Evaluation of external chest supports based on the entire recovery process in and out of the hospital to avoid offset costs of long term complications and medications.

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Abstract

In spite of improved surgical techniques, the incidence of complications after sternotomy procedures have been stable during the last decade, and is costing the health care system enormous sums. A significant number of sternal wound complications are discovered after discharge, which has shifted the focus to postoperative care. There is an increased interest in alternative, non-surgical treatments, such as the use of external chest support devices as an adjunctive method to decrease postoperative complications and the related health care costs.

Several external chest support devices have been shown to decrease the incidence of deep sternal wound infections (DSWI) and dehiscence. If an external support device improves sternal stability but causes discomfort, pain or restrains activities, the clinical and cost advantages are most likely offset by long term complications and medications post-discharge, and it is difficult to assure that patients continue to use a device at home until the sternum has healed properly.

The decision to use a specific device must be based on how the patient’s entire recovery process is improved in the hospital and at home, and how sternal wound infections, dehiscence, pain, and pulmonary complications are addressed, including whether there is a positive effect on patient function, comfort, ease of breathing, and ease of exercise activities.

The purpose of this documentation is to review literature on complications following a sternotomy procedure, and evaluate the experience with external chest supports with regards to clinical evidence, cost justification, and essential functions. The conclusion is that the QualiBreath external chest support presently has the highest potential for improving a patient’s entire recovery in the hospital and at home.

Introduction

Although surgical techniques have improved, the rate of complications after sternotomy procedures have not changed over the last decades [25-28]. Furthermore, 50% to 80% of sternal infections are diagnosed after discharge, which previously was not recognized due to short follow up in research data [32-33].

Sternal infections and dehiscence are typically approached surgically, both with regards to prevention and cure. Additional sternal wires, steel bands, sternal plates, and negative wound pressure therapy (NWPT) have all been used as preventive methods [58-64]. The cure of a deep sternal wound infection (DSWI) is cumbersome and may range from eradication of the infection, followed by stabilization of the sternum and chest wall, open mediastinal packing, debridement with closure over drains, placement of vascularized tissue flaps, to negative wound pressure therapy (NWPT) [31].

Sternal infections and dehiscence are widely discussed in literature [22-33, 36-46, 58-65] while postoperative pulmonary complications and persistent pain are larger problems, and cost the health care system larger sums [1-21, 34-35, 47-57]. The relationship between pulmonary
complications and persistent pain is still not clearly understood [56-57]. Due to concern for drug addiction, many patients don’t ask for pain medication if not offered by personnel, and personnel don’t offer it, if patient’s don’t ask [48]. Consequently, patients may have more pain than necessary, which make them reluctant to breathe deeply and to cough. This has a subsequent negative influence on lung clearance for atelectasis and secretions, and slows down early mobilization and exercise of the upper limbs, which is needed to improve the blood circulation to promote a quicker healing of the sternum bone and wound [12].

There is no clear agreement on the recommended breathing techniques and upper limb exercises for sternotomy patients, and what they may do in and out of the hospital. Furthermore, the recommendations vary from hospital to hospital, and from country to country [55-57, 66-75]. To save health care costs patients are discharged as early as possible, usually after 5-7 days, with responsibility for their own recovery and healing of the sternal wound. There is limited control of how strictly patients follow the recommendations received at the hospital when they are at home, and how they take care of the sternal wound.

Improved surgical techniques have not decreased the rate of sternal infections, and more than half of them are diagnosed after discharge [21, 23, 30-33]. Patients continue to have pulmonary and pain problems several months or years after a sternotomy procedure [2-9, 13, 16-17, 19-20]. These are all reasons that attention has shifted to review preventive methods in the postoperative period, both in the hospital and after discharge.

This documentation is based on literature reviews of complications after sternotomy procedures to clarify whether there is clinical evidence and cost justification for the use of external chest supports as an adjunctive treatment in the hospital and at home, and whether the choice of external support matters for the outcome.

Background

There are no globally accepted definitions or classifications for sternal wound complications, persistent pain, or pulmonary dysfunction. It is relatively recent, that two classification schemes for deep sternal infection, mediastinitis, superficial infection, and sterile sternal dehiscence were suggested [25, 31]. There are no globally accepted evidence based practice guidelines for postoperative care of sternotomy patients in general [46, 72-75], or for patients with postoperative pulmonary dysfunction (PPD), and the frequency of PPD is not clearly documented [12-13, 15-19]. The lack of accepted practice guidelines and classifications for these major complications, complicates an effective prevention of them, and the comparison of results from one institution to another is difficult.

The incidence of sternal wound complications are below 10% in follow up till 90 days postsurgery [25-28], while pulmonary complications and persistent pain occur in up to half of all patients [15-19]. Pulmonary complications are more expensive, and cost the health care system
almost 5 times as much as the costs for persistent pain or sternal wound complications [13, 20-21].

Table 1. Costs and incidence of complications after sternotomy procedures

<table>
<thead>
<tr>
<th>Complications after sternotomy</th>
<th>Additional cost per case</th>
<th>Incidence 90 days follow-up</th>
<th>Approx. additional cost per 1000 cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sternal wound infections (DSWI):</td>
<td>$41,500 to $88,800</td>
<td>0.3% to 7.3%</td>
<td>$0.1 mill.- $6.5 mill.</td>
</tr>
<tr>
<td>Pulmonary complications:</td>
<td>$28,700</td>
<td>8% to 79%</td>
<td>$2.3 mill.- $22.7 mill</td>
</tr>
<tr>
<td>Persistent pain:</td>
<td>$4,500 to 7,700</td>
<td>11% to 56%</td>
<td>$0.5 mill.- $4.3 mill.</td>
</tr>
<tr>
<td>CABG without complications</td>
<td>Average costs $11,900 to $26,100</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Source: [14, 20-22, 24]

Table 1 shows the costs and incidences of these 3 major complications after sternotomy procedures, and the estimated total cost per complication a hospital, which performs 1000 annual sternotomy procedures, would accumulate. Pulmonary complications represent the highest health care problem with the highest costs, followed by pain complications and sternal infections respectively.

Putting the data in Table 1 in perspective, a hospital which performs 1000 annual sternotomy cases will have 38 patients with deep sternal wound infection ($2.5 mill.), 435 patients with postoperative pulmonary complications ($12.5 mill.), and 335 patients with chronic pain ($2.0 mill.).

STERNAL INFECTIONS

The cause of median sternotomy wound infection and dehiscence is not fully understood. It is discussed whether it starts as sternal osteomyelitis, which subsequently cause sternal separation, or, if sternal instability with subsequent skin breakdown cause bacteria to seep into deeper layers and develops into mediastinal wound infection [25].

Table 2 summarizes publications reporting the incidence and mortality of sternal complications. Most studies report the incidence of sternal infection during the hospital stay, or 4 - 6 weeks postoperatively, or there is no follow up at all after hospitalization [32]. The incidence of deep sternal wound infections (DSWI) ranges from 0.3% to 5% during hospitalization with morbidity between 14% and 47%, and with length of hospital stay an additional 4 to 8 weeks. The incidence of DSWI increased to 7.3% at 90 days after discharge. Obesity increased the incidence of DSWI to 6.23% when the BMI was higher than 30, and the sternal dehiscence was increased to 6.46% [25-29, 32].
Superficial sternal wound infections (SWI) are reported to be from 0.5% to 8% in the hospital, and increased up to 9% after 90 days. Twenty five (25) % of SWI and more than 33% of DSWI cases were diagnosed between 30 and 90 days after surgery, while as many as 50% of SWI and 80% of DSWI were diagnosed at 90 days post-discharge [27, 32].

The health care system has additional costs of about $45,000 per patient with DSWI, or almost 3 times the cost of a normal procedure without complications ($18,000) [22]. Some authors report costs as high as $88,800 for treating DSWI, compared to $26,100 for a complication-free CABG procedure [23].

Table 2. Incidence and mortality of sternal complications

<table>
<thead>
<tr>
<th>Reference Publication</th>
<th>Postop. compl.</th>
<th>Incidence of sternal wound complications</th>
<th>Mortality</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rupprecht-Schmid [26]</td>
<td>DSWI</td>
<td>0.6% to 5%</td>
<td>9% to 29%</td>
</tr>
<tr>
<td>Literature review 2013</td>
<td></td>
<td></td>
<td>15% with VAC therapy</td>
</tr>
<tr>
<td>Singh et al. [27]</td>
<td>DSWI</td>
<td>1% to 5%</td>
<td>10% to 47%</td>
</tr>
<tr>
<td>Literature review 2011</td>
<td>SSWI</td>
<td>0.5% to 8%</td>
<td>0.5% to 9%</td>
</tr>
<tr>
<td>Losanoff et al. [28]</td>
<td>DSWI</td>
<td>0.3% to 5%</td>
<td>14 and 47%</td>
</tr>
<tr>
<td>Literature review 2002</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>El Oakley-Wright [25]</td>
<td>DSWI</td>
<td>0.4% to 5%</td>
<td>14% to 47%</td>
</tr>
<tr>
<td>Literature review 1996</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Molina et al. [29]</td>
<td>DSWI</td>
<td>6.46% (obese) BMI&gt;30 1.63% (non-obese)</td>
<td>38.4% (obese) 0% (non-obese)</td>
</tr>
<tr>
<td>3158 patients 2004</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Eklund et al. [30]</td>
<td>DSWI</td>
<td>1.1% CABG 0.8% Valvular surgery</td>
<td>9% within 1 year</td>
</tr>
<tr>
<td>10713 patients 1990 - 1999</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Jonkers et al. [32]</td>
<td>DSWI</td>
<td>1.5% during hosp. 4.6% 30 days after 7.3% 90 days after</td>
<td>0.2% peroperatively 2.6% 30 days after 3.4% 90 days after</td>
</tr>
<tr>
<td>1885 patients 1996 - 1998 2003</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gaardlund et al. [36]</td>
<td>SSWI</td>
<td>4.7% during hosp. 6.8% 30 days after 9.0% 90 days after</td>
<td></td>
</tr>
<tr>
<td>9557 patients 1992-2000</td>
<td>DSWI</td>
<td>1.32%</td>
<td>19% 90-day all cause mortality</td>
</tr>
<tr>
<td>Baillot et al. [37]</td>
<td>Sternal dehiscence</td>
<td>68%</td>
<td></td>
</tr>
<tr>
<td>23499 patients 1992 - 2007</td>
<td>DSWI</td>
<td>1.1%</td>
<td>10.25%</td>
</tr>
<tr>
<td>Fowler et al. [42]</td>
<td>DSWI</td>
<td>3.51%</td>
<td>17.3%</td>
</tr>
<tr>
<td>331,429 patients 2002-2003</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

STSS database
There is agreement concerning the major risk factors for sternal wound infection, which are obesity, diabetes, osteoporosis, breast size, chronic cough, tobacco use, chronic obstructive pulmonary disease (COPD), immuno-suppression, and CABG with use of the Internal Mammary Arteries (IMA) [25-28, 31, 36-42].

Sternal infections can be prevented by a strict adherence to a consistent protocol of preoperative aseptic technique, careful attention to hemostasis, a careful surgical technique with precise sternal alignment, and a stable sternal closure [58-62]. There are many surgical techniques for strengthening the lateral force on the sternum to prevent any excessive movement between the two sternal halves. Additional wire fixation of the lower sternum with 8 wires, not just 5 or 6, has been shown to reduce infections [58-62]. Negative Pressure Wound Therapy (NPWT) has been successfully used to treat infections, which have led some surgeons to use NPWT as a preventive method [31, 63-64], however, the cost impact needs to be investigated.

**PULMONARY COMPLICATIONS:**

Postoperative pulmonary complications (PPC) are complex and not well understood. The frequency is not clearly documented, - incidence is reported from 7% to 79% (Table 3). Incisional pain and reflex diaphragmatic dysfunction cause changes in breathing pattern, lung mechanics, secretion clearance and gas exchange [16-17]. Thirty (30)% to 50% of all sternotomy patients have clinical symptoms of PPC, and acute respiratory distress syndrome (ARDS) is reported in 0.4% to 2%. Mortality of ARDS is more than 50%.

PPC occur almost twice as often as postoperative cardiac complications (9.6% vs. 5.7%), excluding atelectasis which appear in more than 90% of anesthetized patients, particularly in the lower lung lobes [17]. The result is a length of stay (LOS) in the hospital more than twice as long as for patients without this complication (22.7 days vs. 10.4 days)[15-19]. A recent patient safety summit on definition, risk-reducing interventions, and preventive strategies, concluded the clinical burden of PPCs remains under-appreciated compared to cardiac complications [20].

Incisional pain and muscle response have an influence on two pulmonary defense mechanisms: coughing and removal of secretions. It also causes the diaphragm to relax, which combined with the loss of traction of the chest wall and loss of intercostal muscle function, are thought to contribute to reduced functional residual capacity (FRC) [17].

<table>
<thead>
<tr>
<th>Reference Publication</th>
<th>Incidence of post.op. pulmonary dysfunction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wynne et Botti 2004 [16]</td>
<td>8 - 79%</td>
</tr>
<tr>
<td>Duggan et Kavanagh. 2005 [17]</td>
<td>90% of anesthetized patients develop atelectasis</td>
</tr>
<tr>
<td>Renault et al. 2008 [19]</td>
<td>Pleural effusion 32 - 63%</td>
</tr>
<tr>
<td>Shander et al. 2011 [20]</td>
<td>Lung infection 3.5%-10%</td>
</tr>
<tr>
<td></td>
<td>9.6% (excl. atelectasis) Moderate to severe in 38%</td>
</tr>
</tbody>
</table>
Vital Capacity (VC), critical for effective coughing, is reduced by 40 - 50% after surgery. It is crucial to counteract the effect of these changes by analgesia and active lung expansion [18]. Pleural effusion has been found in 32% to 63% the first postoperative day and lung infections range between 3.5% and 10%. Decrease in the expansion of the lower lung lobes is caused by a weak cough, a reduction in mobility and muscle fatigue combined with physiological respiratory and diaphragmatic changes that results in superficial and predominantly thoracic breathing [19].

The cost of pulmonary complications adds $28,500 on top of the costs for the procedure, which are $12,000 [21].

The risk factors for pulmonary complications and sternal wound infections are thought to be the same. In addition, the risk for developing pulmonary complications is linked to atelectasis caused by anesthesia, diaphragmatic dysfunction, the median sternotomy incision itself, pain, immobility and position, ineffective cough, chest tubes, neurological injury, IMA dissection, inflammatory response to cardiopulmonary bypass (CPB), non-ventilated lungs during CPB, low core temperature, topical cooling for myocardial protection, and transfusion of blood products [15-18].

Improved breathing with increased lung expansion prevents PPCs such as atelectasis and pneumonia. Reduced pain and reflex inhibition of the respiratory muscles improve breathing and optimize the postoperative pulmonary function [17, 53]. Deep breathing exercises with or without resistance, incentive spirometry, intermittent positive pressure breathing, and chest physiotherapy are found to be equally efficient, and the rate of restoration of lung function is not affected by type of therapy [16-17, 19, 54]. The intensity and frequency of sessions might be more critical than the form of therapy [55].

The interaction between postoperative pulmonary function and pain management is poorly understood. Greater pain intensity is linked to increased frequency of atelectasis, and poorly controlled pain after surgery causes ineffective breathing pattern, obstructs the patients mobility and prolongs recovery. Strategies to improve pain control may be developed when more is understood about the characteristics of postoperative pain and its influence on pulmonary function [56-57].

Pulmonary rehabilitation such as respiratory muscle training, incentive spirometry, and chest physiotherapy are thought to decrease the risk of PPC, and inspiratory and expiratory breathing exercises may help to prevent postoperative atelectasis [20].

**PERSISTENT POSTOPERATIVE PAIN**

Pain has a negative effect on mood, performance of daily activities and quality of life. Many psychosocial factors are linked to postoperative persistent pain such as anxiety, depression, catastrophizing, illness perception, poor coping strategy, low sense of control, poor social support and expectations [4-13]. The economical impact of treating pain is significant since it requires medical treatment, complicates treatment for other ailments and lowers worker productivity.
Annual costs of pain is greater than the annual costs of heart disease, cancer and diabetes all together. A person with pain has expenditures between $4,516 and $7726, and is increased for women, the elderly, obese, diabetic, persons with asthma and general poor health [14].

Table 4. lists the reported incidence of postoperative pain. Between 11% and 56% of sternotomy patients suffer from persistent postoperative pain, a fact that is largely underestimated [1-9, 13]. The risk factors for persistent pain is complex and not clearly defined: Obesity with BMI>25, younger patients, preoperative angina, low coping capacity, non-elective surgery, re-sternotomy shortly after the first surgery, severe pain on 3rd postoperative day, female patients, psychosocial factors and greater analgesic needs have all been observed as possible risk factors [4, 8, 10, 13, 34-35]. Patients are reluctant to ask for pain relief and health care staff might be reluctant to give patients pain medication if they do not ask, - both caused by caution of addiction to opioids medication [48]. Patients need to receive optimal pain relief to prevent that incisional pain and reflex diaphragmatic dysfunction cause postoperative pulmonary dysfunction [18, 47].

Pain interferes with deep breathing, coughing, general activity, walking and mood, which are all issues the patients deal with after discharge [48, 50-52]. CABG patients have been found to have the highest rate of visits to the emergency department after discharge (22.4%), 6.1% of them visited several times, and 39% were readmitted. This could be a reflection of poor coordination of care and insufficient outpatient follow-up [49].

Postoperative recovery after sternotomy procedures

Postoperative care is a coordination between specialties, and patients are instructed from each specialty how to take care of their sternal incision, diet, medications, control pain, and how to protect the sternum when they cough and perform exercises. Instructions and guidelines vary from one institution to another, from one country to another, and may even give conflicting advise [66-70, 75].
A sternotomy causes significant damage to the soft tissue, the sternal bone, the chest wall, the anterior and superior regions of the arms and shoulders. Performing exercise increases blood flow to the damaged areas which helps the tissue repair. If the arms, the shoulders and the chest area are not exercised, adhesions may develop, and the musculature can become weaker, as well as intensify later problems of poor posture and difficulties in attaining the previous strength and full range of motion (ROM). A delay in performing upper-extremity ROM exercises may result in more discomfort for the patient during the recovery period, and prolong the time required to achieve full recovery [71].

There are no globally accepted clinical guidelines for physiotherapy exercises in patients with an unstable sternum, and there are no clear evidence-based justification for upper limb exercises [74]. The prescriptions for exercises, routinely done by physiotherapists, are presently under scrutiny, and are criticized for being too restrictive or too vague, and for not taking into account the patients daily day functions at home. The common recommendation of not lifting more than 5 pounds means that only 4 out of 32 common daily activities are allowed. The force needed to open hospital doors, car doors, the refrigerator, the microwave, or to lift a coffee pot, all exceeds 5 pounds. Resistance exercise and programs tailored to promote higher fitness levels, increased range of motion, increased strength, greater bone density, and increased patient satisfaction and participation, are increasingly advocated [72-75]. Recently an algorithm for sternal precautions has been proposed which is patient-specific and focus on function and patient characteristics [75].

The use of external chest supports in preventive care

There is an increased interest to evaluate the preventive role external chest supports may have on postoperative complications after sternotomy procedures. In 1998 Laurikka et al. [78] published a prospective study to evaluate the efficacy of an inflatable vest in supporting the sternotomy wound during the early period after coronary artery bypass grafting. The use of the vest significantly reduced cough-associated subjective sternotomy pain score, and the conclusion was that the pain relief may improve the efficacy of coughing and bronchial clearance in the immediate postoperative period.

In 2003 Meisler [79] evaluated a patient-activated sternal support harness [HeartHugger] [87] in patients with complaints of severe sternal pain, or signs of sternal instability. All patients had risk factors for sternotomy complications, eg a BMI >25, history of respiratory condition, harvest of internal mammary arteries, and diabetes. A reduction in pain while coughing was noted in 75% of the patients.

In 2008 El-Ansary et al. [80] compared 3 supportive chest devices used for control of sternal instability. The sternal gap was measured with ultrasound, and self-report measures of comfort, pain, feeling of support, ease of upper-limb movement, and ease of breathing was
evaluated. The 3 devices compared were sports tape, an elastic compression binder and an adjustable fastening brace [QualiBreath[88]]. The authors found that [QualiBreath] was most efficient and closed the sternal gap by 20% compared with no support. The [QualiBreath] device obtained the best score on all measurements both for sternal separation, and for self-report data on the visual analog scale for comfort, pain, support, ease of breathing, and movement. The authors concluded the [QualiBreath] was useful in the management of patients with sternal instability because the use resulted in a reduction of both sternal separation and pain reported after movement.

Gorlitzer et al. 2009 [81] evaluated the effect of a support vest [Posthorax[89]] to prevent sternum wound complications after median sternotomy in 450 patients in a prospective, randomized trial, and showed a significant decrease in DSWI in the vest user group. No significant difference between the groups was found in superficial sternal wound complications, or in pain score evaluated with the visual analogue scale. A significant number of patients (24%) refused to use the vest due to an uncomfortable close fit and slipping of the vest.

In a second publication in 2010 [82] the authors included results from 2 more hospitals with a total of 1560 patients, who were followed up to 90 days after surgery for development of sternal dehiscence or wound infections. A significant decrease in DSWI and dehiscence was confirmed in the vest user group, while there was no significant difference in superficial sternal wound complications. Pain score was not evaluated. A significant number of patients (28%) refused to wear the Posthorax vest due to slippage and discomfort. Hospitalization time was significantly shorter in the vest group than the non-vest group. There was no difference in ICU stay. The authors found that 33% of the patients with sternal wound complications developed within 90 days after discharge.

In the 3rd update [83] in 2013, the authors included 2539 patients from the same 3 hospitals, and confirmed a significant decrease in DSWI and dehiscence in patients wearing the Posthorax sternal vest. No benefit was observed in the rate of superficial wound complications. The number of patients who refused to wear the vest represented 31%. Of all patients with sternal wound complications, 34% developed within 90 days after being discharged.

The conclusion of all 3 studies was that the Posthorax support vest is a valuable adjunct to prevent DSWI, but does not show any influence of superficial wound healing.

Celik et al. 2011[84] showed in a retrospective study of patients with chronic obstructive pulmonary disease (COPD), that the rate of sternal dehiscence is significantly higher in these patients. The authors then prospectively evaluated whether the use of the Robicsek technique for sternal closure, combined with the use of the Posthorax sternum support, could reduce the incidence of sternal dehiscence in patients with COPD. Both the rate of dehiscence and DSWI was significantly lower, and the length of hospitalization shorter. There was no difference in the occurrence of superficial sternal infections and isolated sternal dehiscence. There was a significant number of patients (18%) who refused to use the Posthorax, primarily obese female
patients. The conclusion was that a combination of the Robicsek procedure and the use of the Posthorax could reduce sternal wound complications, and that different treatment options are needed for obese, female patients.

In 2010 Klement and Hermann [85] presented the use of a traditional compression garment vest in a case report concerning a severe case of DSWI, where a secondary closure could only be done after 3 weeks of vacuum-assisted closure (VAC). The patient had considerable wound pain associated with breathing, palpable sternal instability, and local indications of inflammation persisted for a further three months. When an external thoracic support in the form of a customized elastic compression vest was applied, the subjective pain intensity decreased on the visual analog scale, and the need for opioid analgesics was reduced. The sternum showed palpatory stability following conservative treatment for three months.

<table>
<thead>
<tr>
<th>Reference Publication</th>
<th>External support device</th>
<th>Conclusion of evaluation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Laurikka et al. 1998 [78]</td>
<td>Inflatable vest</td>
<td>Significantly reduced cough-associated pain score</td>
</tr>
<tr>
<td>Meisler P. 2003 [79]</td>
<td>HeartHugger Rigid, open sternal support harness Require patient activation to function</td>
<td>Reduced cough-associated pain in patients with BMI&gt;25, respiratory dysfunction, CABG w. use of IMA and patients w. diabetes.</td>
</tr>
<tr>
<td>El-Ansary et al. 2008 [80]</td>
<td>QualiBreath Adjustable, chest circumferential, elastic support, combined w. patient activated cough handles</td>
<td>Closed sternal gap by 20% in patients with sternal instability; highest score in self-report measures of comfort, feeling of support, ease of upper limb movement, ease of breathing and reduction of pain</td>
</tr>
<tr>
<td>Gorlitzer et al. 2009 [81]</td>
<td>Posthorax Non-elastic, chest circumferential support</td>
<td>Reduced significantly sternal wound complications 0,6% vs. 4,9%</td>
</tr>
<tr>
<td>Gorlitzer et al. 2010 [82]</td>
<td>Posthorax Non-elastic, chest circumferential support</td>
<td>Reduced significantly sternal wound complications 0,6% vs. 3,9%</td>
</tr>
<tr>
<td>Gorlitzer et al. 2013 [83]</td>
<td>Posthorax Non-elastic, chest circumferential support</td>
<td>Reduced significantly sternal wound complications 0,7% vs. 1,5% during hospitalization. 0,4% vs. 0,8% within 90 days</td>
</tr>
<tr>
<td>Celik et al. 2011 [84]</td>
<td>Posthorax Non-elastic, chest circumferential support</td>
<td>Reduced significantly sternal wound complications in patients with COPD when using Robicsek sternal closure technique combined w. Posthorax. DSWI: 0% vs. 6,6%. Dehiscence: 1% vs. 11,5%</td>
</tr>
<tr>
<td>Tewarie et al. 2012 [86]</td>
<td>Stern-E-Fix (SEF) Rigid sternal plate combined w. elastic chest circumferential bands</td>
<td>Reduced significantly sternal wound complications 3,4% vs. 9,5% cumulative 2,1% vs. 1,6% superficial 1% vs. 1,9% DSWI 0,3% vs. 5,9% Methillin resistant staphylococcus mediastinitis (MRSA)</td>
</tr>
</tbody>
</table>
In 2012 Tewarie et al. [86] evaluated an external sternal stabilizer, the Stern-E-Fix (SEF), in a prospective, randomized study including 750 male patients, and found the SEF device to be an effective prevention against development of sternal dehiscence and secondary sternal infection in high-risk patients.

Table 5 summarizes the results of the evaluations of the external chest supports.

**Discussion**

Considerable strain is placed on the anatomy of the chest, back, shoulders and neck, when the sternal halves are retracted during the sternotomy procedure, and patients may experience a variety of musculoskeletal and neurological complaints from the intervention. The soft tissue of the sternal wound takes about 4-5 weeks to heal, and the sternum bone between 6-8 weeks to heal properly. In this period there are only the stainless steel wires to keep the thorax integrity intact. If the sternum bone is not stable, the soft tissue of the sternum wound may not be strong enough alone to support the sternum in case of excessive strain.

To save health care costs, patients are sent home as early as possible, generally between day 4-7 postoperatively. Patients and their relatives need to be prepared to take on the responsibility for their full recovery and a healthy healing of the wound and sternum. Success may depend on how clearly they have been instructed, if they fully understood the instructions, and what tools they have available to assists their daily day activities.

Various methods of strengthening the internal sternal closure have been evaluated and described by many authors [58-62]. Adding an external chest support to assist keeping the two sternum halves together from the outside can only increase the odds for an optimal alignment and healing of the sternum.

Health care providers may benefit largely by evaluating their present practice and investment in postoperative care, both with regards to control of complications and of costs. Many hospitals supply patients with pillows, called heart- chest- or cough-pillows, with the purpose to help patients when they need to cough or sneeze, and many charity organizations supply such pillows free of charge. The pillows are often shaped as a heart or bear, which appeals to the comfort feeling in the patients, and they give an impression that the hospital, its doctors and nurses care about each patient and his/her recovery. Other hospitals may roll a small blanket and tape it together to form a rectangular bar. In all cases the patient is instructed to hug the pillow, bear or bar, when they need to cough or sneeze. The problem is that it will only help the patients during the cough or sneeze, and only if the patients manage to reach for and hug it in time. In addition, the patients might do more harm to their sternum by performing a sudden reach for a pillow or bear that would be somewhere in the room, near or on the bed.
Furthermore, rolled blankets, heart shaped pillows or bears may pose a risk for infection of the sternal wound. These objects are not attached to the patient, and they may get in contact with many different potential sources for infection, and are almost certain to fall on the floor at some time. This may introduce a risk for infection at the wound site, when patients hug and press them towards the sternum. Patients continue to use the pillows/bear after discharge for a long time and will bring them around in and out of their home. Research is needed to verify whether such pillows could be a potential culprit for the increase in sternal infections seen post-discharge.

El-Ansary et al. [80] proved that the adjustable fastening brace [QualiBreath] gives an effective and constant, lateral support on the sternum while it was comfortable, reduced pain, gave thoracic support, eased breathing and movement. Several authors have since evaluated the use of external chest supports as an additional tool to improve recovery after sternotomy procedures [81-85].

A strict aseptic technique, careful attention to hemostasis, a precise sternal alignment and reinforced closing technique of the sternum decrease the potential for sternal infections and dehiscence [58-62]. Adding a firm, external support on the chest can be an important adjunctive treatment to stabilize the sternum. QualiBreath closed the gap between the two sternum halves by 20% in patients with an unstable sternum [80], and the studies involving the Posthorax external support [81-83] showed a significant decrease in DSWI and dehiscence, further supporting the use of external chest devices. Although the Posthorax authors did not offer information on the sternal closure techniques used, most likely the same techniques were used in the vest and non-vest groups. Interestingly, there was a decrease in incidence of DSWI in the non-vest group over time in the 3 studies, while the incidence of DSWI remained at the same level in the Posthorax group (Table 5). This leads to speculation that the attention to sternal closure techniques that the studies undoubtedly caused, had a positive effect on surgical precautions for sternal closure.

Pain scores were only evaluated in the first publication on Posthorax, and no difference was found between the vest and the non-vest group [81]. If a chest support does not offer pain relief to patients, it will be difficult to assure that patients use the device in the hospital and keep using it for 6-8 weeks at home. The Posthorax studies reported a significant number of patients that refused usage due to discomfort and slippage (24%, 28%, 31%) [81-83], and the evaluation of COPD patients [84] reported 18% of the patients who refused to use Posthorax. Since up to 80% of sternal infections are discovered after discharge, it is critical that patients comply with the usage of an external chest support, and it is critical that such a device gives pain relief, is comfortable and easy to use.

The Posthorax experience shows that an external chest support is an important adjunctive method to decrease the incidence of DSWI and dehiscence. The evaluation of the Stern-E-Fix [86] device seems to support this hypothesis, however, the group of non-users had a significant high number of patients with diabetes and renal failure, both conditions considered high risk for postoperative sternal complications, which could have obscured results.
Interestingly, 2 of the publications involving Posthorax [81-83], and the Stern-E-Fix device [86] refer to the use of an elastic bandage, binder or brace in the non-vest groups, but offer no further details, such as the type and degree of elasticity, the degree of closure, or the width of such device. Some hospitals apply elastic abdominal binders on the thorax, since they are commonly available and used in general surgery. However, abdominal binders or elastic bandages are not dedicated to sternotomy patients, and they are usually too wide and cover the upper abdominal area. The elasticity of such bands vary widely, depending on the type of material and the specifications of the manufacturer of such devices. Even the most elastic materials can be stretched to a point where it does not stay elastic anymore, and abdominal bands must be closed very tightly on the chest if they are to give a significant chest surrounding support. Since the upper abdominal area is covered by abdominal binders, such closure would hinder respiration and be uncomfortable. Therefore such bandages usually are closed relatively loose and have little effect as an external support of the sternum.

The QualiBreath external sternal and chest support is made of ventilated, elastic material with a defined elasticity of 100% with a margin of +/-10%. It has an adjustable Velcro closure at the front left side, adjustable shoulder straps, and 2 integrated bars at each side of the sternum which function as “handles”. The chest encircling material gives a constant, firm thoracic support for the respiratory muscles and a lateral support on the sternum. The width of the band encircles the lower, and most important part of the sternum [58 - 61] and leaves the upper abdominal area free to allow for abdominal breathing with engagement of the diaphragm muscle and expansion of the lower lung lobes, which is important to clear atelectasis and secretions in the lower lung areas.

The external elastic, yet firm support to the entire circumference of the chest wall, which QualiBreath gives, compliments the respiratory muscles, and helps to improve bronchial clearance because of the pain relief such support gives to the thoracic wall [51, 58, 55, 78]. The QualiBreath support gives resistance to raised intra-thoracic pressure during coughing and sneezing, and gives patients the option to increase the resistance further by activating the integrated bar handles, thereby giving more control to the patients in an increased pain situation. Furthermore, the circumferential chest compression and lateral support on the lower part of the sternum can be increased by tightening the closure of the band.

The QualiBreath is the only dual-functional external chest support. Devices like Posthorax, SEF or abdominal compression bands are single-functional and do not give patients an option for additional support during a cough or sneeze, which means these devices must be closed extremely tight at all times to be efficient during coughing. The HeartHugger device likewise is single-functional, and has a patient-activated function for coughing, and does not give any constant, circumferential chest support. The Posthorax is made of non-elastic cotton and has “shock-absorption” pads placed on each side of the sternum between the patient and the vest to create a constant anterior-posterior pressure. However, since patients do not cough continuously, such inward pressure may be very uncomfortable and may explain the high number of patients who...
refused to use the device. The plastic plate of the SEF device is placed directly over the sternum, and could be uncomfortable for the patient. The plate could also rub against the sternum wound, if the elastic bandages attached to it, are misplaced during activities.

Comfort, pain relief, ease of breathing and activities have not been addressed in the evaluations of the Posthorax, SEF, HeartHugger and compression vest devices. The design and function of an external chest support should address all major postoperative complications after a sternotomy procedure: Sternal infections, dehiscence, postoperative pain and pulmonary complications. Addressing one, and not the others, could be counterproductive, considering the cost implications of each individual complication (Table 1).

Pulmonary complications (PPC) are the most frequent and costly complication after sternotomy procedures. Incisional pain and diaphragmatic dysfunction, thought to be responsible for PPC, can hinder patients in performing breathing exercises with increased lung expansion which can prevent the development of PPC. Since deep breathing techniques with or without resistance, incentive spirometry, intermittent positive pressure breathing, and chest physiotherapy are equally efficient, an external chest support that comfortably compliments any of these exercises, and allows for expansion of the lower lung lobes, is an important adjunctive method to prevent pulmonary complications and decrease costs.

More than 30% of sternotomy patients suffer from chronic pain up to a year or longer after surgery. Anxiety and other psychosocial factors are predictors for persistent pain, and can be addressed by an optimal analgesic management and an educational preparation of the patients before surgery. The use of a comfortable, external chest support device as an adjunctive method for pain control can have an important positive psychological effect.

The treatment of a complication after it has occurred, is more difficult and much more costly than to prevent it in the first place. Although every publication on the clinical use of a variety of external chest supports have revealed significant advantages, external chest supports are not included routinely in postoperative care. Prejudice and doubt still exist concerning the benefits an external chest support can contribute to the surgical solutions in preventive care. In the 2013 review publication by Rupprecht and Schmid [26] on sternal wound complications, the authors discussed methods to reduce sternal instability and consecutive infection. Besides the traditional aseptic and surgical options, they addressed the use of external chest supports and stressed the importance that such vests allow for normal breathing and they banned “over-extension”.

El-Ansary et al. [80] are the only authors that evaluated an external chest support device for more than the effect on the sternum. The authors included pain reduction, comfort for the patient, ease of breathing and mobilization, and found that the QualiBreath sternum and chest support had the best results in all measurements, in addition to that it reduced sternal separation.
by 20% in patients with sternal instability. Gorlitzer et al. [81] included pain score in the first evaluation where Posthorax was compared to a non-vest group. They found no difference between the groups, and did not include pain evaluations in the follow up evaluations [82-83].

Table 6 shows an overview of external chest support devices, the material, type of circumferential chest support, and the function.

**Table 6. External chest support devices**

<table>
<thead>
<tr>
<th>External support device</th>
<th>Material</th>
<th>Chest circumferential support</th>
<th>Function</th>
</tr>
</thead>
<tbody>
<tr>
<td>QualiBreath</td>
<td>Ventilated, uni-directional elastic, polyester/cotton material Latex-free</td>
<td>Adjustable, firm, Elasticity 100% +/-10%</td>
<td>Dual function: Constant breathing support, and Patient activated cough handles</td>
</tr>
<tr>
<td>Posthorax</td>
<td>Non-elastic cotton</td>
<td>Non-adjustable, firm, non-elastic</td>
<td>Single function Constant, passive chest support</td>
</tr>
<tr>
<td>Stern-E-Fix (SEF)</td>
<td>Rigid, silicone-covered plastic sternal plate w. elastic bands attached for chest circumference</td>
<td>Adjustable, elastic</td>
<td>Single function Constant, passive support on the sternum</td>
</tr>
<tr>
<td>HeartHugger</td>
<td>Rigid, nylon band w. plastic handles</td>
<td>No constant, circumferential support. Non-elastic.</td>
<td>Single function Patient activated cough handles</td>
</tr>
<tr>
<td>Traditional compression garment vest</td>
<td>Multi-directional, elastic</td>
<td>Adjustable, elastic</td>
<td>Single function Constant breathing support</td>
</tr>
</tbody>
</table>

**Conclusion**

Prevention of complications after sternotomy procedures continue to be a challenge. Most of the risk factors are known for sternal wound infections, but not fully understood for pulmonary complications and persistent postoperative pain. Both the incidence and health care costs for pulmonary complications and persistent postoperative pain are higher than the incidence and costs of postoperative sternal wound infections, yet, sternal wound infections get most of the attention both in literature and in the design of many external support devices.

The incidence of complications reported during the last decade are stable, yet significant, and costs the health care system enormous sums. External chest support devices are now increasingly used as an adjunctive method to assist the healing sternum with a non-surgical approach in an attempt to decrease postoperative complications and the related health care costs.

Several external chest support devices are available. The decision to use a specific device must be based on how it can improve the patient’s *entire recovery process* in and out of the hospital, and include evaluations of whether there is a positive effect on patient function, pain relief, comfort, ease of breathing, ease of activities and exercise, sternal stability, and a decrease in sternal wound infections. If an external support device improves sternal stability but causes
discomfort, pain and restrains activities, the cost advantages are most likely to be offset by long term complications and medications.

Presently the QualiBreath sternum and thorax support is the only device that has been evaluated for a number of requirements to external chest support devices. QualiBreath has been shown to decrease the sternal gap in patients with an unstable sternum, and improve their discomfort, pain, feeling of support, ease of breathing and their ability to function. Compared to other external chest support designs, QualiBreath has the highest potential to assure that patients will continue to use it after discharge, with the results of decreased sternal wound infections, pain and pulmonary complications, and improved experience of the patient’s overall hospital stay. Further research and evaluation studies of external chest supports are needed to prove this proposition.

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