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Reconstruction of Chronic Aseptic Sternal Pseudoarthrosis after Median Sternotomy: Initial Experience with the Ley Prosthesis

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ABSTRACT

It has previously been reported that the Ley prosthesis, a 0.5-mm–thick titanium alloy plate designed for reconstruction and stabilization of the unstable sternotomy, leads to shorter hospital stay and reduces the need for further surgical procedures in patients with postoperative mediastinitis after open heart surgery. We report our initial experience with the Ley prosthesis in patients with chronic aseptic sternotomy dehiscence. The study included 6 male patients (age 42-80 years) with opiate-derivate–dependent intractable pain and significantly reduced quality of life caused by noninfected sternal pseudoarthrosis and unstable sternotomy with large sternal bone tissue deficit. Four of the patients had undergone various surgical fixation procedures 8 days to 12 months after the primary operation. The patients were treated with reconstruction and stabilization of the sternum with the Ley prosthesis 10 to 40 months after the primary operation. In 1 patient bone transplantation was used. No immediate peri- or postoperative complications were observed, and all patients were discharged 4 to 11 days after surgery. One patient who received a bone transplant developed wound infection, and the prosthesis was removed 5 weeks after implantation. At 6-month follow-up all sternotomies were found stable, and patients reported that pain had decreased and quality of life was significantly improved. Our results demonstrate that the Ley prosthesis can be safely and efficiently used for the reconstruction and stabilization of the sternum in patients with intractable pain caused by noninfected postoperative sternal dehiscence and large sternal bone tissue deficit.

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INTRODUCTION

Median sternotomy is the most used surgical approach in open-heart surgery [Dalton 1993]. This procedure is regarded as a safe access with a low complication rate, although the incidence of deep sternal wound infection after the procedure has been reported to be 0.4% to 5%. Overweight, chronic obstructive pulmonary disease, diabetes mellitus, and history of uni- or bilateral harvesting of the internal mammary artery have been identified as risk factors for the development of sterile dehiscence and mediastinitis after open-heart procedures with median sternotomy [Kouchoukos 1990; Bitkover 1998; Tarelli 1998]. The number of patients with these risk factors who have to undergo open-heart surgery is increasing, and because of the relatively high rates of morbidity and mortality observed in postoperative mediastinitis surgeons are seeking new treatment modalities [Robicsek 1977; McGregor 1999; Astudillo 2001; Casha 2001; Bertin 2002]. We have previously reported our experience with the Ley prosthesis [Astudillo 2001], a 0.5-mm–thick titanium alloy plate designed for reconstruction and stabilization of the unstable sternotomy in the treatment of postoperative mediastinitis after open-heart surgery. In the treatment of patients with postoperative mediastinitis, we observed that the use of the Ley prosthesis compared with conventional techniques was associated with shorter hospital stays and fewer necessary additional surgical procedures.

After open-heart surgery that requires surgical treatment for mediastinitis or sternal dehiscence, some patients develop noninfected sternal pseudoarthrosis, a condition that may lead to severe pain and reduced quality of life. In general, fracture malunions are known to cause pain [Mears 2003] and have for many years represented a therapeutic challenge for orthopedic surgeons [Berin 2002]. Recognizing that fixation of the unstable fracture is the prerequisite for treatment of noninfected and infected pseudoarthrosis, we tested the use of the Ley prosthesis to provide rigid fixation of fractures in patients with intractable wound-related pain caused by an aseptic unstable median sternotomy with large sternal bone loss (Figures 1 and 2). Here we report our initial experience with the use of Ley prosthesis for this condition.

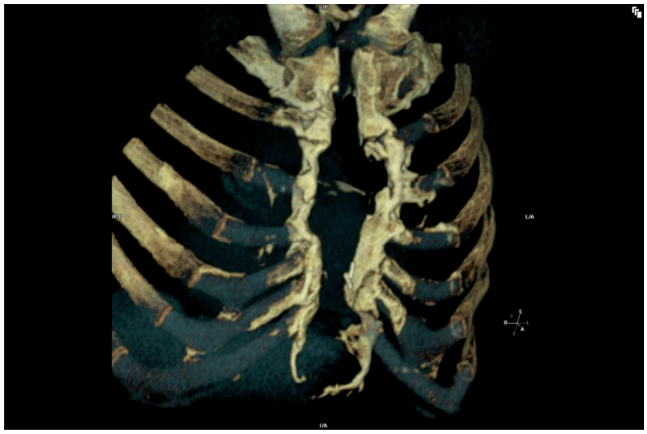

Figure 1. Computed tomographic reconstruction of a patient with a noninfected sternal pseudoarthrosis and large sternal bone tissue deficit.

PATIENTS AND METHODS

Patient Selection and Demographics

The study patients (Table) were 6 men (age range 42-80 years) with noninfected sternal pseudoarthrosis and large sternal bone tissue deficit causing intractable pain after open-heart surgery performed at different institutions. Five patients had a body mass index >30 kg/m^2, 5 had chronic obstructive pulmonary disease, and 3 had diabetes mellitus. All patients had undergone coronary artery bypass graft with the use of the left internal mammary artery, and 1 patient underwent an additional combined procedure with aortic valve replacement. Five patients developed sterile wound dehiscence after the primary surgical procedure, and 1 patient had postoperative mediastinitis caused by coagulase-negative staphylococci. Prior to study inclusion and implantation of the Lev prosthesis, 4 of the patients had undergone various surgical fixation procedures: 1 patient had undergone 1 and 3 patients had undergone 2 reoperations in which different surgical techniques were used to treat sternal dehiscence, 3 patients underwent reoperation with the Robicsek technique, and 1 had an antibiotic-embedded device left in the mediastinal space. One patient was treated with the Ley prosthesis at the time of the primary reoperation, and in 1 patient bone transplantation was used in addition to the prosthesis.

Quality of life was assessed through telephone interviews performed 6 to 18 months after hospital discharge, taking into consideration postprosthesis implantation status, i.e., daily physical activity, subjective pain complaints, and possible pain medicine consumption.

The Ley Prosthesis

The Ley prosthesis (Geister Medizintechnik GmbH, Tuttlingen, Germany) is made of a 0.5-mm–thick titanium alloy that is shaped like a stepladder and is pliable to conform to the sternal profile and possible sharp bone edges (Figure 3). The prosthesis is designed to provide stability in patients with multiple sternal fractures and in patients who have undergone removal of substantial parts of the sternum.

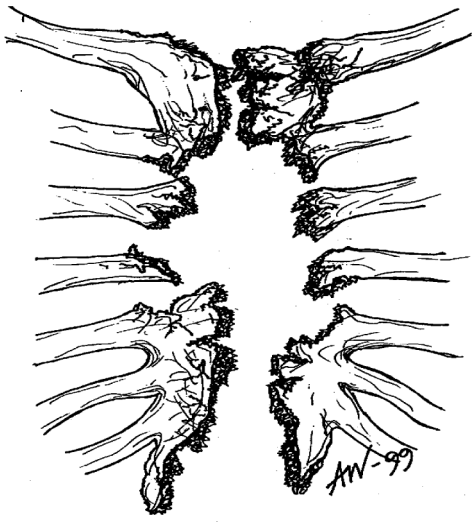

Figure 2. In all the case patients, the sternal wires from prior surgery had cut through the sternal tissue and some of the wires were broken. The disposition of the sternal wires were on both sides of the midline sternotomy incision leaving in some cases the protuberance of the wire knot close to fragile adjacent tissues (i.e. right atrium), always causing pain and also jeopardizing the integrity of the skin, with subsequent risk for infection.

Surgical Technique for Implantation

All surgical procedures were performed while patients were under general anaesthesia. The surgical procedure was performed as previously described [Astudillo 2001]. Remnant wound margins were excised, and the sternum was assessed in detail for fractures and solidity. Any devitalized tissue (soft tissue and sternal bone) was aggressively debrided and excised. The muscular tissue adjacent to the sternum was mobilized bilaterally by lateral dissection up to 5 cm subfascial to the pectoralis major muscle. When using the Ley prosthesis mobilization of both pectorals muscles is recommended.

Accurate hemostasis with diathermy was performed to prevent postoperative haematomas. The size of the prosthesis was selected so that at least 75%-80% of the length of the sternum measured from the jugular notch to the basis of the xiphoid process was covered. To aid correct placement of the sternal wires, the decided position of the prosthesis was marked with diathermy. Up to six wire sutures were introduced to firm tissue, the sternum, ribs or costal cartilages parallel to the sternotomy line, in U-shapes on each side of the transverse fractures, when present, in the sternum. With a minimum of 6 sutures on each side, tightening of the sutures compresses the fractures against the prosthesis. After the sutures were passed through the suitable holes in the prosthesis, but before the prosthesis was pulled down, 3 new wires, or strong, absorbable, monofilament suture material, were applied around the 2 sternal halves to pull them together. This procedure facilitates the introduction of the prosthesis into the field (Figure 4). The wire sutures were pulled as straight as possible directly into the proper hole in the

Patient Characteristics at Baseline*

Patient No.	Age, y	Diagnosis	No. Reoperations	Time from First Operation to Inclusion, mo	COPD	Diabetes	Obesity†
1	42	AP	2	18	+	+	–
2	62	AP	1	22	+	+	+
3	65	AP/AS	1	18	+	–	+
4	65	AP	2	10	+	–	+
5	72	AP	2	14	+	–	+
6	80	AP	1	40	+	–	+

*COPD indicates chronic obstructive pulmonary disease; AP, angina pectoris; AS, aortic valve stenosis.
†Obesity = BMI >30 kg/m^2

prosthesis. The prosthesis was then slid down, and the wires were twisted so that the wires cross each other equidistant from their exit point from the prosthesis. The slack in the wire was taken up, and the wire was twisted carefully to avoid tension build-up that could cause metal fatigue fracture. One or 2 thin (18 Fr) exit drains were placed retro- and antesternally. The muscular fascia was closed over the drains with interrupted, absorbable, monofilament sutures. Subsequently the skin was closed with interrupted, nonabsorbable, monofilament suture.

RESULTS

All patients were treated with Ley prostheses of different sizes implanted according to the technique described above. No immediate peri- or postoperative complications were observed, and all patients were discharged 4 to 11 days after surgery. No blood transfusions were required peri- or postoperatively. Antibiotics were given according to the prophylaxis regimen of the respective center. One patient who received a bone transplant to fill a large bone deficit developed wound infection within 2 weeks after surgery, and the prosthesis was removed 5 weeks after. After the prosthesis and bone transplant were removed, the wound was initially left open, then was closed without any fixation device. The patient did well immediately after the procedure and was sent home. At the time of this report the patient was alive but unfortunately had not returned for outpatient follow-up.

At 12 months follow-up all sternotomies were found to be stable, and patients reported that their pain had decrease and quality of life had markedly improved.

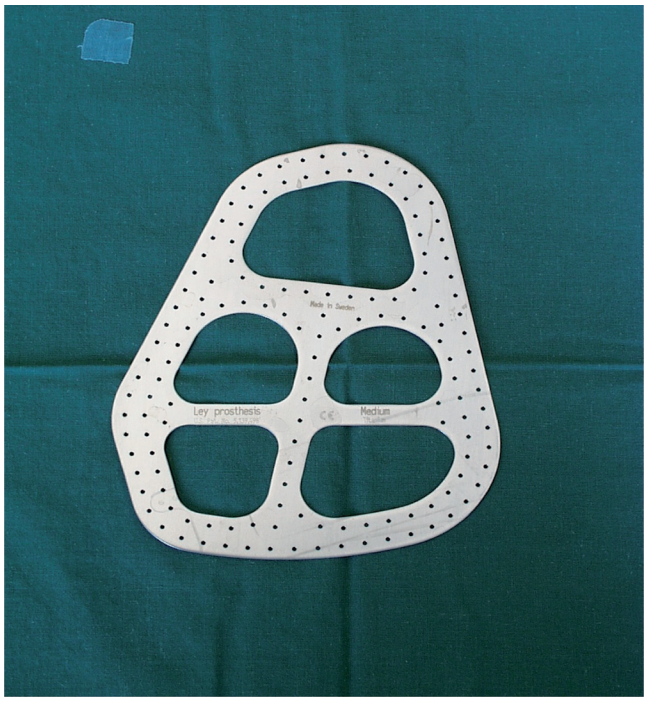

Figure 3. The Ley prosthesis is made of 0.5-mm–thick titanium alloy; it is shaped like a stepladder and is pliable to conform to the sternal profile and possible sharp bone edges.

DISCUSSION

The present series demonstrates that the Ley prosthesis may be safely and efficiently used for reconstruction and stabilization of the sternum in patients with intractable pain caused by noninfected postoperative sternal dehiscence and large bone tissue deficit.

Median sternotomy, a technique first reported more than 100 years ago [Dalton 1993], allows adequate exposure of the heart and great vessels. This procedure is associated with a low complication rate. Although in our experience only a small percentage of patients undergoing reoperation for sternal dehiscence or postoperative mediastinitis develop chronic noninfected sternal pseudoarthrosis, the condition is serious and may lead to chronic pain and reduced quality of life. The number of patients with diabetes mellitus in conjunction with overweight, chronic obstructive pulmonary disease, and bilateral harvested internal mammary arteries, identified as risk factors for postoperative mediastinitis [Kouchoukos 1990, Tarelli 1998] are increasing, and it is accordingly conceivable that the total number of patients developing chronic noninfected sternal pseudoarthrosis will increase.

It has been shown in an experimental biomechanical study [Cohen 2002] that the region close to the xiphi sternum is the most vulnerable part of the sternotomy, a finding that correlates to our clinical experience; mechanical failure of the sternotomy usually occurs at the lower part of corpus sterni. The lower part of the anterior chest wall moves like the handle

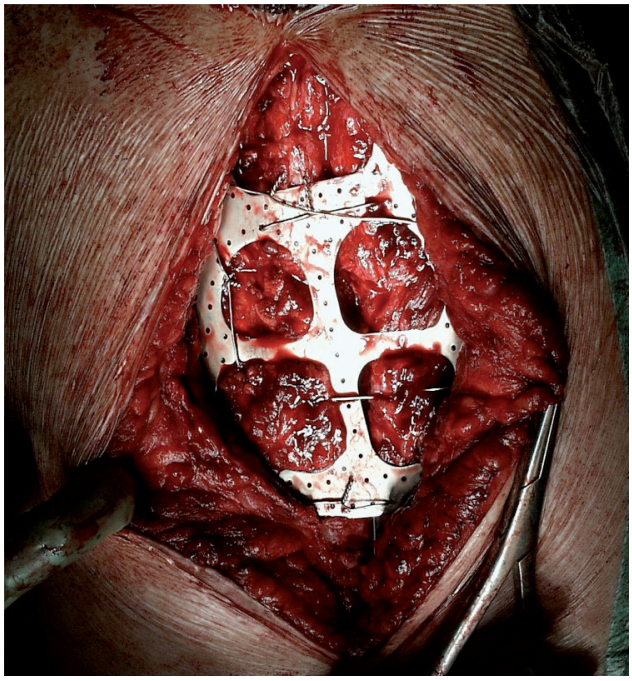

Figure 4. Accurate hemostasis facilitates the introduction of the prosthesis into the field.

of a water pump during respiration, and the lack of anatomical fixation to the surrounding bone structures makes this area vulnerable to dehiscence/rupture. For this reason anchoring and securing this area with the lowest stainless steel suture is recommended. Moreover, the sternal area before the xiphi sternum begins is the thickest and probably one of the hardest parts of the sternal bone. Theoretically, anchoring the last sternal wire to this point should prevent postoperative sternal dehiscence. Nevertheless, in high-risk patients inadequate fixation of the remaining sternum may still occur, leading to complications.

Previous reports suggest that sternal dehiscence can occur under physiologic loads [Cohen 2002], and that improved sternal stability may be readily achieved via mechanical reinforcement near the xiphoid [Pai 2005]. Postoperative sternal separation can occur as a result of wires cutting through the bone. In such cases, stabilization of the sternum can be both challenging and troublesome owing to multiple fractures and fragile necrotic bone.

The reconstruction of the fractured sternum is completely feasible with the technique we describe here, leading to a stable anterior thoracic wall and hence proper respiratory function which, under appropriate circumstances, will shorten respirator treatment time. Unfortunately, no other osteosynthesis devices for sternotomy and sternal fracture fixation are available that can be compared with the Ley prosthesis.

We have previously reported that sternal dehiscence is initially observed in patients with mediastinitis after midline sternotomy in practically all cases (98%), but mediastinitis in patients with intact sternotomy is rare [Astudillo 2001; Szerafin 2001]. These findings support the theory that sternal dehiscence due to mechanical factors usually occurs before infection at the mediastinal space. Further studies are needed to evaluate whether the prophylactic use of the Ley prosthesis in patients with increased risk of developing postoperative mediastinitis will decrease the incidence of mediastinitis after open-heart surgery.

The present study is a retrospective analysis of our experience with the reconstruction of the sternum using the Ley prosthesis and demonstrates a novel surgical technique for managing the difficult-to-treat condition of noninfected post sternotomy pseudoarthrosis with large bone tissue loss and intractable sternotomy-related pain.

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