Potential risk of sternal wires

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Abstract

Objective: To understand the potential fracture mechanism of sternal wires, we collected extracted stainless steel sternal wires from patients with sternal dehiscence following open-heart operations. Surface alterations and fractured ends of sternal wires were inspected and analyzed.

Methods: Eight fractured and 12 non-fractured wires extracted from five patients (closure method: figure-of-eight or straight twisted; two without and three with mediastinitis) with mean implantation interval of 13.2 ± 4.2 days (range 8–20 days) were studied by various techniques. The extracted wires were cleaned and the fibrotic tissues were removed. Irregularities and fractured ends were assayed by scanning electron microscopy and energy dispersive X-ray analysis (EDXA).

Results: All examined fractured wires showed the presence of severe transversal cracks and crevice corrosion. EDAX revealed aluminum oxide inclusion on the fractured surface.

Conclusions: The synergic effect of stress and poor wire quality could be the precursors of material failure for the sternal wire.

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Keywords: Fractured wire; Sternal dehiscence; Scanning electron microscopy

1. Introduction

Although sternal separation, or dehiscence is a rare complication of median sternotomy\cite{1}, it results in a mortality rate between 10 and 40\%\cite{2}. Sternal instability, wound infection, osteomyelitis and dehiscence are related\cite{3}. The most important factor in preventing sternal dehiscence and mediastinitis is a stable sternal approximation\cite{4}.

Dehiscence often occurs within the first 2 weeks post-operatively before significant bone healing\cite{5}. X-Ray examination of the sternum after sternotomy shows evidence of a ruptured suture wire, dehiscence of the sternum, malpositioning of the wire ligature, cutting-through of the fixation wire by the bone fracture, pseudoarthrosis and inflammation.

The strength applied on the sternal wire after wound closure was far below the ultimate tensile strength (UTS) of wire as studied by Losanoff et al.\cite{6} in their biomechanical porcine model. In spite of this finding, sternal wire still fractured after a routine surgical procedure. Therefore, the aim of our study is to analyze the potential risk of wire fracture and to ensure a secure and rigid fixation of the sternum by improving the property of sternal wire materials.

2. Materials and methods

316L stainless steel is the most commonly used suture wire material. 316L stainless steel suture wire has austentic structure with low carbon content (0.03\% weight), and is predominantly iron (60–65\%) alloyed with chromium (17–18\%) and nickel (12–14\%).

The extracted wires were ultrasonically cleaned in distilled water for 15 min and the adhesive fibrotic tissues were gently removed with fingers. Eight fractured and 12 non-fractured wires extracted from five patients (closure method: figure-of-eight or straight twisted; two without and three with mediastinitis) with a mean implantation interval of 13.2 ± 4.2 days (range 8–20 days) were studied and
documented by stereomicroscopy. Irregularities were assayed by scanning electron microscopy. Break ends and striking surface alterations were further examined using energy dispersive X-ray analysis (EDAX).

2.1. Scanning electron microscopy analysis

Surface morphology of wire samples was examined with scanning electron microscopy (SEM, Hitachi model S-800, USA). Representative micrographs were taken in a second electron imaging mode. To prevent charge problem and to enhance the resolution, samples were sputtered with a thin layer of gold using a Polaron G-5000 sputter coater.

3. Results

X-Ray examination of the sternum after sternotomy proved the evidence of ruptured suture wire, dehiscence of the sternum, malpositioning of the wire ligature, cutting-through of the fixation wire by the bone, fracture, pseudoarthrosis and inflammation (Fig. 1).

All of the examined retrieved wires showed severe transversal cracks (Fig. 2, Table 1). These cracks are perpendicular to the wire drawing direction.

Fig. 3 shows the fracture end of a retrieved wire, with abnormal flat fracture surface and enormous inclusions. Flat fracture is an indication of low ductility of the suture wire.

Aluminum oxide inclusions were found on the surface of retrieved wires (Fig. 4); crevice was found along with the inclusions. The gold peak revealed by the EDAX spectrum resulted from the sputtering coating.

Severe oxide particles were found on the stainless steel suture wire, after sterilization as shown in Fig. 5, in an as-received condition from the sternal wire suppliers. These oxide particles could be the precursors for the crevice corrosion after the sternal wire was implanted. Oxide particles were also found on the transversal cracks and surface defect areas (Fig. 6).

Fig. 7 shows the presence of crevice corrosion on the surface cavities of the retrieved suture wires. The dark areas surrounding the surface cavities on the retrieved wires are an indication of crevice corrosion.

4. Discussion

In our institution, figure-of-eight combined with one or two simple interrupt sutures is our routine closure method of sternotomy. The 0.8% incidence of major sternal complications was reported as an average in the literature by most centers [7].

Five of 1170 patients were identified as wire fracture complications by chest X-ray following open-heart operations in our single institution during a 2-year study. The incidence of wire fracture with sternal dehiscence requiring further debridment and refixation is about 0.4% in our patient population.

It has been reported that sternal dehiscence could happen under physiologic loads, e.g. coughing and cyclic respiration. A force/strength of 150 kg (552 ksi) loaded upon a sternotomy closure, at maximum coughing, was reported by Casha et al. [8]. Although force (kg) is the common parameter used in medical research [6,8], it is also correct to use strength (psi or ksi) induced by the applied load (force/unit of cross section area). To pay respect to all the published papers in various journals, units of force and strength are adopted in this paper to accommodate readers in all fields. Given that surgeons generally use six wires to close a median sternotomy, each wire would be required to sustain 25 kg (92 ksi). It would, therefore, take a minimum of three twists of the 0.7 mm wire or two twists of the 0.9 mm wire to withstand a severe cough. Normally, sternal steel wire breaks at maximum strength of $345 \pm 4.8$ ksi ($92.8 \pm 1.3$ kg) in a chest closed with one figure-of-eight twisted wire technique and at $365 \pm 17.9$ ksi ($98.0 \pm 4.8$ kg) for two straight twisted wires. Surgeons generally use 5–7 twists of the wire in a sternotomy closure [6] and, based on these studies, this would appear sufficient to gain maximum strength and prevent possible sternal dehiscence.

Under normal circumstances, the strength induced by the load or force applied on the sternal wire after closure is far below the UTS of wire as studied by Losanoff et al. [6] in their biomechanical porcine model. However, fracture of sternal wire could still occur after routine surgical procedure.

For a wire with perfect surface condition, no wire fracture would occur during the sternotomy closure.
Table 1
Fractured wires with sternal dehiscence

<table>
<thead>
<tr>
<th>N</th>
<th>Closure methods</th>
<th>Mediastinitis</th>
<th>Implantation periods (days)</th>
<th>Types of wire damage</th>
</tr>
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<td></td>
<td></td>
<td></td>
<td>Cracks</td>
<td>Inclusion</td>
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<tr>
<td>1–1</td>
<td>Figure-of-eight</td>
<td>–</td>
<td>15</td>
<td>+</td>
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<td>Figure-of-eight</td>
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<td>15</td>
<td>+</td>
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<td>+</td>
<td>8</td>
<td>+</td>
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Fig. 2. SEM micrographs of transversal cracks on the retrieved 316L stainless steel sternal wire.
However, the induced or derived strength might have exceeded the UTS of the suture wire when severe surface defects such as the transversal cracks and inclusions were found on the retrieved sternal wires. The transversal crack and the inclusion could serve as a stress-concentrated area and lead to the wire breakage, as flat fracture of retrieved suture wire suggested a lack of ductility.

An imperfect manufacturing process and improper sterilization process could weaken or destruct the internal or external structure of the suture wire [10]. Transversal cracks have been widely documented; this defect is due to the insufficient lubrication and cooling during the wire drawing process [9]. The heat generated by the frictional force inside a drawing die, and the cooling by the subsequent lubricant after the wire leaving the drawing die, could generate martensite structure on the wire surface [11]. Wire is susceptible to fracture under pressure or strength due to the huge difference of hardness between the surface martensite and the internal austenite structure, as well as the stress concentration factor.

A heterogenous discontinuity on a wire surface, such as inclusions or a crack, could result in a non-uniform distribution of stress at the vicinity of the discontinuity [12]. Stress concentration occurs at the discontinuity and could reach a value higher than the average stress at a distance away from the defects or average stress that is free from any defect.

Depending on the types of the defects on the wire surface, e.g. inclusions (Fig. 4) and transversal cracks (Fig. 2), the shapes of defects can be either circular or elliptical.

The maximum stress at the ends of the inclusions or transversal cracks can be expressed as: [12]

$$\sigma_{\text{max}} = \sigma(1 + 2a/b)$$

where $a$ and $b$ are the half dimension of the inclusion or crack in each direction, and $\sigma$ is the normal stress far away from the defects or free from defects.

The stress increases with the ratio $a/b$. The average ratio of $a/b$ based on the transversal cracks is 28.6, and 4.8 for the inclusions.

The average tensile strength of a full-annealed 0.7 mm sternal wire is 132 ksi (36 kg) [13]. The applied strength during closure is assumed to be 60% of the tensile strength of the wire, or 80 ksi (21.6 kg). Thus $\sigma_{\text{max}}$ can reach as high as 4678 ksi (1257 kg) at the vicinity of a transversal crack area for a single 0.7 mm sterno wire and as 845 ksi (229 kg) at the vicinity for an inclusion. These $\sigma_{\text{max}}$ values are far above the UTS of the sterno wire. For this reason, a very narrow crack such as transversal crack or non-metallic inclusion normal to the drawing direction and tensile direction would result in a very high stress concentration and damage the sternal wire after closure with a flat fracture surface.

Not only can defects, such as transversal crack and inclusion, create a potential risk of wire fracture after closure, but also contribute significantly toward various implant failures, such as stress corrosion cracking, corrosive wear, and fretting corrosion or corrosion fatigue, due to the synergistic effect from chemical and mechanical parameters.

In addition, a high concentration of chloride ion in the physiological fluid makes the human body a hostile

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Fig. 3. Severe inclusions found on the fractured end surface. Circed area and the arrows indicated the presence of inclusions.

Fig. 4. Alumina inclusions on a sternal wire.
environment for suture wire. Although problems such as electrochemical corrosion, chemical attack on the suture, and inflammation produced in reaction to the suture have been minimized by the application of stainless steel wires, complication and failure of the wires still occur.

The favorable corrosion environment due to the high concentration of chloride ion in the physiological fluid and the mechanical strength applied to the sternal wire during closure could lead to stress corrosion cracking and ultimately, cause serious damage to the wire [14].

For a patient with mediastinitis, adherent bacteria could create an electrochemical reaction with a current flow of metallic ions and dramatically accelerate the corrosive process [15]. Also, the presence of crevice along the aluminum oxide inclusions and the cavities on the wire surface could serve as the precursor for the corrosion.
Crevice corrosion not only happens on the inclusion areas and cavities but also on the heavy surface oxide clustering areas. Localized oxygen accumulation could occur, due to adherent fibroblasts, white blood cells or activated osteoclast, after the suture wire is implanted into human body [16]. The difference in oxygen concentration on the wire surface and inside the crevice can create a concentration cell and generate a galvanic corrosion cell [17].

In addition to the risk of mechanical loss of integrity, degradation products such as metal ions during the corrosion process are a real concern because of their potential adverse biological effects, namely allergy, cytotoxicity, and carcinogenicity. Degradation products are well known for their proinflammatory effects and may be subtle contributors to the inflammatory reactions commonly associated with persistent wound pain and scar formation. The release of nickel, chromium and molybdenum ions may trigger chronic inflammatory reactions through an immunologic mechanism, which would in turn potentiate fibroblast activity and scar formation [18–20].

Histological studies have also shown that the constituent elements of implanted alloys could be detected in the local tissues and the tissue reaction around an alloy was related to the concentration of metal ions released into the tissues [21]. Local tissues at the site of a fixed wire are exposed continuously to gradually accumulated concentrations of the metallic ions comprising the alloy [22]. Nickel ions particularly have been reported in vitro to induce soft tissue inflammation at sub-toxic concentrations through direct activation of monocytes and cytokine-indirect stimulation of endothelial cells [20]. These inflammatory conditions may accelerate the corrosion of the devices, which further increases the release of these proinflammatory substances.

5. Conclusions

To prevent the occurrence of sternal wire failure after closure, improvement of sternal wire quality is mandatory. Cell-induced electrochemical corrosion, active cellular destruction of surfaces, and sterilization method are well-known mechanisms that must be investigated for their possible roles in the material failure of sternal wire.

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