Health Policy Advisory Committee on Technology

Technology Brief

Sternum support vests to prevent sternal dehiscence

May 2013

HealthPACT
emerging health technology
Technology, Company and Licensing

Register ID: WP160

Technology name: Posthorax™ and Stern-E-Fix sternum support vest to prevent sternal dehiscence

Patient indication: For patients who have undergone a median sternotomy during cardiac surgery

Description of the technology

A sternal support vest aims to restrict movement of the sternal wound thereby protecting the incision and reducing the risk of complications. Designs which aim to achieve this may be variable. The Posthorax™ device is the best characterised in the peer reviewed literature. The cotton Posthorax™ sternum support vest is a type of ‘halter’ that provides antero-posterior stabilisation of the thorax via a pad placed on each side of the sternum to prevent intrinsic movement of the two sternal halves. The front of the vest is non-flexible to stabilise the sternal bone. Lateral flaps, ‘designed for optimum fit’, allow for normal breathing and stop over-extension (particularly with coughing or sudden movements) while upper straps stop the vest from sliding down (Figure 1).1 With nursing help, about 48 hours after surgery, vests are individually fitted for men and women. There are five sizes available for women (plus an inserted bra in four cup sizes) and four sizes available for men.2 The vest is intended to be worn 24 hours a day for at least six weeks after surgery, ‘like a cast’. It is hand washable and can be laundered several times.

Another sternum support garment is the Stern-E-Fix corset. This garment is comprised of a front plate in the shape of the sternum and a number of adhesive elastic bandages which follow the rib cage and prevent excessive movement of the rib cage in the anterior or lateral direction. The front plate is made of a strengthened plastic with a smooth silicon surface.4
The device was described in one publication in the peer reviewed literature and appears to have been designed by the study authors. The device does not appear to have a registered trademark. Of the various sternal support vest designs available, Posthorax™ appears to be the only design widely marketed.

Company or developer
The manufacturer of Posthorax™ has offices in Austria (Eppl Inc., Vienna) and the United States (US) (Posthorax, Inc.; Orland, Florida). The manufacturer of the Stern-E-Fix is based in Germany (Fendel & Keuchen GmbH, Aachen Germany).

Manufacturers of two other vests with Therapeutic Goods Administration approval are Qualiteam SRL, based in Italy, (the Qualibreath vest) and Pongratz O&P, General Cardiac Technology Inc., based in the US (the HeartHugger™ vest). These vests are sternum support garments but do not appear to have an inflexible front plate which is characteristic of the Stern-E-Fix corset and the Posthorax™ devices.

Reason for assessment
A novel device used to prevent post-operative morbidity in a large patient population, with the theoretical advantage of reducing the costs associated with treating these post-operative complications.

Stage of development in Australia

☐ Yet to emerge  ☐ Established
☐ Experimental  ☐ Established but changed indication or modification of technique
☐ Investigational  ☐ Should be taken out of use
☐ Nearly established

Licensing, reimbursement and other approval
Posthorax™ (regulation number 590-3025) received US Food and Drug Administration (FDA) approval as a Device Class I ‘bandage/cast’ under prosthetic and orthotic accessories in 2013 and is 510(k) exempt. The device is also patented in the European Union (patent # 19401339). This product is not included in the Australian Register of Therapeutic Goods (ARTG).

Limited information regarding the Stern-E-Fix vest was identified, and licensing information could not be found. This device was not identified in the ARTG.

Various other support garments are included on the ARTG, but due to their variable descriptors, the number and nature of these garments could not be garnered.
Median sternotomy is a specialised surgical technique used for open heart procedures such as coronary artery bypass graft and aortic or mitral valve replacement. Post-operatively, sternal instability caused by dehiscence (separation of the wound layers) or infection is a serious complication, with wound dehiscence in up to 10 per cent and infections in 1 to 4 per cent of patients. The consequences can be severe with in-hospital mortality of up to 25 per cent, high morbidity, prolonged hospital stay and additional cost. Risk factors include obesity, older age, diabetes, chronic obstructive pulmonary disease (COPD), surgical use of bilateral mammary arteries, prolonged surgical duration, prolonged mechanical ventilation and re-exploration for bleeding.\textsuperscript{1,4,6}

Coronary artery bypass grafting (CABG) is the main surgical procedure associated with the need for a median sternotomy. Age standardised rates of CABG procedures in Australia decreased steadily between 2000-01 and 2007-08 (87 per 100,000 population to 61 per 100,000\textsuperscript{7}) and in 2007-08 the reported number of CABG procedures was 13,612. Overall CABG procedures are performed more frequently on males than females.\textsuperscript{7} More recent figures were not able to be calculated for this report; however, it is expected they would not be more than 20 per cent below this figure. Earlier estimates from the Australian Institute of Health and Welfare indicated that approximately 17,000 CABG procedures were conducted in Australia in 2000.\textsuperscript{8}

Overall trends in the characteristics of patients undergoing CABG procedures from 2001 to 2006 indicate that the mean age of patients undergoing surgery is increasing, as is the proportion of patients with multiple comorbidities such as hypertension or respiratory disease.\textsuperscript{9} It is unclear as to how many of those patients would be considered high-risk for sternal dehiscence and infection.
Sternum support vests to prevent sternal dehiscence: May 2013

Speciality: Surgery
Technology setting: Specialist hospital

Impact

Alternative and/or complementary technology

A sternal support vest is complementary to the current conventional closure of a median sternotomy surgical wound. Posthorax™ appears to be the most common device of this type and it has been adopted as mandatory treatment after median sternotomy in at least one hospital in Germany that participated in the largest randomised controlled trial (RCT) reported to date.¹⁰ Other manufacturers have entered this market as well, e.g., Stern-E-Fix (Fendel & Keuchen GmbH, Aachen, Germany), a silicon and elastic chest corset for use after sternotomy to prevent sternal instability and mediastinitis.⁴ The latter authors commented that “worldwide, many external sternal stabilizers have been introduced” and indeed it may be difficult to track the size of this market as the devices do not necessarily require regulatory approval.⁵ Other support garments identified included the Heart Hugger™ and Qualibreath devices. New suture techniques are also being explored for sternal closure to reduce traction and sheer forces on the sternum and to reduce sternal instability that can lead to dehiscence and mediastinitis, for example, implanting of titanium hooks for steel wire attachment.¹¹

Current technology

Measures for reducing the risk of sternal complications are known as sternal precautions and include wound support and restrictions to mobility and sternal load.¹² There is a paucity of evidence-based guidelines and literature evaluating the efficacy and appropriateness of sternal precautions or describing current practice protocols in Australia.¹² Furthermore, sternal precautions:

- Do not have a universally accepted definition;
- Are infrequently evidence-based; and
- Are generally uniformly applied irrespective of individual patient characteristics.¹³

A recent survey of senior cardiothoracic physical therapists investigated the use of sternal precautions in hospitals throughout Australia. Of the 51 invited participants, 30 responded. The results demonstrate substantial variability in the nature of postoperative protocols for sternal precautions, particularly with regards to the recommended duration of postoperative restrictions or wound support.

The majority of respondents indicated that they employ sternal wound support following surgery (91.7%), although the length of use associated with sternal wound support ranged from less than one week postoperatively to greater than 14 days.¹² The report also indicated
that lifting, transfer and mobility restrictions were commonly utilised, although the nature of these restrictions and the length of enforcement were varied. The definition of ‘wound support’ was not reported and it is not clear whether it included support vests.

External support measures are varied and may include bandages, braces and support vests. Sternal support vests aim to protect the incision, thereby reducing the risk of complications. To repair a median sternotomy incision, a number of tissue layers must be closed. The closure routine described in the largest Posthorax™ RCT included seven-gauge stainless steel wires for sternum closure, synthetic absorbable braided sutures for the subcutaneous layer and final wound closure according to the surgeon’s choice, for example, using vinyl sutures. Patients were given cefazoline 1 g eight-hourly for 72 hours and control patients were wrapped with elastic bandages.\(^1\)\(^{14}\) Whilst the Posthorax™ device and the Stern-E-Fix are the focus of this technical brief, similar devices (the Hearthugger and the Qualibreath) used for reducing sternal dehiscence post-sternotomy were also identified. Neither of these devices appears to have been the subject of published literature.

**Diffusion of technology in Australia**

The state of diffusion of sternal support vests in Australia is unclear. The Posthorax™ device does not have a listed distributer in Australia\(^2\) and does not appear to be included on the ARTG; however, at least two chest or sternum binders are included in the ARTG. Although these devices are not direct substitutes for the Posthorax™ vest or Stern-E-Fix corset, given the variability in their design (rigid restriction of movement versus cushioning/binding restriction of movement, respectively), they also aim to reduce sternal dehiscence in post-sternotomy patients.

A search of the Australian New Zealand Clinical Trials Registry (ANZCTR) identified one trial (not yet recruiting) using one of the products included on the ARTG (Qualibreath). The interventional group is to wear the Qualibreath device post median sternotomy for the duration of their inpatient stay. The comparator group will receive ‘routine sternal precautions’ post-operatively; these may include holding a pillow against the chest while coughing. The outcomes of interest include pain, sternal instability, functional difficulties, patient satisfaction and inspiratory reserve volume. Notably, patients in this trial will only wear the support product for approximately seven days, not the six weeks associated with the sternal support vests reported in the published literature.\(^15\)
International utilisation

<table>
<thead>
<tr>
<th>Country</th>
<th>Trials underway or completed</th>
<th>Limited use</th>
<th>Widely diffused</th>
</tr>
</thead>
<tbody>
<tr>
<td>Austria</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Germany</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Sweden</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Switzerland</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Turkey</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>United Kingdom</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Cost infrastructure and economic consequences

Prices for the Posthorax™ devices range from €108 to €126. The Posthorax™ bra costs €86. Each device is a single use product.12

A conference abstract noted that health care savings were achieved with use of the vest at the researchers’ institution in Germany, where a before-and-after study of about 2,000 patients showed a 20 per cent drop in hospital days for post-operative infection (from 1,676 to 1,350 days) after the vest became mandatory.10

The potential cost savings associated with avoidance of deep sternal wound infection are primarily centred around the reduced hospitalisation times and reduced risk of readmission and reoperation. The cost effectiveness of sternal support devices will be dependent upon the efficacy of the device in preventing sternal wound infection, patient compliance with instructions for use and the cost of the device.

A 2010 case-control study conducted in Germany investigated the economic aspects of deep sternal wound infection in patients undergoing CABG procedures.17 The study compared 17 CABG patients with deep sternal wound infection to 34 matched controls and found that the median overall costs for a CABG patient with deep sternal wound infection was significantly higher than for a control patient (36,261€ versus 13,356€; p<0.001). Median overall length of stay for patients with deep sternal wound infection was also significantly longer.

Ethical, cultural or religious considerations

No ethical, cultural or religious considerations were identified in the published literature.

Evidence and Policy

Safety and effectiveness

Most reports on the Posthorax™ vest were drawn from the same multisite Austrian/German RCT (Level II Intervention evidence), comparing use of the Posthorax™ vest versus the traditional elastic bandage after median sternotomy surgery.1,14,18 The most recent
published study report for the RCT is presented below. An additional RCT was conducted in Turkey to assess use of the Posthorax™ vest specifically in patients with COPD who had undergone median sternotomy for cardiac procedures. The final included RCT reports on the Stern-E-Fix device. Details of the included studies are provided in Table 1.

<table>
<thead>
<tr>
<th>Study</th>
<th>Gorlitzer 2010&lt;sup&gt;14&lt;/sup&gt;</th>
<th>Celik 2011&lt;sup&gt;6&lt;/sup&gt;</th>
<th>Tewarie 2012&lt;sup&gt;4&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level of evidence</td>
<td>II</td>
<td>II</td>
<td>II</td>
</tr>
<tr>
<td>Number of patients</td>
<td>1814</td>
<td>244</td>
<td>750</td>
</tr>
<tr>
<td>Patient details</td>
<td>All patients underwent median sternotomy for cardiac surgery</td>
<td>All patients had moderate or severe COPD</td>
<td>All patients were male, 78% underwent CABG with pedicled IMA harvesting, 22% underwent other cardiac procedures</td>
</tr>
<tr>
<td>Comparative treatment</td>
<td>Elastic bandage (n=905)</td>
<td>“no additional procedure” (n=221)</td>
<td>Elastic thorax bandage (n=380)</td>
</tr>
<tr>
<td>Comparison of patient populations</td>
<td>Patient characteristics were similar between groups. Operative data were similar between groups except the rate of aortic valve replacement surgery which was slightly higher in the control group (18% versus 16%; p=0.03).</td>
<td>At baseline, there were no significant differences in patient characteristics or procedure-related variables</td>
<td>Incidence of renal failure was significantly higher in the bandage group compared with the Stern-E-Fix corset group. A larger proportion of patients with renal failure in the bandage group also had diabetes mellitus</td>
</tr>
<tr>
<td>Randomisation</td>
<td>NR</td>
<td>Computer-generated list and sealed envelopes</td>
<td>NR</td>
</tr>
<tr>
<td>Intervention</td>
<td>Posthorax™ vest (n=909)</td>
<td>Posthorax™ vest (n=221)</td>
<td>Stern-E-Fix corset (n=380)</td>
</tr>
<tr>
<td>Follow-up</td>
<td>90 days</td>
<td>6 months</td>
<td>6 weeks</td>
</tr>
<tr>
<td>Conflict of interest</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
</tr>
</tbody>
</table>

CABG: Coronary artery bypass surgery; IMA: internal mammary artery; NR: not reported; n: number of patients.

**Gorlitzer, 2010<sup>14</sup>**

Beginning in September 2007, a prospective RCT (Level II Intervention evidence) was conducted at three centres in Austria (Vienna) and Germany (Hamburg and Nuernberg) to assess the effectiveness of the Posthorax™ sternum support vest in preventing complications in patients undergoing cardiac surgery via median sternotomy. Immediately after surgery and closure of the median sternotomy wound, 1,814 patients were randomised (method not described) to a Posthorax™ support vest (n=909) or the traditional elastic bandage (n=905). Exclusion criteria included age under 20 years, congenital heart defect, mechanical reanimation, and chest irradiation.

Seventy-two per cent (655 of 909) of patients originally allocated to the treatment group, who actively wore the vest and fulfilled the inclusion criteria (not reported), were included in the per-protocol analysis. Patients who failed to use the vest (n=118; 13%) or refused to
use the vest (n=136; 15%) were excluded. The reasons provided for failure to use the vest included prolonged stays in the intensive care unit (ICU), an ‘open sternum’, transfer to a different hospital within 48 hours and slippage/discomfort, the last of which was the most common reason for patients refusing to use the vest.

Patients in the intervention arm were fitted for a vest 48 hours post-operatively. The vest was to be worn 24 hours a day for at least 6 weeks. Follow-up extended for 90 days (visit frequency not reported) to assess development of sternal dehiscence and superficial and deep wound infection. Loss to follow-up was not reported although all patients assigned to the control arm and to the intervention arm (655, excluding the 254 of 909 who refused or did not receive the vest) were included in the analysis.

Of the patients in the study, 29 per cent were female, with a mean age of 67 years. Relevant comorbidities included diabetes (30%), COPD (17%), chronic renal failure (9%) and peripheral artery disease (9%). At baseline, there were no significant differences reported in patient characteristics between study arms. Likewise, operative data were similar between groups, except the rate of aortic valve replacement surgery was slightly higher in the control group (18% versus 16%; p=0.03).

The reporting of this study is less than ideal, for example, blinding was not possible; there were no descriptions of the randomisation method, inclusion criteria or loss to follow-up; follow-up was relatively short at 90 days (the authors have committed to 6-month follow-up in future); and the analysis was per-protocol rather than intention-to-treat (ITT) with a significant number of patients (28%) excluded from the analysis of the intervention arm.

With respect to companion publications:

- Gorlitzer (2009)\(^1\) reported on the initial phase of the RCT when only the Vienna site was involved; 455 patients were enrolled with 228 assigned to the vest group (of which 53 refused the vest) and 227 assigned to the control group. The results for these patients were presumably incorporated into the Gorlitzer (2010)\(^1^4\) results.

- Santarpino (2011)\(^1^9\) participated in the Nuernberg site of the RCT and reported their local interim results in a conference abstract. Consecutive eligible patients (n=183) were randomised about 1:2 to vest versus control. Again, the results for these patients were presumably incorporated into the Gorlitzer (2010)\(^1^4\) results.

- Gorlitzer (2011)\(^1^8\) reported in a conference abstract about the RCT’s ‘final results’. Patients were enrolled to March 2010 with 2,632 altogether (45 per cent women; mean age 67 years): 1,351 to the vest group and 1,188 to the control group (although 12 of the latter group did receive the vest). However, in contrast to the per-protocol analysis reported above, this analysis of results was ITT.
**Effectiveness**

Outcome measures during hospital stay and at 90 days included sternal dehiscence, and superficial and deep sternal infection. The significance of the latter is that patients generally require re-operation and morbidity rates are high (including death). Comparing treatment arms, the difference in total complications by 90 days favoured the intervention group (0.15% versus 1.33%; p=0.628 for the vest group versus control groups, respectively) (Table 2). Overall (hospital stay and 90 days), rate of dehiscence was lower for the vest group (0% versus 0.77%), as was the rate of deep sternal infections (0% versus 1.99%; p=0.0001). The occurrence of superficial wound infections was not significantly different. Length of stay in hospital (including complications) was significantly shorter in the intervention group versus controls (14.7 versus 17.3 days; p=0.04), with no significant difference in length of ICU stay.

**Table 2** Gorlitzer et al (2010): Clinical outcomes during hospital stay, at 90 days and total

<table>
<thead>
<tr>
<th>Complication</th>
<th>Vest group (%) (n = 655)</th>
<th>Control group (%) (n = 905)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>During hospital stay</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dehiscence</td>
<td>0</td>
<td>0.55</td>
<td>0.08</td>
</tr>
<tr>
<td>Superficial wound infection</td>
<td>0.46</td>
<td>0.88</td>
<td>0.38</td>
</tr>
<tr>
<td>Deep wound infection</td>
<td>0</td>
<td>1.10</td>
<td>0.007</td>
</tr>
<tr>
<td>Cumulative</td>
<td>0.46</td>
<td>2.54</td>
<td>0.002</td>
</tr>
<tr>
<td><strong>At 90 days follow up</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dehiscence</td>
<td>0</td>
<td>0.22</td>
<td>0.51</td>
</tr>
<tr>
<td>Superficial wound infection</td>
<td>0.15</td>
<td>0.22</td>
<td>1.0</td>
</tr>
<tr>
<td>Deep wound infection</td>
<td>0</td>
<td>0.88</td>
<td>0.02</td>
</tr>
<tr>
<td>Cumulative</td>
<td>0.15</td>
<td>1.33</td>
<td>0.02</td>
</tr>
<tr>
<td><strong>Total complication rate</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dehiscence</td>
<td>0</td>
<td>0.77</td>
<td>0.046</td>
</tr>
<tr>
<td>Superficial wound infection</td>
<td>0.61</td>
<td>1.10</td>
<td>0.418</td>
</tr>
<tr>
<td>Deep wound infection</td>
<td>0</td>
<td>1.99</td>
<td>0.0001</td>
</tr>
<tr>
<td>Cumulative</td>
<td>0.61</td>
<td>3.87</td>
<td>0.047</td>
</tr>
</tbody>
</table>

n: number of patients

**Celik 2011**

A prospective RCT (Level II Intervention evidence) was conducted in Istanbul, Turkey, enrolling 244 patients with moderate or severe COPD (a major surgical risk factor) who were undergoing median sternotomy surgery between December 2007 and September 2009. Exclusion criteria were patients with chronic infectious disease, emergency sternotomy, repeat sternotomy, prior radio/chemotherapy, off-pump surgery, or previous thoracic trauma.

Patients were randomly assigned to a Posthorax™ vest group or a control group one to two weeks before open heart surgery via a computer-generated list and sealed envelopes. A
total of 221 patients were eligible for analysis; 100 in the vest treatment arm and 121 in the control arm. Reasons cited for withdrawal from the trial including difficulty wearing the vest in the 21 patients excluded from the vest arm and wanting to wear the vest in the one patient excluded from the control arm.

Of the included patients, 33 per cent were female, with a mean age of 67 years. Significant additional comorbidities were diabetes (44%) and peripheral artery disease (25%). At baseline, there were no significant differences in patient characteristics or procedure-related variables. Follow-up was 6 months.

**Effectiveness**

Per protocol results showed a sternal dehiscence + superficial + deep sternal infection rate of one per cent in the vest group versus 11.5 per cent in the control group ($p=0.002$). Incidence and types of dehiscence are reported in Table 3. There were no deaths among patients in the vest group whereas 36% of the controls who required additional surgery for their complications ($n=14$) died of mediastinitis or sepsis. Patients in the vest group had significantly shorter durations of mean hospitalisation (13.7 days) compared with the control group (17.8 days) ($p=0.03$).

**Table 3 Incidence and type of dehiscence reported by Celik et al (2011)**

<table>
<thead>
<tr>
<th>Dehiscence Type</th>
<th>Vest group (%) (n=100)</th>
<th>Control group (%) (n=121)</th>
<th>$p$ value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isolated sternal dehiscence</td>
<td>1</td>
<td>2.5</td>
<td>0.628</td>
</tr>
<tr>
<td>Superficial sternal wound infection</td>
<td>-</td>
<td>2.5</td>
<td>0.253</td>
</tr>
<tr>
<td>Deep sternal wound infection</td>
<td>-</td>
<td>6.6</td>
<td>0.009</td>
</tr>
<tr>
<td>Total</td>
<td>1</td>
<td>11.5</td>
<td>0.002</td>
</tr>
</tbody>
</table>

$n$: number of patients

**Tewarie 2012**

A prospective randomised study (Level II Intervention evidence) was conducted at a single centre in Aachen, Germany from January 2009 until January 2011. The study randomised 750 male, high-risk patients to receive the Stern-E-Fix corset ($n=380$) or elastic thorax bandage ($n=370$). All patients had undergone median sternotomy for a cardiac procedure. Both interventions were carried out for six weeks postoperatively beginning on the first postoperative day. The authors reported that patients were advised on the appropriate use of the corset and that evaluations were carried out daily. Outcomes of interest included sternal dehiscence, mediastinitis and wound infection. Sternal wound infection and mediastinitis was classified according to the El Oakley and Wright classification and the US Center for Disease Control and Prevention guidelines.20, 21

Regarding baseline risk factors for sternal dehiscence, the study groups were comparable. Incidence of renal failure was significantly higher in the bandage group compared with the...
Stern-E-Fix corset group and a larger proportion of patients with renal failure in the bandage group also had diabetes mellitus. The authors also reported that pre-operative preparation and postoperative wound management were similar between both groups and that the sternal wiring techniques were the same in both. The mean follow up period was eight weeks (standard deviation ± 3.6). The authors report that a validated questionnaire (no details provided) was completed to prevent non-compliance to treatment protocols and that patients were evaluated in the first postoperative week and then via telephone in the sixth week. No information regarding rates of non-compliance was reported.

Effectiveness

Sternal wound infection with Methicillin resistant staphylococcus (MRSA) occurred in one patient in the vest group compared with three patients in the control group. The incidence and type of sternal wound infections are reported in Table 4. Overall, one patient in the vest group and 22 patients in the control group experienced mediastinitis infection. The authors later state that more than 50 per cent of patients in the control group developed sternal dehiscence following discharge or during the rehabilitation period. Of the 22 patients who developed mediastinitis in the control group, all required surgical treatment followed by antibiotics and there were two cases of mediastinitis related mortality. One patient in the vest group developed mediastinitis necessitating surgical treatment and antibiotics. Overall, sternal wound infection occurred in 13 patients in the vest group and in 35 patients in the bandage group. Treatment failure (definition not reported) was more than five times higher in the control group as compared to the vest group (p=0.056).

<table>
<thead>
<tr>
<th>Table 4</th>
<th>Sternal wound infection, ventilation time, length of ICU stay and length of hospital stay</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Vest group (n=380)</td>
</tr>
<tr>
<td>Sternal wound infection</td>
<td>13 (3.4%)</td>
</tr>
<tr>
<td>Superficial</td>
<td>8</td>
</tr>
<tr>
<td>Deep</td>
<td>4</td>
</tr>
<tr>
<td>MRSA mediastinitis</td>
<td>1*</td>
</tr>
<tr>
<td>Ventilation time</td>
<td>1.28 days</td>
</tr>
<tr>
<td>Length of ICU stay</td>
<td>3.43 days</td>
</tr>
<tr>
<td>Length of hospital stay</td>
<td>12.5 days</td>
</tr>
</tbody>
</table>

Note: fisher square and student t-test, p-value <0.05 considered significant. *sternal wound debridement and conservative therapy were needed. NR: not reported; MRSA: methicillin-resistant Staphylococcus aureus; n: number of patients.

The mean length of hospital stay in the vest group (12.5 days, ± 7.4) was significantly shorter compared with the control group (18 days, ± 15.1; p=0.002). Mean ventilation time was also shorter in the vest group (p=0.01) and the authors report that postoperative rehabilitation and mobilisation was “very effective in group A (vest group), because of increase in sternum
stability, less discomfort and pain”. Chronic wound pain was reported by two patients in the control group. It is unclear whether wound pain did not occur or was not reported in the Stern-E-Fix corset group. Most patients (96%) were “very pleased and satisfied” with the Stern-E-Fix corset.

Safety

Safety issues, specifically related to the use of this device, were not expected and were therefore not specifically reported. However, refusal to wear the vest was common, for example, in Gorlitzer et al (2010)\(^1\) 15 per cent of patients randomised to the intervention arm declined participation due to slippage and discomfort with the vest. In Celik et al (2011)\(^6\), 10 per cent of patients (mainly obese women) refused to wear the vest and withdrew consent before the trial commenced.

Economic evaluation

No economic evaluations regarding the cost effectiveness of Posthorax™ or Stern-E-Fix corset were identified in the literature. However, Tewarie et al\(^4\) states that the average cost of hospitalisation of patients with wound infection is three times higher compared with that of a patient with an uncomplicated postoperative course. The increased costs are likely associated with higher morbidity, prolonged hospital stay and the need for repeat surgery in these patients. Theoretically, if sternum support vests prevent sternal dehiscence and infection, they should reduce the length and cost of hospitalisation.

Ongoing research

No clinical trials with the primary outcome of sternal dehiscence for any support vest were identified. However, the Posthorax™ manufacturer’s US website lists upcoming 2013 conference presentations describing trials of the Posthorax™ vest in other countries:\(^2\)

- Sweden: Dr. Hans Jonsson, Karolinska University Hospital, Stockholm; Cardiovascular Surgical Symposium in Zürs, Austria; March 2013
- United Kingdom: N. Nicolaidis et al., Southampton General Hospital; SCTS Annual Meeting & CT Forum in Brighton, UK; April 2013
- Switzerland: Professor Genoni and Dr. Löblein, Zurich Heart Center; European Multidisciplinary Conference in Lugano, Switzerland; May 2013

One Australian trial (not yet recruiting) using one of the products included on the ARTG (Qualibreath) was identified. The interventional group is to wear the Qualibreath device post median sternotomy for the duration of their inpatient stay and the primary outcome of interest is postoperative pain.
Other issues

Length of follow-up

The main RCT followed patients for 90 days/3 months. When queried by a colleague in a discussion following the published RCT report, the lead author suggested that follow-up will be doubled to six months as sternal healing is not complete at three months.14

Study funding

Funding information and author conflict-of-interest (COI) were not reported in any case, aside from the most recent RCT study abstract for the Austrian / German RCT that declared no authors had a COI.18

Reporting of other important outcomes

Differences in amount of pain experienced by patients were not addressed quantitatively in any of the included studies.

Patient experience (quality of life and satisfaction) was not discussed in the available studies. The one study which did discuss satisfaction did not report results for both groups.4

Issues with the device

A high proportion of patients assigned to the support vest arm of the studies either refused to wear the vests or were not eligible for one reason or another (15 per cent and 13 per cent respectively).14 Patients complained that the vest was not comfortable, particularly when supine, although apparently a new design is being developed to address comfort issues.16

Variance in analyses

A number of patients assigned to the vest group either refused the vest or were not able to receive it. Analyses should therefore be conducted ITT, rather than per-protocol which was the case for the included studies, so that it can be determined if there is still a significant benefit to the vest even when non-compliant or excluded patients are assessed.

Economic analyses

The economic aspects of vest versus no-vest use have not been reported, although there is a suggestion that hospital days are saved with vest use.10,16

Summary of findings

Three RCTs were included in this Technology Brief. Two studies assessed the effectiveness of the Posthorax™ support vest with a total of about 1,000 patients assigned to the intervention arms of the studies. Safety issues specific to the use of the vest were not reported; however, there was a relatively high level of vest intolerance and abandonment. All three of the included studies reported effectiveness data, with a focus on deep sternal...
infection/mediastinitis and sternal dehiscence. Results indicated that the vest decreased these complications (when only the compliant patients were analysed). For example, in the largest RCT, rates of deep sternal infection at 90 days were zero per cent in the vest group versus 0.88 per cent in the control group ($p=0.02$). The second RCT, specific to patients with COPD undergoing median sternotomy, reported a complication rate (stenal dehiscence + superficial + deep sternal infection) of one per cent in the vest group versus 11.5 per cent in the control group ($p=0.002$); in the latter group, 14 patients required major follow-up surgery and the group suffered a 36 per cent mortality rate.

The results of the RCT, which compared the Stern-E-Fix device to elastic bandages, showed a similar direction of effect, with rates of postsurgical complications being lower in the vest group.

Overall, this Technical Brief identified a paucity of evidence regarding protocols or guidelines for the use of sternal precautions following cardiac surgery. It is clear that protocols may vary between clinicians and across jurisdictions. There is a range of support garments available for post-surgical sternal support; the similarities and differences between them are not well characterised in the published literature. Additionally, the optimal length of time associated with the use of sternal support vests is not well defined, nor is the specific patient population who will benefit most from using the device (it has been suggested use in patients at high-risk of developing sternal dehiscence/infection alone may be optimal).

**HealthPACT assessment**

Despite the promising results observed in the three available RCTs (particularly in regards to reduction in rare but very significant major complications) it is recommended that no further research by HealthPACT is necessary at this time for sternal support vests. This recommendation is based on the unlikelihood of their widespread implementation in an Australian clinical setting.

**Number of studies included**

All evidence included for assessment in this Technology Brief has been assessed according to the revised NHMRC levels of evidence. A document summarising these levels may be accessed via the HealthPACT web site.

- Total number of studies: 3
- Total number of Level II studies: 3
References


Sternum support vests to prevent sternal dehiscence: May 2013


**Search criteria to be used (MeSH terms)**

Vest, wound, Posthorax, sternotomy