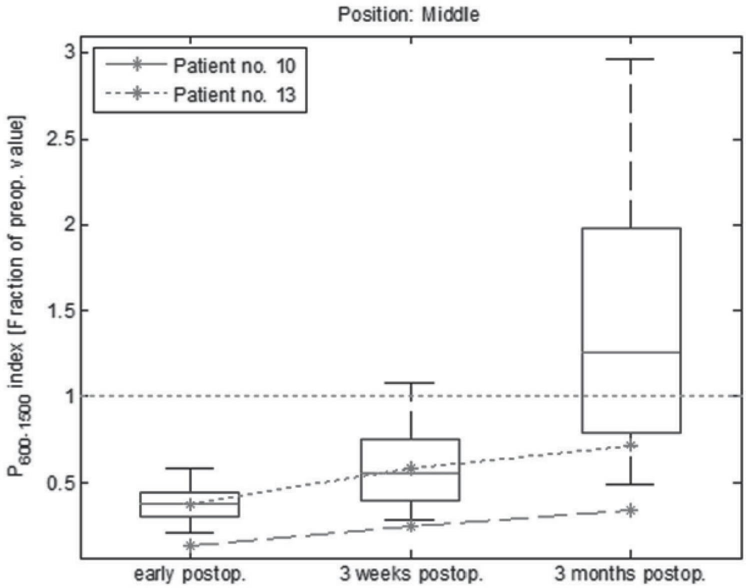

Figure 11. Distributions of P600–1500 index of the study patients in Study II at three different time points. Normalization with the preoperative values was done. The differences between the time points were statistically significant at middle (third costal) and lower (fifth costal) levels. Clinically unstable sternums of patients 10 and 13 are shown individually (Reprinted from The Annals of Thoracic Surgery, 2012 Jul;94(1):260–4. Hautalahti J, Beev N, Hyttinen J, Tarkka M, Laurikka J. Postoperative sternal stability assessed by vibration: a preliminary study. Copyright (2012). With permission from Elsevier).

5.4 Vibration transmittance for sternal instability detection

In experimental settings using human cadavers, vibration transmittance across the sternum decreased due to the sternotomy. The transmittance was lowest in loose sternotomy closure and tight steel wire fixation raised it closer to the preoperative levels irrespective of the tested costal level as presented in Figure 12.

The vibration transmittance power was not statistically significantly different between the three costal levels tested (level 3 vs. level 2; level 4 vs. level 2; level 4 vs. level 3. T-values and p-values respectively t=-0.36, p=0.723; t=0.35, p=0.728; t=0.71, p=0.484). The soft tissue thickness in the cadavers showed a moderate inverse correlation to the total vibration power when all tested levels were studied in the intact sternums (Spearman's nonparametric rho=-0.478).

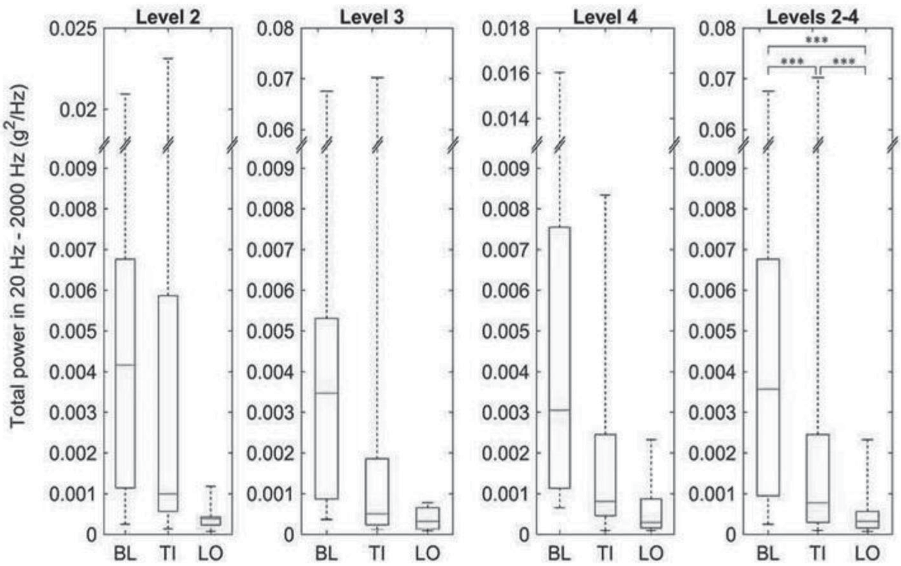

Figure 12. The results at the second (Level 2), third (Level 3), fourth (Level 4) and combined at all costal levels (Levels 2–4). The Y-axis shows the total power in the 20–2000 Hz band calculated from the power spectral densities (PSDs) of the measurements. Stable fixation indicates sternum attached tightly with 6 steel wires and unstable fixation indicates 10 mm distance between sternal halves. Red lines indicate the medians, blue boxes indicate 1st and 3rd quartile and whiskers the range of the data. BL = baseline (intact sternum), TI = tight (stable wire fixation), LO = loose (unstable wire fixation). *** signifies p ≤ 0.001

5.5 Symptoms of sternal instability late after sternotomy

A total of 1,918 patients (93.4%) responded to the postal survey on symptoms of sternal instability late after sternotomy, of whom 2.3% (44 patients) reported sensations of movement or clicking in the sternum during body movements and during coughing. Symptomatic patients living within 200 km of the hospital (21) and their asymptomatic controls (21) were selected for further clinical and imaging studies. The mean period between the initial operation and the examinations was 36 (22–56) months. Sternal palpation pain was significantly associated with reported symptoms suggestive of sternal instability (OR 22.0; 95% CI 2.5–195); however, none of the patients had clinically unstable sternum or nonunion in sternal imaging. The symptoms of sternal instability were more frequent in patients whose bone mineralization rate (as measured with t-scores) was higher, Table 1. There were no differences in the measured vibration transmittances between symptomatic and asymptomatic control groups.

Table 1. Number and proportion (in %) of symptomatic and control patients in tertiles of bone mineral densities in relation to symptoms of sternal instability. (The T-score tertile cutpoints of -3.067 and -1.833 were used.)

			Control	Symptoms	Total
Tertile	Lowest (<-3.067)	n	8	6	14
		%	57,1%	42,9%	100%
	Middle	n	9	5	14
		%	64,3%	35,7%	100%
	Highest (>-1.833)	n	4	10	14
		%	28,6%	71,4%	100%
Total		n	21	21	42
		%	50%	50%	100%

Pearson Chi-Square 4.000, p= 0.231

6 Discussion

6.1 Vibration transmittance measurements

To the best of my knowledge no reports have been presented describing thoracic anterior wall or sternum stability analysis utilizing transmittance of vibration energy. I therefore also discuss in detail the technical environment in our experiments and some notations regarding potential errors.

6.1.1 Sources and causes of interference and errors

The actuator and sensor are held in the hands during measurements. The distance between the units must be kept precisely the same to be able to compare the values between the measurements. An important issue in physical phantom tests seemed to be the need to hold the units perpendicular to the tissue surface to maximize the mechanical coupling and hence the transmittance. The hands holding the units rest lightly on the chest surface studied, possibly affecting the transmittance to some extent. Also, the exact position of the units right on top of the costal cartilages to maximize the vibration transmission is essential.

The first postoperative measurement session in Study II was taken on average on the fourth postoperative day. Hence the sternotomy wound had to be covered by sterile adhesive plastic film to minimize the risk of infecting the wound. About 1-centimetre sector just on top of the wound was covered by a strip of sterile gauze to prevent the film from adhering to the wound edges. This composition dressing may have affected the vibration signal transmission across the sternal junction. The effect of the soft tissue of the wound and the suture technique may affect the measured vibration transmittance even if the main part of the vibration energy is transmitted through more solid tissues, such as cartilage and bone. The normal postoperative swelling throughout the whole body and especially in the wound region may to some extent have affected the vibration powers detected in the early postoperative period.

The superficial anatomy is relatively straightforward to examine by palpation if the patient being studied is lean. Obese patients are more difficult to measure accurately in this aspect. Also, the natural variation in the anatomy of the sternum and its surrounding tissues must be kept in mind as a source of variability for the transmittance measurements. In addition, the steel wires used for sternotomy closure may possibly provide an auxiliary pathway for transmission affecting the transmittance results.

Heating of the actuator was experienced during the long measurement series of 20 sweeps in Study III. Extra heat sinks and cooling spray (1,1,1,2-tetrafluoroethane) were used to remove the excess heat. Cooling may not be needed if fewer sweeps are used. Later analyses showed that a significant decrease in the power emitted was seen during the sweep set of twenty. To confirm that the sweeps with the highest energy and best quality were included the first five sweeps were chosen for analyses. This practical conclusion solves the problems of excess heat and the question of adequate sweeps per measurement position. Initially 20 sweeps were chosen empirically to obtain maximally solid datasets, but this assumption proved wrong due to the attenuation.

Earlier experimental studies indicate that fresh cadaveric tissue may be used for passive mechanical testing and that certain biochemical properties are unchanged up to seven days post mortem (Tuttle, Alperin, & Lieber, 2014). However, low temperature of the tissues and the absence of normal postoperative swelling of soft tissues was lacking when the cadaver tests were conducted. Also, the electromechanical properties in a cadaver may differ from those of living tissue. Studies II and III nevertheless yielded similar results. Air in the cadaver sternotomy wound (Study III) could easily be seen during the measurement sessions. To overcome the obvious bias caused by the air in the wound, the wound was filled with ultrasound gel from the third measured case on. Thus, the two cases without gel were excluded from the reported cadaver study but included in Study I in addition to the physical phantoms. The last cadaver was CT-scanned during the measurements to enable computer aided simulations of the technology. Surprisingly we saw, that lateral traction steel wires had caused wide bilateral pneumothoraxes, which again may have affected the vibration energy transmitted. The incidence of this phenomenon in the rest of the series can only be speculated. However, solid tissues, bone and cartilage transmit the vibration energy across the sternotomy and thus the conditions below that layer most likely do not play a significant role for the measured signal. Nevertheless, cold and stiff cadaver tissues may affect the vibration transmission and the possible effect of pneumothoraxes and air in the studied wound must be kept in mind when interpreting our data.

According to the literature, the damping effect caused by soft tissues covering the studied body parts is an essential limitation to the use of vibration transmittance (Nokes et al., 1984). However, our findings from the Study II of patients recovering from cardiac surgery and from the experimental cadaver Study III imply that soft tissue thickness does not alter the vibration powers detected or affects the results only slightly, respectively.

6.1.2 Interpretation of the results

From these studies we know that the SVD differentiates between solid and discontinuous objects in a physical phantom mimicking sternotomy junction. The device detects rising transmission in clinical settings as the normal sternotomy healing process goes on and the device is also capable of differentiating between tight and loose sternotomy closure. These findings are logical and in accordance with the study hypothesis. Due to the different anatomical regions studied in previous works, different technical applications, different signal processing and analyses used, comparing these studies is difficult. However, our results do not seem to be inferior to those of earlier studies on e.g. fracture healing monitoring or detection of hip prosthetic loosening (Siffert & Kaufman, 1996; Li, Jones, & Gregg, 1996).

6.2 Chest wall symptoms versus imaging findings

Various chest wall symptoms among post-sternotomy patients are relatively common. For example, Lahtinen et al. reported incidences of 14%, 1% and 2% for mild, moderate and severe pain respectively one year after cardiac surgery (Lahtinen et al., 2006) and Taillefer et al. higher numbers of 23% 1–3 years after surgery (Taillefer et al., 2006). Taking the bone healing biology and the stability requirements described in chapter 2.3.2 into consideration, one may speculate that the routine steel wire sternotomy closure does not ensure optimal stability for the early healing process even if indirect endochondral healing mechanism allowing strain up to 10% is considered. This may predispose patients to different symptoms later after the sternotomy. In Study IV 2.3% of the patients experienced symptoms suggestive of sternal instability and nonunion approximately three years after surgery. Late sternal instability is rarely seen in clinical practice, but its possible role can only be speculated if no surveys on the subject are done. However, we found that patients' symptoms did not correlate with CT scans or provocation ultrasound although palpation pain was evident. Thus, the pain derived from non-mechanical aetiologies. For some reason unknown to us lower bone density seemed to protect against abnormal symptoms of the sternal wound.

Symptomatic patients were more obese. Obesity has also been reported to correlate with post-sternotomy pain in an earlier study by Bruce et al. (Bruce et al., 2003). Furthermore, our findings in Study IV corroborate those of other recent studies, which show a weak correlation between late postoperative chest pain and quality of sternal reunion. However, an extensive radiological gap more than 3 mm (affecting at least two thirds of the sternum) has been found to lead to higher pain intensity (Papadopoulos et al., 2013). In our cohort nonunion, as evaluated by CT, affected only one sternal third at the time and was found equally often in the symptomatic and asymptomatic patients. Since our aim was to detect the sternal stability and symptoms possibly related to it, we did not report separately on pain in our questionnaire study cohort.

Ultrasound during standardized sternal pressure provocation, i.e. the protocol used in Studies II and IV, could be useful in clinical practice but this should be elucidated in further studies. A similar approach has also been reported by other groups (El-Ansary et al., 2007; Balachandran et al., 2017). It is noteworthy that in the immediate postoperative period ultrasound examination carries a risk of infecting the wound with skin bacteria even if the wound is cleaned with sterile solution and sterile transducer cover and gel are used. Hence it is advisable to delay ultrasound examination until the skin is healed.

Vibration transmittance was also used in Study IV, but due to the stable sternums the analysis of the vibration data was not meaningful.

6.3 Study strengths and limitations

This project on monitoring sternotomy healing from the mechanical perspective has been a collaboration involving the disciplines of cardiac surgery, biomedical engineering, clinical radiology and forensic medicine. The multidisciplinary approach can be regarded as a strength of this project.

Sternal vibration transmittance analysis is an innovative, non-invasive and fast tool for bedside evaluation of postoperative sternum. Earlier this kind of technology has been useful in assessing long bone healing and implant stability, but our group is the first to use it for postoperative sternotomy stability assessments. This pioneering aspect is an important strength of our study. However, a more systematic approach to validate and test the SVD in laboratory settings would have improved the technical replicability and reliability of the measurements before proceeding to human studies on cadavers and live patients. The current status that both preoperative and early postoperative reference measurements are needed to enable the sternotomy stability estimation is a limitation of this concept in wider clinical use.

The cadaver model is a good platform for such studies because objectively different mechanical settings can be created, but it has certain limitations as already discussed in chapter 6.1.1. From an ethical point of view, similar tests are not possible with live patients. Compared to creating an anatomical model using artificial material, cadaver seems to be a more realistic and reliable platform for this kind of research, also in the future.

Our sample sizes were relatively small, which is a limitation of this work. Due to the novel approach of the study and to the type of data gathered, no proper preceding sample size calculations were achievable.

6.4 Future aspects

Despite the current trend towards less invasive solutions in the treatment of structural heart disease, sternotomy is still the standard exposure in cardiac surgery. However, partial sternotomy, a minimally invasive video-assisted approach and especially catheter-based techniques will play a more significant role in the treatment of cardiac conditions in the future. Despite that, full sternotomies will still be needed. The biomechanics of sternotomy during the healing process can be studied more thoroughly and should be understood better. Recognition of early instability of sternotomy enables earlier support measures and avoids complications.

The need for technical improvements is apparent when devices are in the development stage. The actuator even in the third version of the SVD is not fully encased, which makes it difficult to disinfect; this should be remedied in future versions. According to the findings of Studies II and III, the most informative frequency bands were different. In future work this should be studied more profoundly to be able to optimize the vibration stimulus. In addition, the replicability and reliability of the whole instrumentation should be improved.

The role of soft tissue damping effect must be explored in more detail in future work. The usability and accuracy of the SVD to detect partially unstable sternum and narrower diastases is clearly an approach worth studying.

Current knowledge suggests that vibration propagation is deflected from the bone to the metallic implant. Thus, the sternal vibration device cannot be used for detecting changes in sternotomy junctions fixated by plates and screws (Augat et al., 2014a) which is a drawback for future applications especially if these fixation techniques become more prevalent.

A database for reference values of different mechanical circumstances is needed to rationalize wider clinical use since it could eliminate the current need for multiple measurements and could help in diagnostic conclusions in the later postoperative period.

The possibilities of signal acquisition and processing tools may enhance the understanding of this technology and enable true bedside diagnostics with no need for off-line analysis on a PC. According to Study III, the need for a real time data quality indicator is obvious to maximize the useful data and to exclude non-usable artefact data. In addition, computer aided simulations offer new opportunities to develop the device and to further the understanding of sternotomy healing.

Hopefully in the future, after supplementary development work, the SVD will be a reliable tool for postoperative sternal stability assessment leading to cost savings, improved quality of life and saved lives after cardiac surgery.

7 Summary and Conclusion

Based on these studies the following conclusions can be drawn:

1. The Sternal Vibration Device is applicable for the evaluation of the mechanical stability of the sternotomy junction as it differentiates between solid and discontinuous objects in experimental laboratory settings.
2. Vibration transmittance across the sternum decreases due to the sternotomy but increases as normal healing proceeds.
3. The Sternal Vibration Device distinguishes between intact, split but appropriately closed sternotomy junction and a loose sternotomy with a gap.
4. Symptoms of sternal instability late after cardiac surgery are due to non-mechanical aetiologies.

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Publications

PUBLICATION
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A device for measuring sternal bone connectivity using vibration analysis techniques

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A device for measuring sternal bone connectivity using vibration analysis techniques

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Declaration of Conflicting Interests

The authors declare that there is no conflict of interest. TAYS Heart Hospital Co. holds a patent for the Sternal Vibration Transmittance Technology (U.S. Patent No. 9,788,726 B2; EU: 2717779; Canada: 2,837,121; Russia: 2601097). Nikolai Beev, Juha Hautalahti, Jari Laurikka, Matti Tarkka, and Jari Hyttinen are named as the inventors in the patent.

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Abstract

Objectives: Stability of bone splitting sternotomy is essential for normal healing after open cardiac surgery. Mechanical vibration transmittance may offer a means for early detection of separation of bone (diastasis) in the sternotomy and prevent further complications. This paper describes the technical implementation and validation of vibration analysis-based prototype device built for measuring sternal bone connectivity after sternotomy.

Methods: An in-house built measurement system, Sternal Vibration Device, consisting of actuator, sensor, and main controller and signal acquisition unit was designed and manufactured. The system was validated, and three different test settings were studied in mockups (polylactide rods in ballistic gel) and in two human sternums: intact, stable wire fixation, and unstable wire fixation with a gap mimicking bone diastasis. The transmittance of vibration stimulus across the median sternotomy was measured.

Results: The validation showed that the force produced by the actuator was stable and the sensor could be calibrated to precisely measure the acceleration values. The vibration transmittance response to material cut and sternotomy was evident and detectable in the 20 Hz – 2 kHz band. The transmittance decreased when the connectivity between the sternal halves became unstable. The trend was visible in all the settings.

Conclusion: Technical solutions and description of validation process were given. The device was calibrated and the vibration transmittance analysis differentiated intact and cut polylactide rod. In the sternum, intact bone, wire fixation with exact apposition, and with a gap were identified separately. Although further studies are needed to assess the accuracy of the method to detect different levels of diastases, the method appears to be feasible.

Keywords: Biomechanical Testing/Analysis, Biomedical Devises, Bone Biomechanics, Frequency Analysis, Sensors/Sensor Applications

Introduction

Sternotomy is the surgical division of the breast bone, the sternum, to gain access to the organs inside the thorax for corrective surgery. It is the most common exposure in cardiac surgery. Over 500,000 median sternotomies are performed yearly in the U.S. during cardiothoracic surgery [1]. The incised sternum is fixed using surgical steel wires which support the sternum and allow the bone to regenerate during the healing process. Stability of the sternum is essential for normal recovery after sternotomy [2,3]. Postoperative sternal instability occurs in 0.9-1.9 % of patients [4,5] and may lead to pain, disability, and wound infection. Sternal instability is often associated with deep sternal wound infection [6], but a sterile form of instability, i.e. dehiscence, is also known [7]. The exact percentage of deep sternal wound infection with concurrent sternal instability is not reported in the current literature since these complications are most often categorized as a single complication [5]. Mediastinitis, deep sternal wound infection, is the gravest complication of sternotomy, and is associated with mortality ranging 10 % to 25 % [8]. The incidence of mediastinitis varies from 0.5 % to 5.0 % [5]. If the complication progresses to mediastinitis the costs are drastically increased up to 50 000 $, which is triple compared to the average hospital costs of cardiac surgical patients due to the need for prolonged hospitalization and multiple surgical procedures [9].

In clinical practice palpation of the sternum [10] and computed tomography (CT) are currently the methods for evaluating and imaging of postoperative sternum [11]. Palpation is subjective and difficult to standardize. Despite advances (e.g. iterative reconstruction) in CT technology there remains a considerable radiation burden on the patient. The average radiation dose in lung CT in Finland in 2017 was 4 mSv, which is equivalent to 130 thorax plain radiographs or 16 months' background radiation [12]. The sternotomy may have abnormal motion even if the sternal halves are close to each other when the patient lies still in the supine position. The radiological signs of healing and bone formation also appear months after surgery [1,13,14]. A study on using normal imaging ultrasound as a measure of postoperative sternal micromotion was published in 2017 [15] but its usability must be proven in larger studies. Besides, it should be noted that the skin should be healed prior to ultrasound assessment to avoid the risk of wound infection caused by opening the fragile healing soft tissues by transducer pressing in approximately the earliest ten days of the postoperative period.

Detection of sternal instability in the early phase of the pathological process is difficult by simply palpating the sternal wound or using conventional imaging modalities. Early detection of sternal instability could enable preventative measures such as the use of supportive vests as well as surgical re-fixation of the sternotomy that may prevent more severe complications later [3,16,17]. Easily accessible light, but precise diagnostic tools would be of value. Any clinically applicable method for sternotomy stability assessments must be noninvasive. Potential noninvasive biomechanical methods include vibration transmittance analysis, quantitative ultrasound, telemetric implants and radiostereometric analysis [18]. Mechanical vibration has been used to detect discontinuity in bones [19,20], as well as in the assessment of dental and orthopedic implant stability [21,22]. Vibration transmittance examination is quantitative, low-risk, non-invasive, fast, battery operated, and utilizes light instrumentation. It is therefore potentially applicable in the bedside diagnostics of postoperative sternal stability. Use of quantitative ultrasound for sternotomy assessment is most likely excluded due to the damping effects of the covering relatively thick soft tissue layer [18]. Telemetric implants for fracture healing assessments are currently available only for long bones and the experiences are relatively limited so far [23]. Radiostereometric analysis requiring implantation of metallic landmarks on each side of the sternotomy and the need for specialized imaging techniques makes it cumbersome for sternotomy evaluation in clinical work [24]. However, Vestergaard et al. recently published the first report on using radiostereometric analysis for sternal stability assessments in research work settings [25].

Our proposed solution is a vibration transmittance-based device (Sternal Vibration Device, SVD) for the detection of early disruption of the sternal fixation. The patient would go through SVD measurements before and after surgery. In the follow-up the sternal healing is assessed, and a simple score is given for the integrity compared to the baselines. The first prototype and proof-of-concept of the SVD was developed by Beev and Hyttinen [26]. A preliminary clinical study was conducted with patients recovering from sternotomy using the first prototype. The vibration transmittance decreased postoperatively and increased during recovery [27]. In addition, we have also completed a human cadaver study, which showed that vibration transmittance analysis differentiates the intact sternum, wire fixation with exact apposition and wire fixation with a gap [28]. The previous studies present results from clinical studies using the sternal vibration device keeping the technological discussion at a superficial level sufficient for readers from the non-technical fields. The technical solution of the present prototype version of the SVD has not been published earlier. This current article describes and justifies in detail the electromechanical design, component selection, signal processing and device validation process. Following the validation results feasibility measurements from ballistic gel mockups and two human cadavers are given to show that the device is capable of producing meaningful data in both simplified setup and realistic anatomy. The data have been recorded as part of the device development process leading to the human cadaver study [28].

Materials and methods

The Sternal Vibration Device

The SVD consists of three units: the main, the actuator, and the sensor unit (Figure 1). The main unit sends commands to the actuator to initiate the vibration sequence and simultaneously records the sensor data. The actuator houses a mechanical mass which is deflected using a magnetic field. The mass introduces a mechanical stimulus, which propagates through a chain of tissues and arrives at the sensor, where the vibration is detected. The vibration propagates efficiently through solid tissues, whereas discontinuities, such as a sternotomy with a gap, may attenuate the vibration detected.

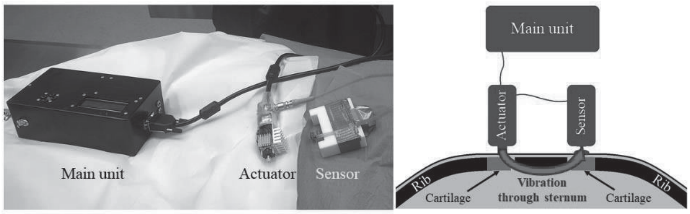

Figure 1. Left panel from left to right: the main unit, the actuator, and the sensor. A pen-shaped actuator and short wiring to the sensor allow easy handling of the unit during measurements. Right panel: the Sternal Vibration Device in use on the human sternum [28].

The design utilizes commercial off-the-shelf components and one family of microcontrollers for cost-efficiency and component availability. The main unit houses the main microcontroller (Atmel ATmega8515), the main circuit board, battery, indicator LEDs, and connectors for the actuator, the sensor, and the charger. The user interface consists of a liquid crystal display and four buttons. The buttons are used for starting the measurement, running hardware tests and setting the time and date. The time, date, and operating mode (ready, recording) are shown on the display.

The actuator is realized using a microcontroller (Atmel ATtiny861), latching type solenoid (BLP Components Series 65), and a cylindrical magnet (10 mm in height, 5 mm in diameter and 1 g in weight) acting as the piston. During use the actuator is placed on the skin to take measurements. The magnetic piston is pressed fully inside the solenoid and the piston tip rests on the skin with a force of 1.37 N and pressure of 17 kPa. The force creates a preload which compresses the soft tissues facilitating the vibration transmission to the hard tissues. As the user pushes the start button, the main microcontroller sends a command to the sweep generating microcontroller to initiate the vibration sequence. The solenoid drive voltage is toggled on-off using a switching transistor. The pulse width modulation produces a 3.7-second-long linear frequency sweep starting from 20 Hz and ending in 2 kHz. As a result, the piston causes the tissues to vibrate with standard force and frequency.

The vibration is detected by a MEMS accelerometer (ST LIS352AR) inside the separate sensor unit and sampled with a 10 kHz and 16 bit analog-to-digital conversion (Analog Devices AD7680). The Z-axis (perpendicular to the skin) of the accelerometer is used to acquire the vibration data. The sensor is designed to be as lightweight as possible by having only the essential components and wiring in the sensor unit to minimize bias and to maximize measuring sensitivity. The A-shaped sensor handle is machined out of a polytetrafluoroethylene block. The accelerometer and supporting components are on a separate 12.4 mm diameter circular circuit board. The board is spring loaded to standardize the force and pressure (4.41 N, 37 kPa) of the board on the skin. Due to the handle design the board-to-skin pressure is independent of the pressure the user exerts on the handle. The digital data from each sweep is thereafter sent over an USB connection to a flash drive for storing. The block diagram of the SVD is presented in Figure 2.

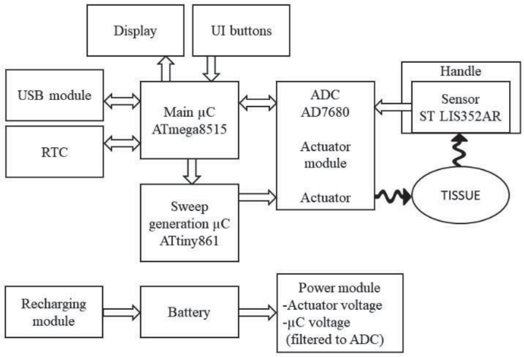

Figure 2. The connections between the main unit, the actuator module, and the sensor. The vibration path from the actuator through the tissues and into the sensor is shown with the wave arrows. Abbreviations: RTC = real time clock, μC = microcontroller UI = user interface

Design efforts are directed at reducing noise levels. The wiring between the accelerometer and the analog-to-digital converter (ADC) is as short as possible. Differential signaling is used in communication between the ADC and the main microcontroller. The actuator is driven by a separate microcontroller to ensure as clean frequency sweep as possible, to ensure that the main microcontroller can read the ADC without interruptions, and to enable enough processing time to write the converted data on-the-fly into the USB storage.

The USB flash drive is used to move the collected data from the SVD for off-line signal processing on a personal computer. MATLAB scientific computing environment is used to process the signals (Mathworks, MA, USA). The power spectral density over 1 Hz - 5000 Hz of the signal is calculated using the Welch method [29]. Total power is calculated for each sweep by integrating the power spectral density over the 20 Hz - 2 kHz stimulation band.

Validation

Validation was done using independent devices to measure the performance of the actuator and the sensor of the SVD. The dynamic force produced by the actuator was measured using a piezoelectric load cell by Kistler (Type 9712B500, SN 2023135, Sensitivity 2.42345 mV/N, Kistler, Riihimäki, Finland). A jig was constructed to hold the actuator and the load cell firmly in mechanical contact during the measurements. It had 3D printed polylactide (PLA) parts which were fitted to four threaded steel rods that formed the frame of the jig. The actuator and the load cell were placed inside the jig along with an adapter block that was screwed into the cell's frame and contacted the piston of the actuator (Figure 3). The adapter was necessary to separate the piston and the load cell housing as they were magnetically attracted. The load cell was connected to an IMC CS-7008 real-time measurement device with built-in amplifiers. The device was controlled by a PC laptop running IMC Studio ver 5.0.10 (IMC Test & Measurement GmbH, Berlin, Germany). The measurement unit was set to measure in DC-Linear mode with a range from -2.084 N to 2.043 N and a sample rate of 20 kHz. A Manfrotto camera arm and clamp were used to fix the jig to the lab table (Vitec Imaging Solutions Spa, New Jersey, USA). Altogether 47 sweeps were recorded using the above setup. The force characteristics were calculated off-line in MATLAB. The force amplitudes of the sweeps were calculated by sliding a 1000 sample (50 ms) long window over the absolute values of the sweep data and extracting the peak amplitude values inside the window. These max values were used to calculate the relation of the actuation force to the resting force of the actuator piston on the target surface in decibels. Further the repeatability of the actuator produced sweeps was assessed using root-mean-square deviation (RMSD, Equation 1), where S_i is a sweep force vector and $\bar{S}_i$ is the average of all the sweep force vectors.

Equation 1. $RMSD = \sqrt{\frac{\sum_{i=1}^{n}(S_i - \bar{S}_i)}{n}}$

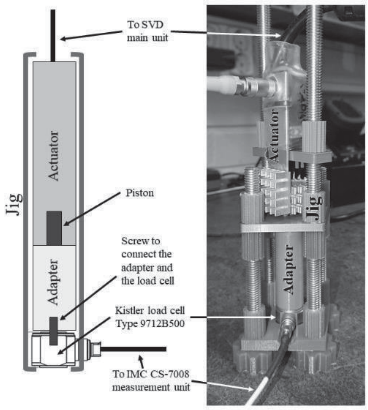

Figure 3. The validation measurement setup for the actuator. The force produced by the actuator was measured using a Kistler piezoelectric load cell, which was connected to the IMC CS-7008 measurement device.

The MEMS accelerometer in the sensor unit was calibrated by applying manufacturer's instructions [30]. The sensor was placed 'face up' and 'face down' such that the accelerometer experienced 1 g and -1 g acceleration in the earth's gravity field. Thereafter the sensor was placed on a Brüel & Kjær Type 4291 accelerometer calibrator (Brüel & Kjær Sound and Vibration Measurement A/S, Nærum, Denmark), and the calibrator was adjusted to the weight of the sensor. The calibrator caused the accelerometer to vibrate along the Z-axis of the component, which was perpendicular to the earth's gravity field. The vibration was at 80 Hz and sinusoidal such that in the peaks the accelerometer experienced an acceleration of +/- 1 g over the earth's gravity (0 g and -2 g). Thirty sweeps were recorded for each of the above settings (1 g, -1 g, 0 g and -2 g). The accelerometer output was AD-converted and written into the USB flash drive. In the off-line MATLAB analysis, the thirty sweeps in each of the four setting were averaged to yield four ADC vs acceleration data points. Linear regression was used to get a calibration equation.

Finally, the MEMS accelerometer was attached to the actuator of an Instron Electropuls E1000 (Norwood, MA, USA), which is a test instrument designed for dynamic and static testing of materials and components. The accelerometer was subjected to a sinusoidal movement in the frequencies of 20 Hz, 100 Hz, 500 Hz and 1000 Hz to find out how accurately the actuator measures them.

Mockup study

First a bench test was set up to study the function of the SVD in conditions that model the sternal mechanics in a simplified manner. Three mockups were manufactured to simulate intact, split and steel wire fixed, and split sternums. A 3D printed 20 mm x 5 mm x 200 mm PLA rod (PLA silver gray 2.85 mm filament by Ultimaker B.V., Geldermalsen, The Netherlands) modeled the rib-sternum-rib combination. The rods were embedded into 150 mm x 60 mm x 210 mm ballistic gel blocks (10 % ballistic gelatin by Clear Ballistics, Fort Smith, AR, USA) to a depth of 5 mm (Figure 4). The actuator-to-sensor distance was 60 mm. Five repeated measurements were made on the mockups and the total power over the 20 Hz – 2 kHz band was calculated to assess the vibration transmittance.

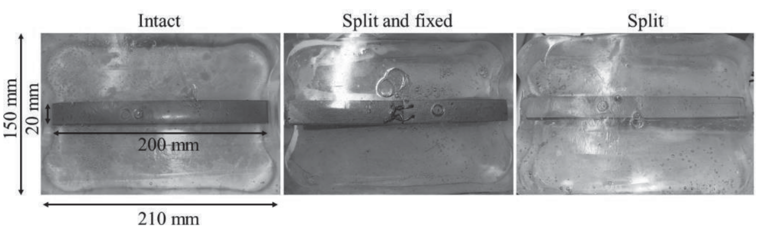

Figure 4. The mockups used in the study: intact, split and fixed (stable), and split with a gap of 2 mm (unstable).

Human cadaver study
To test the device in realistic conditions, we conducted a study using two human cadavers (Table 1). The study followed the ethical principles for medical research involving human subjects as stated in the World Medical Association Declaration of Helsinki. The study protocol was approved by the Regional Ethics Committee of Tampere University Hospital (Approval number ETL R14131). The relatives of each study subject were contacted by the coroner (SG) and their consent sought before inclusion in the study. These two cadavers were not included in the earlier published human cadaver study [28].

Table 1. Human cadavers used in the study

Cadaver case #	**Sex**	**Weight (kg)**	**Height (cm)**	**BMI (kg/m²) and category**	**Age**	**Soft tissue thickness (mm)**	**Thoracic temperature start/end (C)**
1	M	72	173	24 normal weight	59	18	18 / 20
2	F	64	163	24 normal weight	64	13	16 / 19

The study consisted of three states of *in situ* sternums and modeled them before and after surgery: baseline (intact sternum), stable tight wire fixation closure (sternum bound tightly with surgical steel wires) and unstable wire fixation with a gap (wires slightly loose and sternal halves moving; mimicking a complication inducing sternal instability). After each manipulation of the cadaver the soft tissue was closed by suturing. The sternal midline and costal cartilage level 3 were marked on the skin. Level 3 has previously been shown to provide useful data [27]. The actuator and sensor were placed on the costal cartilage bilaterally 30 mm from the sternal midline and perpendicular to the skin (Figure 5). Five repeated measurements were recorded, and their total powers integrated for each state. The measurement data of the mockup and cadaver studies is available in the Mendeley Data [31]. The usability and ergonomics of the instrumentation were also evaluated during the measurement sessions.

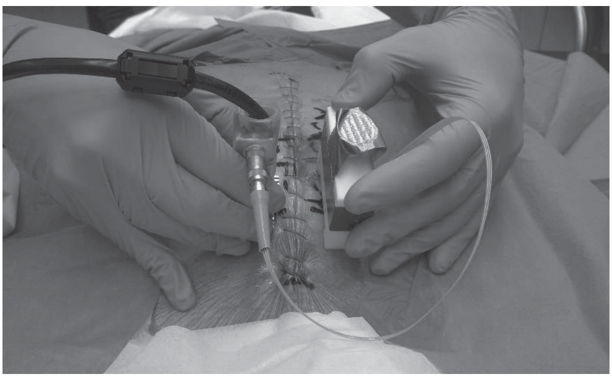

Figure 5. The Sternal Vibration Device in use. The actuator (left) and the sensor (right) placed 60 mm apart over the cadaver sternum and sutured thoracic skin. The units were held manually during the stimulation and measurement process [28].

Results

The actuator validation measurements consisted of recording the actuator forces using a load cell over a set of 47 vibration sweeps. The resting force of the actuator piston on the target surface was 1.37 N. The dynamic force recorded by the load cell fluctuated around this baseline level. The max absolute values of the recorded force amplitude in the data set was related to the piston resting force to get decibels over the frequencies swept. The actuation force median, Q1 and Q3 of all the 47 sweeps were 259 mN (-14.5 dB), 237 mN (-15.2 dB) and 288 mN (-13.6 dB) respectively. The Q1 and Q3 inter-quartile range was 19.6 % of the median, and the overall actuation force was fairly even throughout the actuation sweep, despite the few peaks (Figure 6).
The repeatability of the sweeps was calculated using root-mean-square deviation. For that the average of all the 47 sweeps was subtracted from the individual sweeps before the root-mean-square calculation. The RMSD median (min-max) over all the 47 sweeps

was 96 mN (79 mN-129 mN). This was 7.0 % (5.7 % - 9.4 %) of the resting force. The results show that the actuation force sweeps were repeatable.

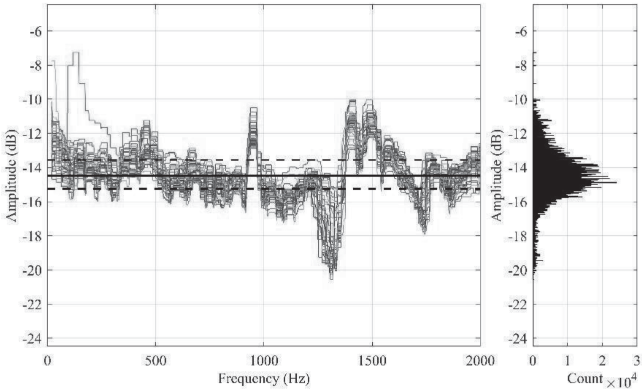

Figure 6. Actuator performance during the validation testing. Left panel: A decibel plot of the absolute amplitudes over the frequencies swept related to the resting force of the actuator piston. All the 47 recorded sweeps are shown with the data median -14.5 dB (solid line), Q1 -15.2 dB and Q3 -13.6 dB (broken lines). Right panel: the distribution of the data in the 47 sweeps where the y-axis is the relative amplitude in decibels and the x-axis is the count of the data samples per bin.

The accelerometer was calibrated by subjecting it to four known accelerations (1 g, - 1 g, 0 g and -2 g). The data was used to do a linear fit between the raw data, the 16-bit ADC output, and the corresponding known accelerations. The data points had a high correlation (Pearson`s correlation r = 0.99962) and the linear regression equation obtained from the data fitting was used to later convert the recorded data from the mockup and cadaver studies into acceleration in g (Equation 2, Figure 7). In Equation 2 *ADC* is the output of the analog-to-digital conversion and *a* is acceleration.

Equation 2. $a = 9.6 \cdot 10^{-5} \cdot ADC - 3$

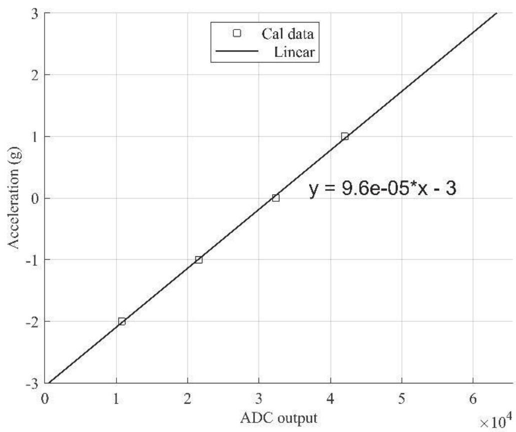

Figure 7. Linear regression was used to find how the ADC output data related to the actual acceleration in g. The regression line from the four data points is shown, and the line equation was used for calculating the acceleration in the mockup and cadaver studies.

The accuracy of the frequency measurement was tested by subjecting the accelerometer to varying sinusoidal stimulation frequencies. The set and measured frequencies were compared. The relative differences are very small indicating that the accelerometer can be used for precise frequency measurements (Table 2).

Table 2. The differences of the measured frequencies to the set frequencies using the Brüel & Kjær Type 4291* and the Instron Electropuls E1000.

Set frequency (Hz)	Measured frequency (Hz)	Difference (%)
20	19.5	-2.5 %
80 *	80.6	0.7 %
100	100.1	0.1 %
500	500.5	0.1 %
1000	1001.0	0.1 %

The usability evaluation indicated that the sensor and actuator were ergonomic to handle due to their form factor and lightness. Placement was easy after the correct positions on the tissues were determined and marked. The SVD made it possible to measure several consecutive sweeps by keeping the trigger depressed. Each sweep start and end were marked by audible beeps. These features made the execution and following the measurements easy. The device battery was charged before each measurement session and the charge sufficed for a complete session.

The actuator sweeps were in the range 20 Hz – 2 kHz and the accelerometer output showed the highest amplitudes and signal power in the low frequency range (example in Figure 8). In both mockup and cadavers the vibration transmittance decreased when the sternal setting became more unstable. The calculated total power of the signal in the 20 Hz – 2 kHz band was the highest in the intact state and decreased when the sternal halves were split and bound. The unstable state had the lowest power indicating a poor transmission of vibration between through the sternum (Table 3).

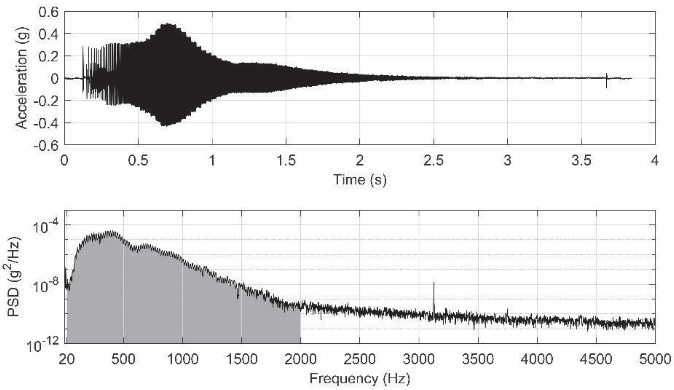

Figure 8. An example of measured data from Cadaver 1. Above: Raw accelerometer data in 0-4 s from intact sternum, third level costal cartilage (base level subtracted to show the transmitted signal). The raw data frequency climbed as the stimulus sweep progressed. Below: Power spectral density of the raw data. Total power was the integrated gray 20 Hz - 2 KHz area [28].

Table 3. Numerical results of the transmitted vibration total power in the 20 Hz – 2 kHz band. Five sweeps were recorded in each state: intact, stable and unstable. The results are median, min and max of the five calculated powers. All the results are x10-3 g^2.

Model	**State of bone**	**Median (min-max)**
Mockup	Intact	86.42 (70.57-87.35)
	Stable wire fixation	20.59 (9.12-25.53)
	Unstable gap	2.28 (1.98-4.22)
Cadaver 1	Intact	7.12 (5.09-7.85)
	Stable wire fixation	5.20 (4.68-7.11)
	Unstable wire fixation with a gap	1.96 (1.46-2.94)
Cadaver 2	Intact	18.17 (16.96-26.93)
	Stable wire fixation	5.22 (4.23-5.63)
	Unstable wire fixation with a gap	0.61 (0.60-0.77)

Discussion

Current methods in clinical practice, manual palpation and CT imaging, are imprecise in detection of sternal instability in patients recovering from cardiac surgery. Earlier diagnosis of loosening sternotomy junction would enable measures for restabilisation of sternotomy and avoidance of more serious complications including deep wound infection leading to death in about one fifth of the cases [8].

This motivated us to develop and test vibration transmittance as an objective, replicable, fast, and noninvasive tool for sternotomy diastasis detection. This method does not carry the risks of ionizing radiation and intravenous contrast medium, which are obvious problems when fairly expensive CT is used. As far as we know our group is the first to use vibration for postoperative sternotomy stability assessments. We have earlier reported promising preliminary clinical and experimental results using this approach [27,28] and now we present the technical implementation of the concept. The validation of the SVD was done using independent instruments for assessing the performance of the actuator and the accelerometer. The actuator's output force was repeatable over the test sweeps. The actuation force was relatively stable throughout the actuation frequency sweep. The accelerometer was calibrated using known accelerations. The calibration line was an excellent fit to the data. The calibration equation was used to convert the data recorded in the mockup and cadaver studies into accelerations. The accelerometer also detected the set stimulation frequencies accurately. The SVD can therefore yield precise results of the vibration transmittance to assess sternal connectivity.

Our present findings prove that various mechanical settings can be differentiated by vibration transmittance analysis. In earlier studies on vibration-based bone connectivity assessment the transmitted vibration has mostly been in the range 100-500 Hz corresponding the natural frequencies at which the long bones resonate [18,19,22,32,33]. In our earlier pilot study on patients' sternums the stimulation range used was 20-1500 Hz, giving the best separation between conditions in the 600-1500 Hz range [27]. In the present study the total power at 20 Hz – 2 kHz gave a good separation between the settings and the same conclusion was drawn in in the following larger scale human cadaver study [28]. We did not optimize the analysis frequencies as these may be different in patients than in cadavers. However, in the upper panel of Figure 8 the most transmitted power is early in the stimulus sweep corresponding to lower frequencies. Of note is that the feasibility results reported herein were part of the device development and were not included in the larger scale cadaver study. Consequently, our reports are published in reverse order.

In the mockup study the materials selected, 3D printed polylactide for bone and ballistic gel for soft tissue, may not exactly model the mechanical properties of human tissues. The PLA rod was embedded at a depth of 5 mm, whereas the cadavers had 18 mm and 13 mm thick soft tissue over the sternum. As seen in Table 3, the mockup results have a higher transmitted power than the cadaver results. Even though the absolute values do not match, there is a similar trend in the mockups and as in the cadavers. The intact rod/sternum shows the highest transmitted vibration power, and the power decreases first as the rod/sternum is cut and bound and then even more when there is a gap between the halves. The anatomical diversity may account for the differences of the results between the cadavers (Table 2, Table 3), and therefore in the intended clinical use the patients' follow-up results should always be compared to their own baseline.

The actuator and sensor were held manually during measurements. With the mockups it was important to hold the units perpendicular to the tissue surface to maximize the mechanical coupling and hence the transmittance. As seen in Figure 4, the craniocaudal angle of the sensor is perpendicular to the studied surface due to the sensor handle. Instead the lateral angle must be determined by the examiner. Regarding the actuator both angles are defined by the examiner. The hands holding the units rest lightly on the studied thorax surface, possibly affecting the transmittance to some extent. The distance between the units must be kept the same to be able to compare the values between the states. It is also essential to maintain the exact position of the units right on top of the costal cartilages to maximize vibration transmittance. The superficial anatomy is relatively straightforward to examine by palpation if the patient studied is lean, but in obese patient accurate measurement positions are more difficult. Moreover, the steel wires used for sternotomy closure provide an auxiliary pathway for vibration propagation thereby affecting the transmittance results [18]. However, this phenomenon does not interfere with the interpretation of the results since the transmittance measurements are made with the same sternotomy closure material included.

The cadaver model is a valuable platform for vibrational sternotomy stability studies because it offers opportunities to objectively determine different mechanical conditions in the human thorax. We concede that in cadavers tissue rigidity and temperature, for example, differ from those of living tissue, and this may somewhat limit the translation of our findings to clinical postoperative patients. Due to the stiffer consistency of cadaver tissues the presence of trapped air in the wound is more likely. Use of liquid or gel (e.g. ultrasound gel) to supplant the air could overcome this problem.

In future work the detection accuracy of the SVD for narrower gaps in sternotomy junction and partially unstable sternotomy junction should be explored. The effect of soft tissue dampening should be studied as well.

Conclusions

In this paper the technical solutions and validation process of the Sternal Vibration Device were given. We have developed a technology and shown that wide band mechanical vibration transmittance can be used for detecting discontinuities of material and bone in conditions resembling surgery performed on the sternum. The SVD offers quantitative data on sternal mechanics and enables earlier detection of diastasis and the resulting instability. Potentially it could be used to prevent the serious consequences of failed sternotomy. However, further device development and studies with larger sample sizes are needed.

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PUBLICATION II

Postoperative sternal stability assessed by vibration: A preliminary study

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Postoperative Sternal Stability Assessed by Vibration: A Preliminary Study

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Purpose. **Mechanical stability of the postoperative sternum was assessed using novel analysis based on vibration response.**

Description. **The response to controlled vibration in the 50 Hz to 1,500 Hz range was studied in 22 elective cardiac surgical patients with an accelerometer, recorded, and processed on a personal computer. Each patient had four measurement sessions. The mechanical transfer function of the sternum was estimated, and several descriptive factors were extracted from it to determine how they reflect changes occurring in the bone during the recovery from sternotomy.**

Evaluation. **Complete datasets were obtained from 14 patients. The most informative variable for the sternal healing was the $P_{600-1500}$ index, which reflects transmittance in the wide frequency band between 600 Hz and 1500 Hz. The index dropped after surgery, indicating a decrease in transmission. The postoperative measurements revealed a reverse trend in the same variable, which can be attributed to healing.**

Conclusions. **Significant changes caused by the sternotomy and subsequent healing processes were observed using vibration measurement.**

(Ann Thorac Surg 2012;94:260–4)

Clinical methods for bedside assessment of post-sternotomy wound stability would be well warranted. In this article, we evaluate a method that employs mechanical vibration to judge the healing of the sternum after median sternotomy.

Postoperative sternal instability may cause discomfort and pain and lead to mediastinitis [1, 2]. The estimates on the incidence of post-sternotomy instability range from 0.39% to 5% [1]. The diagnosis of instability is still largely based on palpation. Technologies used in experimental biomechanical studies cannot be used clinically [3]. Computed tomography is the most accurate imaging modality at the moment for the assessment of the sternum. However, owing to bone formation occurring slowly, it is far from being an optimal method for evaluating the healing of sternotomy. In studies such as described by Bitkover and colleagues [4], none of the computed tomographic scans showed radiologic signs of healing at 3 months after surgery, and at 6 months after surgery only half of the symptom-free patients had sternal union in the computed tomography scan. Ultrasonography has been used in the evaluation of gross sternal instability years after surgery, but there are no comparisons of its use in the early postoperative period [5]. It is obvious, therefore, that new tools are needed for detecting early stages of sternotomy separation.

Externally applied low-power, low-frequency vibration excitation and measurement is widely used in experimental mechanical analysis of various machine parts and structures. The method is based on the principle that the response to vibration depends on the geometry of the studied object, its material properties, and the boundary conditions, namely, the surrounding materials. Both theoretic and experimental studies show a considerable shift of natural resonant frequencies toward lower bands in fractured bones [6–8]. Vibration has also been used to assess bone density and dental or orthopedic implant stability [8–10]. Compared with imaging methods, the vibration analysis does not use ionizing radiation and is technically relatively easy to implement also in bedside clinical settings. The main challenge in vibration analysis of osseous structures is the damping effect caused by soft tissues surrounding the bone, especially in obese patients.

Our study applied a new approach, vibration measurements, to the assessment of postoperative sternal stability. Our main hypothesis was that the vibration response to the healing sternum should approach that of the intact one.

Technology

A special measurement system was designed and constructed for the purpose of this study. It generated

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controlled vibration and obtained the response of the sternum. The measurement system consisted of a main board generating the controlled stimulus waveform and performing data acquisition; vibration actuator providing vibration to the tissue; sensor module; and optical isolation module for patient safety. All measurement data were collected on a portable computer for further data processing and analysis in MATLAB programming environment. Different vibration modalities were tested, and the most appropriate modality was used for further analysis of clinical patients recovering from cardiac surgery and sternotomy.

Wideband vibration excitation was produced by a specially constructed electromagnetic actuator that generated frequency in the range of approximately 50 Hz to 1,500 Hz. Vibration was transmitted through the skin and soft tissues to the underlying cartilage and bone, where it propagated with less attenuation. Accelerometer was used as the sensor module to pick up the response. Its bandwidth was limited to about 1,450 Hz, which matched the applied excitation.

Technique

A total of 22 elective patients were recruited for clinical measurements from March 2010 to June 2010. Patients having permanent cardiac pacemaker or implantable cardioverter defibrillator were excluded. All patients received oral and written information about the methods and objectives of the study and signed informed consent forms. The study protocol was approved by the Institutional Ethical Committee.

Sternal closure was done with no. 7 standard steel wire either with five to seven single loops round the sternum or in combination with figure-of-eights or no. 6 double wires.

According to the established protocol, four measurement sessions were organized for each patient. The first session was usually carried out 1 day before the operation. The second session was organized on the fourth postoperative day. The following sessions were 3 weeks (21 ± 3 days) and 3 months (90 ± 10 days) postoperatively. In addition to vibration measurements, pain related to sternotomy was registered, as well as clinical findings on the stability of the sternum and possible signs of wound infection. Ultrasonography imaging of the sternotomy was done under manual palpation provocation 3 weeks and 3 months postoperatively.

Three locations for the vibration measurements in sternum were defined: upper (heads of clavicles), middle (third costal cartilages), and lower (fifth costal cartilages). Stimulation was applied 3 cm laterally to the right of the midline, and acquisition was done 3 cm laterally to the left of it. The spectrum of the input excitation was known and fixed, while the recorded response could be seen as the mechanical system's output. Based on the recorded response, the mechanical transfer function of the studied sternum could be estimated. Several descriptive parameters were extracted from the estimated mechanical transfer functions (Fig 1). They included magnitudes and frequencies of various peaks, as well as more general indices that cover wider frequency bands. The $P_{600-1500}$ index represents the integrated transmittance within a wide band in the higher frequency range. This index was normalized with respect to preoperative values, yielding all subsequent values as dimensionless ratios (Fig 2). Normalization is important for parameters that do not correspond directly to physical quantities, have no assigned units, or result from transformations that obscure the initial measured magnitudes. Normalized parameters are suitable for the approach implemented in this study, which counts primarily on repeated consistent measurements that could be compared and cross-referenced.

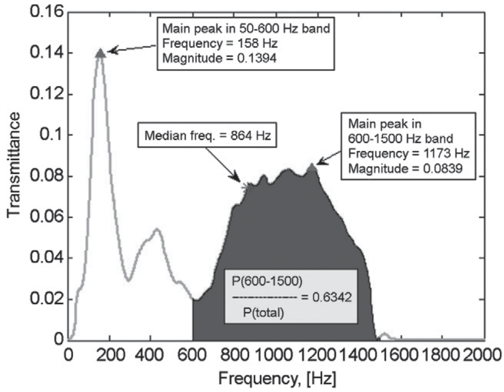

Fig 1. Descriptive parameters extracted from the estimated transfer function.

Because the parameter distributions were nonnormal, we preferred nonparametric testing and median value with range as indicators. The Wilcoxon signed rank test was used to determine the significance of changes in the transfer function parameters between the consecutive measurements. A p-value was considered significant at the 0.05 level.

Clinical Experience

The device and measurements worked well, and generally, the patients felt comfortable with the measurements. No side effects related to the measurements were noted. A complete series of preoperative and three postoperative measurements were obtained from 12 patients with normally healing sternum and from 2 patients with delayed healing. In the first patient with delayed healing, a sensation of clicking and instability in the upper third of the sternum occurred immediately after operation and lasted 3 weeks postoperatively, but spontaneous stabilization was observed 3 months after the operation. In the second patient, the lower third of the sternum was unstable very clearly as seen on ultrasonography done at

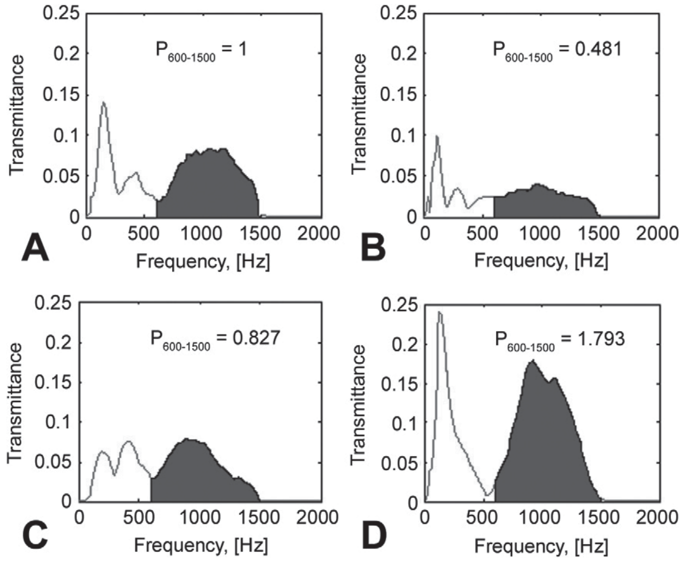

Fig 2. Relative values of the $P_{600-1500}$ index at different postoperative stages; the preoperative value is used for normalization and is equal to unity by definition. (Patient number 2, middle position). (A) Preoperative; (B) early postoperative; (C) 3 weeks postoperative; (D) 3 months postoperative.

3 weeks and 3 months postoperatively. The mean age of these 14 patients was 61.9 ± 12.8 years. Nine of the 14 patients (64.1%) were male, the mean logistic European System for Cardiac Operative Risk Evaluation (EuroSCORE [with SD]) was 4.47% (± 6.00%), and mean body mass index (with SD) was 29.3 (± 4.2).

Results

Eight patients out of 22 were excluded from the analysis. The vibration spectral range was widened after the first patient's preoperative measurement, and 1 patient withdrew consent after the operation for reasons not related to this study. We recruited 2 patients with a clinically evident sternal instability in the postoperative period. For 1 patient, a permanent pacemaker was implanted postoperatively, 1 patient was at district hospital ward at the time of the 3-week measurements, and 2 high-risk patients died before the last control.

Two patients had minor redness in their sternotomy wounds 3 weeks postoperatively. The rest of the cases had no clinical signs of infection or inflammation postoperatively.

The analysis of the spectrum of the vibration revealed interesting details. The most informative measurement for the sternal healing was the $P_{600-1500}$ index. Figure 3 shows the distributions of $P_{600-1500}$ index at three different postoperative timepoints; the measurements were normalized with the preoperative values. The $P_{600-1500}$ index dropped to low level in the early postoperative period, indicating a decrease in transmission. The sequence of postoperative measurements revealed a reverse trend in the same variable, which can be attributed to bone healing. At middle position, the index exceeded its preoperative level. That may have been due to sternal fixation steel wires, which enhance the transmission. The differences in transmittance between consecutive postoperative measurements were statistically significant at the middle and lower position in the sternum (Table 1).

The possible damping effect of thick subcutaneous tissue was studied by comparing the transmittance to subject's body mass index. No association between transmittance ($P_{600-1500}$ index greater than 1 at 3 months) and body mass index (less than or above) 28 could be found (as studied in a 2-×-2 contingency test). Thus, it can be concluded that obesity did not interfere with transmittance measurements.

Comment

If postoperative sternal instability could be detected at earlier phase, action could be taken to stabilize it before fragmentation and infection of the sternum. That could decrease morbidity and mortality after cardiac surgery, improve considerably patients' quality of life, and lead to economic savings in patient care. We present a new approach for clinical sternal stability assessment. Vibration proved to be applicable, reliable, and safe for clinical measurements; and the method enabled easy bedside measurement even in the early postoperative phase. The preoperative measurements offered valuable references for the measurements taken in the postoperative period.

Our data consisted of 14 cases with sequential measurements, enabling us to get longitudinal estimate of the sternal healing over time. The most remarkable changes occurred in the higher frequency (600 Hz to 1,500 Hz) band of the studied transfer functions, which corresponds with results from other studies [6, 7]. The effect of the sternotomy gap could be observed shortly after the operation in the significant drop of the vibration transmittance in the 600 Hz to 1,500 Hz band. Soon after that, it increased gradually, but only in the middle and lower sternal areas. The upper sternal positions mostly yielded nonusable data. In this position, the vibration actuator and the accelerometer were placed on the clavicular heads, which made the vibration signal travel across the sternoclavicular joints causing the response of the clavicles to dominate.

Summary

The results of this preliminary study are encouraging and may relieve the difficult decision-making process when the suspicion of sternal wound instability has been raised. Our initial findings with unstable sternums hint that this method can further be utilized in detecting also the failing sternum with clinical instability. Also, for normal healing and stability evaluation, the results are in concordance, and therefore promising. More research data based on vibration measurements in different sized patients, different fixation wire configurations, and patients of different ages are still needed to further quantify the stages of sternal healing.

Table 1. Differences in Transmittance Between Consecutive Postoperative Measurements

Measurement	Stage I[a]	Stage II[b]
Middle position	$p = 0.0034$ Signed rank = 4	$p = 0.00097656$ Signed rank = 1
Lower position	$p = 0.0024$ Signed rank = 3	$p = 0.0522$ Signed rank = 14

[a] Between early postoperative and 3 weeks after operation measurements. [b] Between 3 weeks and 3 months after operation measurements.

The $P_{600-1500}$ index normalized using preoperative value was used, and the significance determined with the Wilcoxon signed rank test.

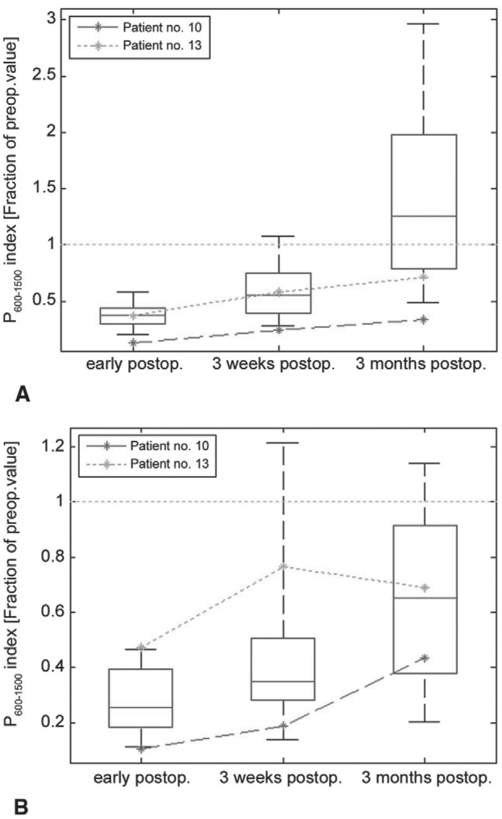

Fig 3. Figures of the distributions at (A) middle level and (B) lower level. The horizontal unity line represents the preoperative level ($P_{600-1500} = 1$). The box plots represent the group of uneventful 12 cases. The box plots include the median value (red), upper and lower quartiles (blue), and range (whiskers). Patient 10 (purple) and patient 13 (green) had sternal instability and are depicted individually. (postop. = postoperative; preop. = preoperative.)

The work of research coordinator, Kati Peltomäki, the nursing staff on the cardiothoracic surgical ward and cardiac care unit in Heart Center, and the valuable advice from hospital engineer, Tero Nieminen, on the electrical safety of the measurement system are greatly appreciated.

Disclosures and Freedom of Investigation

Nikolai Beev's Master's thesis comprises the technology setup described in this paper.

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Disclaimer

The Society of Thoracic Surgeons, the Southern Thoracic Surgical Association, and *The Annals of Thoracic Surgery* neither endorse nor discourage use of the new technology described in this article.

INVITED COMMENTARY

In this paper [1], the authors describe a novel and potentially useful method for evaluating the healing of median sternotomy incisions based on the transmittance of sound. It is important to note that a preoperative transmittance observation is required for each patient because the measurement is a dimensionless ratio of the postoperative to the preoperative transmittance. This ratio determines if the sternum has healed back to the preoperative state in terms of response to vibration, and assumes that transmittance is a valid metric for the strength of the healed sternum. Transmittance measurements were made at the level of the manubrium, midsternum, and distal sternum. Measurements at the manubrium were not useful, presumably due to interference from the clavicles. The authors propose measuring the cumulative (ie, integrated) transmittance between a frequency band ranging from 600 and 1,500 Hz as the basis for the preoperative to postoperative ratios. There was no association between body mass index and transmittance, suggesting that this test can be used despite soft tissues (eg, adipose tissue) that lie over the sternum. Steel wires were used to approximate the sternum after surgery. The authors showed a progression from diminished transmittance shortly after surgery toward the preoperative condition in a small group of elective cardiac surgery patients (only 14 patients had complete datasets).

Sonic transmittance as described in this paper is a potentially useful method for following the progress of healing in the sternum with serial measurements. Transmittance measurements avoid the adverse effects of ionizing radiation (eg, from serial computerized tomographic scans). Transmittance is probably more sensitive than ultrasound imaging of the sternum, although this has not been directly tested. This study is a preliminary one. Before transmittance ratios are accepted for research or clinical use, the concept must be validated in a larger number of patients who experience a variety of suboptimal healing conditions (eg, wire fracture with minimal to severe sternal instability or mediastinitis) and a variety of methods for sternal closure (eg, cerclage of the sternal halves with wires or plastic bands, and sternal plating). The requirement for a preoperative baseline transmittance measurement in every patient may limit the use of this technique to research due to cost constraints.

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PUBLICATION
III

Vibration transmittance measures sternotomy stability – A preliminary study in human cadavers

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RESEARCH ARTICLE Open Access

Vibration transmittance measures sternotomy stability – a preliminary study in human cadavers

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Abstract

Background: Stability is essential for the normal healing of a sternotomy. Mechanical vibration transmittance may provide a new means of early detection of diastasis in the sternotomy and thus enable the prevention of further complications. We sought to confirm that vibration transmittance detects sternal diastasis in human tissue.

Methods: Ten adult human cadavers (8 males and 2 females) were used for sternal assessments with a device constructed in-house to measure the transmittance of a vibration stimulus across the median sternotomy at the second, third, and fourth costal cartilage. Intact bone was compared to two fixed bone junctions, namely a stable wire fixation and an unstable wire fixation with a 10 mm wide diastasis mimicking a widely rupturing sternotomy. A generalized Linear Mixed Model with the *lme* function was used to determine the ability of the vibration transmittance device to differentiate mechanical settings in the sternotomy.

Results: The transmitted vibration power was statistically significantly different between the intact chest and stable sternotomy closure, stable and unstable closure, as well as intact and unstable closure (t-values and p-values respectively: $t = 6.87$, $p < 0.001$; $t = 7.41$, $p < 0.001$; $t = 14.3$, $p < 0.001$). The decrease of vibration transmittance from intact to stable at all tested costal levels was 78%, from stable to unstable 58%, and from intact to unstable 91%. The vibration transmittance power was not statistically significantly different between the three tested costal levels (level 3 vs. level 2; level 4 vs. level 2; level 4 vs. level 3; t-values and p-values respectively $t = -0.36$, $p = 0.723$; $t = 0.35$, $p = 0.728$; $t = 0.71$, $p = 0.484$).

Conclusions: Vibration transmittance analysis differentiates the intact sternum, wire fixation with exact apposition, and wire fixation with a gap. The gap detection capability is not dependent on the tested costal level. The method may prove useful in the early detection of sternal instability and warrants further exploration.

Keywords: Sternum, Sternotomy, Wound healing, Postoperative complications, Integrity, Vibration transmittance, Electronics

Classifications codes: 10.050 Cardiac / Basic Science, 20.030 Thoracic / Pleura and Chest wall

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Background

Median sternotomy is the most common access in open heart surgery. The estimated annual number of sternotomies in Finland is approximately 3800 per a population of 5.5 million, and the equivalent figure in the USA is about 500,000 per a population of 323 million [1, 2]. The disruption of sternal steel wire fixation occurs when the separating forces exceed the mechanical holding properties of the closure. The reported incidence of post-sternotomy instability ranges from 0.39 to 1.6% up to 6 months postoperatively [3–5]. Even minor instability may cause subjective symptoms and can progress to complete wound disruption often complicated by deep sternal wound infection. Early detection of sternal instability may enable preventative measures such as the use of supportive vests as well as surgical exploration and re-fixation of the wound that may prevent the later more severe complications [6–8]. Risk factors for instability include numerous patient factors, as well as operative and postoperative variables [9–18].

The mechanical stability of the bone fracture or osteotomy is crucial for the formation of a callus and the maturation phase of the lamellar bone [19]. Stability is also essential for successful bone healing after sternotomy [9, 10], but it is fairly difficult to measure. Detection of a failing sternotomy is commonly done by manual palpation, which is a subjective method and prone to misinterpretations [20]. Computed tomography offers only indirect information on sternal stability, and signs of sternal bone healing appear months after surgery [21–23], whereas sternal instability leading to wound disruption and infection most often occurs within the first month of the operation [3]. Ultrasound has been used to evaluate sternal nonunion and gross instability years after surgery [24], but the method obviously carries a risk of contaminating the wound in the immediate postoperative period.

Vibration transmittance has been used to assess bone fractures and bone density as well as dental and orthopedic implant stability [25–27]. With fixed input excitation, i.e. power emitted by the vibration actuator, the detected power measured by the accelerometer sensor acts as a measure of the mechanical integrity of the studied object. We have reported vibration transmittance as a tool to assess and follow postoperative sternal stability [28], and we postulated that non-invasive detection of early sternotomy diastasis could be possible. The aim of the present study was to describe vibration transmittance in the human sterna in a cadaver model. The hypothesis of the study was that vibration transmittance assessment could be used to differentiate intact, surgically fixated, and unstable sterna.

Methods

The study population consisted of 10 human cadavers. The age, height, weight, post-mortem time, soft tissue thickness, sternum thickness and presternal soft tissue temperature were recorded in each case, as shown in Table 1. The vibration transmittance measurement device used in this study was the third-generation version of an in-house-constructed, embedded vibration measurement system consisting of an actuator, a sensor, and a main controller unit. The device is compact, portable, and battery driven (Fig. 1). The actuator introduces a vibration stimulus to the tissue, sweeping a band of 20–2000 Hz over 3.7 s. The sensor consists of an accelerometer that records the transmitted vibration at a 10 kHz sample rate. During measurements, the actuator and sensor are held manually on the chest surface (Fig. 2). Figure 3 shows a typical vibration transmittance graph.

The skin was covered with an adhesive plastic film. Three measurement levels were used: on the top of the second, third, and fourth costal cartilage. The vibration actuator was positioned 3 cm to the right and the sensor 3 cm to the left of the midline. The vibration transmittance measurements were first performed on an intact chest, followed by unstable chest, and finally in a closed chest, five times at each setting and costal level. In the unstable chest model, a standard median sternotomy was conducted, followed by the insertion of six single no. 7 sternal wires (Ethicon, NJ, USA), and by leaving a 10 mm space between the sternal halves. Ultrasound gel

Table 1 Descriptive characteristics of study cadavers (8 males, 2 females)

	Median	Range
Age (years)	63	43–78
Height (cm)	171	157–187
Weight (kg)	79	51–100
BMI (kg/m^2)	27.0	20.7–28.6
Temperature[a] (°C)	19	16–21
Post-mortem interval (days)	5	2–7
Soft tissue thickness[b] (mean, mm)	12.5	4–19
Sternum thickness[b] (mean, mm)	13	10–21

[a]Presternal soft tissue temperature at the end of the study session
[b]Measured at the 2nd, 3rd, and 4th costal level

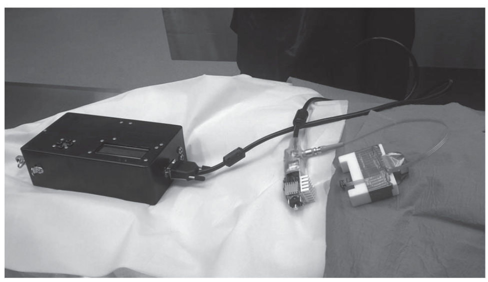

Fig. 1 Vibration transmittance measurement device. Main unit, actuator and sensor (from left to right)

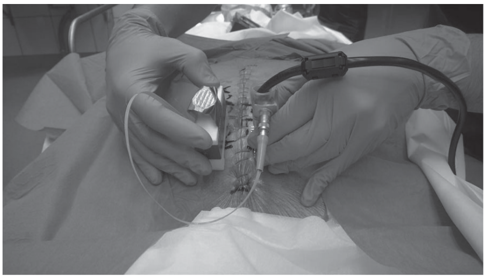

Fig. 2 Measurement of vibration transmittance. The sensor and actuator are held by hand and placed perpendicular in relation to the chest surface

was used to fill the gap and to mimic fluid accumulation. As there was a tendency for the gap to close in rigid cadaver chests, lateral rib traction was used to maintain the gap without obstructing the measurements. The chest was then tightly closed and the soft tissues sutured in two layers for the final measurements.

The data were processed off-line on a personal computer using routines implemented in a MATLAB (Mathworks, MA, USA) scientific computing environment. Total vibration power (g^2) in the 20-2000 Hz band was calculated for each measurement and logarithmic (ln) transformation was applied before statistical testing, since the raw data were not normally distributed. A generalized Linear Mixed Model with the *lme* function was used to determine the ability of the vibration transmittance device to differentiate mechanical settings in the sternotomy regardless of the costal level. The mean response was modelled as a linear combination of the population characteristics shared by all individuals (fixed effects), and subject-specific effects unique to a particular cadaver constituted the random effects. Three different mechanical settings and three costal levels were modelled as fixed effects and the number of repeated measurements per each cadaver constituted a potential source of variation and was included as random effects in the model [29]. The generalized linear mixed model analyses were performed with the Statistical Package R version 3.3.0 package lme4 (The R Foundation, www.r-project.org). All *p*-values are two-tailed. A *p*-value less than 0.05 was considered statistically significant.

The study was conducted in accordance with the Declaration of Helsinki. The study protocol was approved by the Regional Ethics Committee (Approval number ETL R14131). The relatives of each study subject were contacted by the coroner (SG) and their consent sought before inclusion in the study.

Results

The measured vibration transmittances are given in Tables 2 and 3 shows the total amount and percentage of vibration transmittance reduction at different costal levels and each state of the sternum, calculated from the medians of raw data. There were clear and statistically significant differences between intact, stable, and unstable sterna, and the reduction in vibration transmittance was able to differentiate between stable and unstable sternum, as shown in Fig. 4. There were no statistically significant differences in the vibration transmittance between the three costal levels that were tested, which is presented in Table 4. The soft tissue thickness in cadavers showed a moderate inverse correlation to

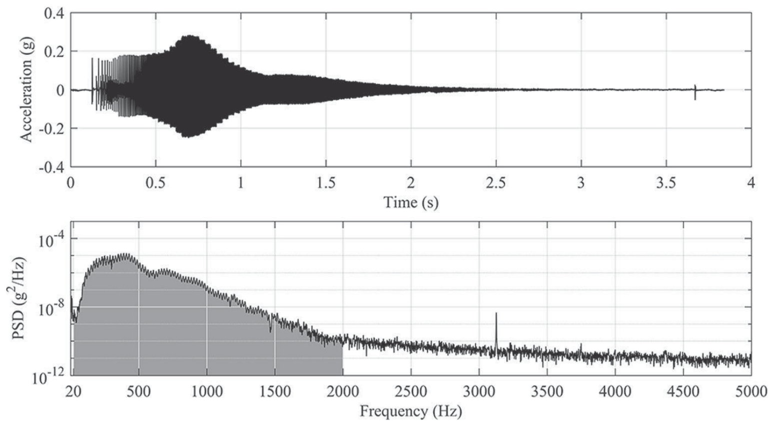

Fig. 3 An example of a vibration sweep output. Above: a vibration sweep output picked up by the accelerometer sensor according to the time. Below: the same vibration sweep results according to the measured frequencies. The gray-shaded area under the curve represents the total power integral in the 20-2000 Hz band

Table 2 The median measured vibration transmittance levels ($\times 10^{-5}$) in the 20 Hz – 2000 Hz band (g^2)

	Intact		Stable		Unstable	
	Median	(range)	Median	(range)	Median	(range)
2^{nd} rib	416	(24–2094)	99	(13–2312)	38	(7–118)
3^{rd} rib	346	(36–6756)	50	(12–7025)	32	(9–78)
4^{th} rib	305	(65–1603)	81	(9–834)	29	(9–233)
Levels combined	357	(24–6756)	77	(9–7025)	32	(7–233)

Stable fixation indicates the sternum is attached tightly with 6 steel wires and unstable fixation indicates a 10 mm distance between the sternal halves

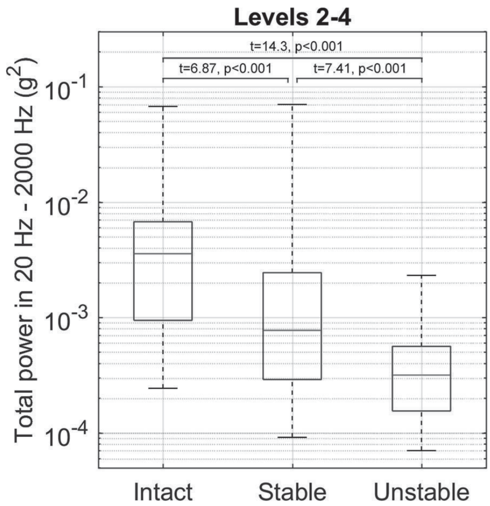

Fig. 4 The combined results at the 2nd, 3rd and 4th rib. Stable fixation indicates the sternum is attached tightly with 6 steel wires and unstable fixation indicates a 10 mm distance between the sternal halves

the transmitted vibration power when the raw data of all tested levels were analysed in the intact sterna (Spearman's nonparametric rho = – 0.478).

Discussion

Current clinical practice is lacking proper methods for sternal stability assessment. This motivated us to test vibration transmittance as an objective, repeatable, fast, inexpensive and noninvasive tool for the sternotomy dehiscence detection. This method lacks the risks of ionizing radiation and intravenous contrast medium, which are obvious problems when fairly expensive computed tomography is used. Our main finding was that vibration transmittance can be applied as a measure of postoperative sternal integrity.

With the transmittance measurement we achieved diagnostic separation between the intact and split sterna, especially when there was a gap. While the magnitude of vibration transmittance reduction was greatest between an intact sternum and a loose closure with a gap, the method appeared to be able to differentiate between a tightly closed and an unstable sternum as well, the situation with the most clinical relevance. The analyzed 20–2000 Hz band was the same as the stimulation band. Generally, in the low frequency vibration transmittance analysis, the optimal frequency band may differ depending on the device function and measured objects. A deeper search could have also revealed other sub-bands that in turn might better discern sternal stability, however, it was not the goal to optimize the test performance on the cadavers, as the intended use is in postoperative patients recovering from surgery. Indeed, in the preceding study we discovered that the optimal band to depict the stability of normally healing sternotomy is 600–1500 Hz in clinical patients [28], probably because the patients studied were normothermic and recovering from a cardiopulmonary bypass with tissue swelling. The reduction in the vibration transmission caused by the sternotomy was roughly the same even when the explored frequency band was different from our preceding study. As the device technology development is still in the early phase, a10 mm gap resembling widely broken sternum fixation was chosen as a pathological reference. The gap detection capability in the current study was not dependent on the tested costal level which is a sound and clinically relevant finding.

The main problem of in vivo vibration measurements of bone arises from the damping effects of skin and soft tissues, especially in obese patients [25]. A minor damping effect of soft tissues was seen in our series. It should

Table 3 The change in the median vibration transmittance between different states of the sternum ($\times 10^{-5}$ g^2)

	At 2^{nd} rib	At 3^{rd} rib	At 4^{th} rib	Levels combined
Intact → Stable	– 317 (– 76%)	– 296 (– 86%)	– 224 (– 73%)	– 280 (– 78%)
Stable → Unstable	–61 (– 61%)	– 18 (– 37%)	–52 (– 64%)	– 45 (– 58%)
Intact → Unstable	– 378 (– 91%)	– 314 (– 91%)	– 276 (– 91%)	– 325 (– 91%)

Table 4 Vibration transmittance power comparisons between the three tested costal levels. Statistical comparisons were calculated from ln-transformed data using a generalized Linear Mixed Model analysis

	t-value	*p*-value
3^{rd} vs 2^{nd}	–0.36	0.723
4^{th} vs 2^{nd}	0.35	0.728
4^{th} vs 3^{rd}	0.71	0.484

be noted, however, that this series was a proof of concept and feasibility test, and we intentionally chose cadavers with near normal body mass index to exclude the possible bias caused by excessive soft tissue damping. The role soft tissue thickness needs to be confirmed in a larger series. The cadaver model is a valuable platform for vibrational sternotomy stability studies because it offers opportunities to objectively settle different mechanical conditions in the human thorax for serial, repeated measurements. We acknowledge that e.g. the tissue rigidity and the temperature in the cadavers differ from living tissue, and this may somewhat limit the translation of our findings to clinical postoperative patients. The accuracy of the vibration transmittance method to detect smaller bone diastases, as well as characterizing the different stages of normal and disturbed healing in the sterna, requires further clinical study.

Conclusions

In conclusion, vibration transmittance analysis was applicable and able to differentiate intact sterna, tightly wire-fixed sterna, and sterna with diastasis in the wire-fixed bone halves. The gap detection capability is not dependent on the tested costal level. The concept was proven to be promising, as it offers a tool for the earlier detection of diastasis in sternotomies, which potentially enables the prevention of sternotomy wound complications.

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Availability of data and materials
The datasets used and analyzed in the current study are available from the corresponding author upon reasonable request.

Authors' contributions
JHa took part in designing the work, performed the sternotomies and vibration transmittance measurements, and participated in the interpretation of the data and manuscript writing. AJ took part in designing the work, and the prototype device, participated in the vibration transmittance measurement sessions, conducted the signal processing and data analysis, and participated in the interpretation of the data and manuscript writing. SG took part in designing the work, chose the cadavers for the measurements, and participated in the measurement sessions. TL conducted the statistical analysis of the data and took part in the manuscript writing. JK took part in the interpreting of the results and manuscript writing. JHy and JL took part in designing the work, interpreting the data, and writing the manuscript. All authors have read and approved the final manuscript.

Ethics approval and consent to participate
The study was conducted in accordance with the Declaration of Helsinki. The study protocol was approved by the Regional Ethics Committee (Approval number ETL R14131). The relatives of each study subject were contacted by the coroner (SG) and their consent sought before inclusion in the study.

Consent for publication
Consent was obtained from the relative of the study subject for publication of Fig. 2.

Competing interests
Tampere Heart Hospital Co. holds a patent on the vibration transmittance device, as agreed upon by the inventors (Nikolai Beev, Juha Hautalahti, Matti Tarkka, Jari Hyttinen, Jari Laurikka; U.S. Patent No. 9,788,726; EU: 11867251.8–1657 – EPO. PCT Pub No: WO2012/168534). The authors declare that they have no competing interests.

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PUBLICATION
IV

Symptoms of Sternal Nonunion Late after Cardiac Surgery

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-Post print version-

Title: Symptoms of sternal non-union late after cardiac surgery

A short title: Late post-sternotomy complaints

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Abstract:

Objectives: A cohort of patients having symptoms of sternal non-union late after sternotomy was studied to find out if the complaints were related to true sternal non-union or decreased bone density.

Methods: A survey was mailed to 2053 cardiac surgical patients operated in our institution between July 2007 and June 2010. The patients were requested about symptoms referring to sternal instability. A group of symptomatic individuals as well as 1:1 age- and time-matched asymptomatic controls were examined with sternal palpation, ultrasound during standardized sternal pressure provocation and computed tomography.

Results: 1918 patients (93.4%) replied in the survey. 2.3% (44 patients) reported sensation of movement or clicking in sternum during body movements and during coughing. Symptomatic patients living within 200 km to the hospital (21) and their asymptomatic controls (21) were selected for further clinical and imaging studies. Mean period between the initial operation and the examinations was 36 (22-56) months. Sternal palpation pain was significantly associated with reported symptoms suggestive of sternal non-union (OR 22.0; 95% CI 2.5-195); however, none of the patients had clinically unstable sternum or non-union in the sternal imaging. The symptoms of sternal instability were more frequent in patients whose bone mineralization rate (as measured with t-scores) was higher.

Conclusions: 2.3 % of patients experienced symptoms suggestive of sternal non-union. However, their symptoms did not correlate with CT scans or provocation ultrasound although palpation pain was evident. Thus, the pain is derived from non-mechanical etiologies. Higher bone mineralization rate correlated with abnormal symptoms of sternal wound.

Keywords: Sternum, Computed tomography, Surgery/incisions, Wound healing

Introduction:

Median sternotomy is the basic exposure in cardiac surgery. The stability of sternal closure is essential for normal wound healing and abnormal motion between sternal halves postoperatively prolongs it [1,2]. Sternal instability in the absence of infection up to six weeks postoperatively is defined as dehiscence [3]. Sternal non-union is a case of instability in which the two halves remain partially or completely separated more than 6 weeks after surgery [3]. The reported incidence of post-sternotomy instability is from 0.39 to 1.6 % up to six months postoperatively [1,4,5]. Incidences as high as 8 % have been presented in a review by Robicsek [3]. Risk factors for sternal wound instability include diabetes, chronic obstructive pulmonary disease, obesity, smoking, older age, immunosuppression, renal failure, osteoporosis, use of bone wax, re-sternotomy due to bleeding, and prolonged cardiopulmonary bypass [3,6].

The diagnosis of sternal instability is still largely based on palpation [7]. Plain radiographs in the early postoperative period may detect sternal stripe which reflects air between the separated sternal halves. Sternal wire displacement, sternal fractures and pseudoarthrosis in chest radiographs are also described as a sign of sternal non-union and thus may be detected in those patients [7,8]. Computed tomography (CT) is the most useful and informative imaging modality for sternum at the moment and depicts gaps between the sternal halves. Gaps of less than 3 mm are usually not associated with clinical instability [9]. Sternal union in CT should be complete within 1 year after the procedure [10]. Ultrasonography has been used in the evaluation of gross sternal instability years after surgery [11].

Sternal instability is associated with disability and pain restricting breathing. Unstable sternum in the early postoperative period is a risk factor for deep sternal wound infection [12,13] which is a major cause of morbidity and mortality following cardiac surgery [14]. In the later postoperative period prolonged sternal pain is also relatively common. Current publications dealing with post-sternotomy symptoms generally have not evaluated sternal ossification, as based on imaging, nor described the mechanical stability of sternotomy. Thus, the possible influence of sternal non-union to the late post-sternotomy symptoms is unclear.

In this study we wanted to find out the prevalence of sternal complaints and to characterize in detail the patient group expressing late sternal symptoms generally recognized as suggestive of sternal non-union a few years after the surgery. Our aim was to find out if symptoms suggestive of non-union correlate with the findings in the clinical examination, stress echography and in the computerized tomography, and if they were related with decreased bone density or operation-related factors.

Material and methods:

On October 2011 a survey was mailed to all 2053 cardiac surgical patients who were alive and who had been operated via sternotomy between July 2007 and June 2010 in our tertiary level teaching hospital. 1918 patients returned the mailed structured survey. The patients were asked about symptoms referring to sternal instability. Patients were graded as highly suspicious for sternal non-union if they had sensation of abnormal movement (or clicking) in sternum during body movements and during coughing. Chest pain was also asked and graded using numeric rating scale score (NRS), which is an 11–point scale for patient self-reporting of pain (0 indicating no pain, 1-3 mild pain, 4-6 moderate pain and scores from 7 to 10 referring severe pain).

Exclusion criteria from the clinical and imaging studies were distance longer than 200 kilometers to the hospital and age over 85 years. Ten cases were excluded due to long distance and three cases due to an old age. In addition, ten more cases could not be caught for tests: Two cases turned out to be asymptomatic, one was coming for cardiac reoperation during test days, one case was at hospital at the time of the study, six patients refused to participate or could not be reached despite multiple calls. 21 patients were eligible and willing to participate in the clinical and radiological examination and all had 1:1 matched control, in whom the operation time was close and the age matched (within 5 years). Altogether 42 patients (21 symptomatic individuals and 21 asymptomatic controls) were examined by using the standard protocol described in detail below.

The studied individuals were interviewed as well as bimanual sternal palpation estimating regional tenderness and unilateral compression to induce the possible movement between the sternal halves were performed by one surgeon (JH). Computed tomography (CT) imaging was done with Philips Achieva 64 slice scanner without intravenous contrast material. The scout view was used in estimating the position and possible migration of sternal wires compared to the immediate postoperative plain chest radiograph. Computed tomography covered the thoracic area from the cervical spine plane C6 to lumbar spine plane L3. The axial slice thickness was 0.625 mm. All images were estimated using soft tissue, lung and bone windowing. Sternal ossification was estimated at three anatomic parts of the sternum: at the level of manubrium and second and fourth costal level in axial projection. Ventrodorsal displacement without impairment in sternal ossification was called step off (Fig. 1). Sternal gap was defined as smaller than two-millimeter gap between the sternal halves (Fig. 2). Gap of two or more millimeters between sternal halves was concerned as significant in estimating sternal non-union (Fig. 3). The bone density was evaluated using the Philips quantitative computed tomography software. Vertebral bodies Th12, L1 and L2 were used in bone density measurements. T-score between +1 and −1 is considered normal or healthy. A T-score between −1 and −2.5 indicates low bone mass, but not low enough to be diagnosed as osteoporosis (osteopenia). A T-score of −2.5 or lower indicates osteoporosis. The greater the negative number, the more severe the osteoporosis. Interpretations of the immediate postoperative plain radiographs and CT scans were performed by one radiologist (IR-K) who was unaware of the symptoms of the studied individuals.

Fig. 1 Ventrodorsal displacement without impairment in sternal ossification was called step-off.

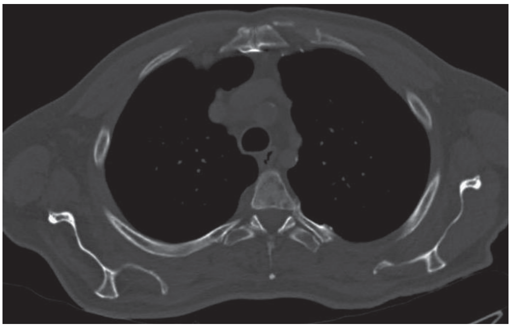

Fig. 2 Sternal gap was defined was defined as smaller than 2 mm gap between the sternal halves.

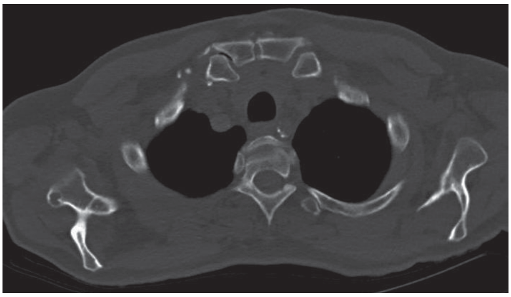

Fig. 3 Gap of 2 or more mm between sternal halves was concerned as significant in estimating sternal non-union.

Ultrasound examination of the sternum was performed patient lying in supine position during sternal provocation and without loading to rule out the possible movement between the sternal halves. Siemens Acuson S2000 ultrasound system with 14L5 linear probe (6-14 megahertz) was used for evaluation. The side of the possible step off was evaluated according to the sternal outer cortex and the more dorsal side of the sternal half was chosen for mechanical provocation. The provocation was implemented using a specially designed and manufactured bar, which produces a force of 50 to 70 Newton to round area with a diameter of 5 cm simulating normal clinical palpation (Fig. 4). This manually controllable force was focused on top of second and fourth costal cartilage by the surgeon (JH) and the position of the sternal halves in relation to each other were recorded at rest and under provocation by the radiologist (IR-K).

The study was conducted in accordance with the amendment Declaration of Helsinki. The study protocol was approved by the Institutional Ethical Committee (Pirkanmaa Health District´s ethical committee, approval number ETL R11062). The patients received oral and written information about the methods and objectives of the study and signed the informed consent.

Independent samples t- test was used for continuous normally distributed variables and Pearson chi square test for cross-tabulated data, and Fischer’s exact test for used in comparisons in 2x2 tables.

Fig. 4 The provocation was implemented using a specially designed and manufactured bar simulating normal clinical palpation.

Results:

44 patients (2.3% of all in the mail questionnaire study) reported symptoms suggestive of non-union. In the clinical study group (21 with symptoms and their matched controls), clinical, ultrasound and computed tomography scans were obtained in all. Characteristics of the patient groups are presented in table 1. The patients in the symptomatic group were more obese than the controls, BMI 32.8 and 27.6 respectively (p=0.006). On the basis of the other characteristics the groups were equal. Sternal closure was done using standard stainless-steel wires, either no. 7 single or no. 5 double wire in different configurations. The wires were put round the sternal edges except at manubrium where the wires were put through the bone (Table 2).

Mean period between the initial operation and the examinations was 36 (22-56) months. There were two superficial sternal wound infections in the early postoperative period treated conservatively in the symptomatic group and one in the control group. There were no cases with deep sternal wound infection in this clinical study cohort. Only one patient in the symptomatic group had re-sternotomy or sternal revision surgery. The indication was sternal dehiscense with no signs of infection which was related to earlier reoperation due to bleeding. Twelve patients in the symptomatic group had also pain in addition to having symptoms referring to sternal instability. The numeric rating scale (NRS) scores for pain (range 0-10) were 1.58 (0-4), 3.25 (0-7) and 4.33 (1-8) at rest, during coughing and during body movements, respectively. However, the pain caused only mild constraint to daily activities or night´s sleep among these patients. Six patients (28.6%) had tenderness in one of the sternal thirds in symptomatic group and one (4.8%) in the control group. Three patients in the symptomatic group had palpation tenderness exactly located in the sternal steel wires, and in one patient the later removal of the wires relieved the tenderness. According to the clinical evaluation, two cases in the symptomatic group had neuralgic type pain in the sternal region and two cases had recurrent angina pectoris.

None of the patients had sternal wire displacement on CT. Ten patients had partial sternal non-union based on CT. This was mainly 2 mm in width (7 patients), two patients had 3 mm non-union and one 4 mm non-union. All of these affected sterna only partially, complete (all sternal length) radiological non-unions were not found. Of note is that all these sterna were stable as judged with palpation and ultrasound under compression provocation. Radiological sternal non-union, step of- and sternal gap -findings are shown in table 3. Interestingly, no statistically significant difference was found between patients having symptoms when compared to those showing no symptoms. The effect of bone mineral quality to symptoms was studied by using bone density as a measure. Table 4 shows the relation between bone densities determined as T-value and sternal imaging abnormalities. There were no significant differences between the T-value and sternal gap, step off or non-union. The role of bone density, as judged from t-scores of vertebrae, in relation to any symptoms after sternotomy was studied comparing patient tertiles with lowest and highest T-scores. The results are presented in table 5.

Pain in the clinical palpation was strongly related with the reported sternal symptoms, and patients having pain in palpation of sternum at examination (11 out of 12 patients) had symptoms suggestive of nonunion (odds ratio 22.0; with 95% confidence interval 2.5 to 195).

Table 1. Patient´s characteristics (BMI = body mass index; EF = left ventricular ejection fraction; ASO = arteriosclerosis obliterans; cabg = coronary artery bypass grafting; osteoporosis = patient has osteoporosis medication; avr = aortic valve replacement; mitral = Mitral valve repair or replacement; Bentall = Bentall procedure; Other= resection of left atrial myxoma; reconstruction of sinus of Valsalva; LITA = left internal thoracic artery used as coronary graft; BITA = bilateral internal thoracic arteries used as coronary grafts)

	Symptomatic	**Control**
Male sex (%)	18 (85,7)	17 (81,0)
Mean age	61,9	63,1
BMI	32,8	27,6
Diabetes	10 (47,6)	3 (14,3)
Smoker	2 (9,5)	2 (9,5)
Ex-smoker	9 (42,9)	4 (19,0)
EF < 50 %	1 (4,8)	5 (23,8)
ASO	1 (4,8)	2 (9,5)
Osteoporosis	0	1 (4,8)
Urgency		
elective	11 (52,4)	11 (52,4)
urgent	6 (28,6)	6 (28,6)
emergent	4 (19,0)	4 (19,0)
Procedure		
cabg	13 (61,9)	17 (81,0)
avr	3 (14,3)	1 (4,8)
mitral	1 (4,8)	3 (14,3)
Bentall	2 (9,5)	0
Other	2 (9,5)	0
LITA	13 (61,9)	17 (81,0)
BITA	0	1 (4,8)
Delay from operation	37,1 months	34,1

Table 2. Sternal steel wire configurations. (6-7 S = 6 or 7 single wires; 6 D = six double wires plus 0, 1or 2 single wires; 3 D + 3 S = three double wires plus 3 or 4 single wires; 3 S + 2 Fo8 = 2-4 single wires plus two figure-of-eights; 4 Fo8 = four figure-of-eights)

	6-7 S	**6 D**	**3 D + 3 S**	**3 S + 2 Fo8**	**4 Fo8**
Symptoms	12	2	4	2	1
Control	14	2	3	2	0

Table 3. Sternal findings in computed tomography at the level of manubrium (Manu), second (2nd) and fourth (4th) rib.

	Step off			**Sternal gap**			**Non-union**		
Level	Manu	2nd	4th	Manu	2nd	4th	Manu	2nd	4th
Symptoms	2	6	11	14	5	11	4	1	0
Control	1	10	12	11	4	5	3	0	2

Table 4. Bone mineral density shown as T-score. Sternal gap, step off or non-union observed at any level (manubrium, second or fourth rib).

	Sternal gap		Step off		Non-union	
	No	Yes	No	Yes	No	Yes
T-score, average	-3,0	-2,3	-2,2	-2,6	-2,4	-2,6
T-score, median	-3,1	-2,4	-2,2	-2,8	-2,7	-2,8
Number of patients	10	32	18	24	32	10

Table 5. Bone mineral densities in three tertitles in relation to symptoms of sternal instability. (The T-score tertile cutpoints of -3,067 and -1,833 were used.)

			Control	**Symptoms**	Total
Tertile	Lowest (<-3,067)	n	8	6	14
		%	57,1%	42,9%	100%
	Middle	n	9	5	14
		%	64,3%	35,7%	100%
	Highest (>-1,833)	n	4	10	14
		%	28,6%	71,4%	100%
Total		n	21	21	42
		%	50%	50%	100%

Pearson Chi-Square 4,000, p= 0,231

Discussion:

Median sternotomy is easy to perform and gives good access to the heart. The routine method for sternal closure is steel wires due to the low costs, the simplicity to use them and the relatively good bone healing rate performance. Rigid plates or other more advanced means of closure are still used in special situations, e.g. in patients with high risk for sternal dehiscence or for secondary sternal closure [6]. In our study cohort the sternal closure was done using steel wires. There were no relevant differences in the closure techniques between two patient groups (symptomatic or asymptomatic) from this aspect.

Discomfort and disability due to sternal healing problems are quite common; patients often complain about temporary pain in their sternotomy wound. The clinical difficulty is to differentiate sternal bone pain from other pain modalities and origins. The reported incidence of chronic non-anginal post-sternotomy pain is 23-56 % one to three years after cardiac surgery [15-18]. Sternal instability is potential cause of the pain, and suggested other etiologies of the pain are multifarious including osteomyelitis, sternal or costal fracture, sternocostal chondritis, injury of brachial plexus, entrapment of the nerves due to sternal wire sutures or hypersensitivity reaction against the metal wire [19-24]. Our results confirm that pain in the clinical examination is significantly associated with reported subjective symptoms, and that the absence of symptoms tends to indicate normal healing in the sternum, also when studied in ultrasound compression tests later after cardiac surgery.

The previously reported incidence of postoperative sternal instability is approximately one per cent in the earliest postoperative months. In the clinical practice patients with true sternal instability late after cardiac surgery are relatively rare, and the incidence of sternal instability in the late postoperative period is not well known. This motivated us to explore our latest patient cohorts, and we assessed sternal stability on average of 3 years after surgery. Interestingly, despite patients´ fairly common symptoms we could not verify a single case with complete non-union by using a thorough diagnostic protocol with high sensitivity imaging, such as CT scanning nor with clinical palpation or sternal ultrasonography under mechanical provocation. There were few partial non-unions based on CT but those turned out to be stable during mechanical provocation. Our patients were selected on the basis of their sensations of sternal movement in the sternotomy area. Based on the mail survey 44 patients were graded as highly suspicious for having mechanically unstable sternum. Since the geography of our catchment is fairly large, we could not ask all the patients to participate in the clinical study, and we selected 200 kilometers as a comfortable range for recruitment. This leads naturally to potential selection bias, and this is a weakness of our study. A majority (57.1 %, 12 patients) out of these 21 symptomatic patients had also sternal pain. In this group three patients had focused local tenderness in the sternal steel wire and two were characterized as having neuralgia and two expressed recurrent angina. Neither clinical evaluation nor the chest computed tomography revealed clear explanations for the rest of the five patients having sternal pain.

We found out that the symptomatic patient group was more obese. Obesity is one of the known risk factors for sternal complications causing excess load to sternotomy and it negatively affects the normal tissue healing. Thus, our finding is logical in this patient cohort. The number of smokers in both groups were equal (2/9,5%) but, interestingly, the number of ex-smokers was greater in symptomatic group (9/42,9% vs. 4/19,0%) even if this difference did not reach statistical significance. Smoking might have altered the anatomy of the rib cage and made patients more prone to prolonged symptoms after median sternotomy. However, none of the cases had COPD though, and none of the patients in these two study groups had deep sternal wound infection history postoperatively. Thus bone-related severe infection might not be a risk factor for late symptoms referring to instability. For some reason there seemed to be a positive association between normal bone density and symptoms. However, since the evaluation of bone density is based on CT scanner software, its limitations also must be kept in mind.

Based on our experience and results, sternal symptoms are annoying to the patient and severe symptoms occur in 2%. However, as judged from our results, symptoms are relatively insensitive in revealing sternal bone non-union. Thus, the exact etiology of the pain remains obscure, but our findings indicate that they may be related to sternal wires, neuralgia or other non-mechanical causes. Since the numbers of obese and other high-risk patients undergoing cardiothoracic surgery through sternotomy are high, easy to use, safe and noninvasive clinical tools are needed in order to reveal delayed healing of sternal wound in more detail, especially in the earlier postoperative period. One option for this is based on using calibrated compression stress ultrasound or even bone vibration transmittance analysis, as shown in our earlier report [25].

Based on our results, it is remarkable that palpation pain is common and highly related to reported symptoms even late after cardiac surgery using midline sternotomy. This was evident and independent of time span between the operation and the examination. Interestingly, the imaging modalities showed only minor patho-anatomic differences in the healed sternum and did not correlate well with the symptoms the patients expressed. However, the fact that the patients with symptoms were more obese and had higher bone density needs to be studied in more detail.

Conclusion:

Our results confirm that symptomatic and mechanically unstable sternal non-union is uncommon a few years after cardiac surgery and may not play an important role among patients suffering from sternotomy related pain or movement related symptoms late after the initial cardiac surgery. Therefore, other reasons for pain, such as sternal wire irritation or neurinomas, might better explain the patient´s symptoms. Simple clinical tests are fairly accurate in distinguishing these symptomatic patients from those having fewer symptoms. Higher bone mineralization rate as measured by quantitative computed tomography correlated with symptoms of sternal instability.

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Conflicts of interest:

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