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Loosen Zipfix: A Case Report

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Authors' contributions

This work was carried out in collaboration among all authors. Author BAK designed the study, performed the statistical analysis, wrote the protocol and wrote the first draft of the manuscript. Authors IIM and HH managed the analyses of the study. Author HH managed the literature searches. All authors read and approved the final manuscript.

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Case Study

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ABSTRACT

Traditional primary sternal closure after cardiac surgery by steel wire cerclage is the standard technique for most centers worldwide. There is an increase usage of other methods, namely the zipfix (DePuy Synthes CMF, West Chester, Pa), as an alternative to standard wire cerclage, which claimed to be of superior functionality and outcome. We share our experience in using zipfix in one of our patients post Coronary Artery Bypass Grafting (CABG) Surgery, in which the latch within locking mechanism became loose nine months after surgery. The aim of this case report is to shed light on the usage of zipfix. We believe that the incidence of tear and wear of mechanical device, zipfix is under reported.

Keywords: Loosen Zipfix; cardiac surgery; CABG; coronary artery.

1. INTRODUCTION

Cardiac surgery cohort nowadays shows more patients with advance age, diabetes, renal failure, lung diseases, osteoporosis, poor nutritional status as predisposing patient-related factors with increased complexity of surgery [1]. These comorbidities have crucial impact on bone composition of corticalis and spongiosa. Therefore, it influences bone and wound healing.

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Primary sternotomy closure using steel wires may be the immaculate closing strategy in a strong and durable sternum, but might be suboptimal in fragile and soft bones. During chest physiotherapy, weight lifting or coughs, the steel wires can cut through the sternum, as the force is concentrated on a very tiny surface diameter of the wire. In regard to this, a new technique has been developed to minimize the aforesaid complication. A sternal zipfix is a biocompatible poly-ether-ether-ketone (PEEK) cable-tie-based sternal closure device [2]. This device is flexible, easy handling, able to close the sternum with high stability and with high biocompatibility. It is believed that it could reduce sternal closure complications and enables a higher rate of sternal fusion. The system consists of implant and applicator. The implant has a flat and rounded edge which will reduce the soft tissue irritation and bone cut through. Biomechanical enforcement across the sternum ensures immobility and increases sternal stability [3]. Even though zipfix shows promising data superior among metal wire in the aspects of strength and fatigues load comparison, the disadvantage of the device is insufficiently available.

2. CASE PRESENTATION

A 60-year-old male with underlying three vessels disease and diabetes, underwent CABG in September 2019. He was a well build man with good nutritional status. He was grafted on the left anterior descending and left circumflex coronary artery using his left internal mammary artery and saphenous vein grafts (SVG). There were no significant intraoperative issues encountered. The sternal closure was performed with four sternal zipfix in the sternal body and stainlesssteel wire in manubrium and distal end of sternum. Post-operative period was uneventful and the patient discharged well five days after surgery. During initial follow up, patient recovered well without any complaints and was able to carry normal routine activities as expected. On the 3rd follow up roughly 9 months after surgery, patient complained of a small painless swelling measuring 1x1cm at the right lower lateral edge of the sternum. The swelling appeared unprovoked and slowly increasing in size over the last one month. There was no history of trauma to the chest wall or chronic coughs. On examination, no sign of inflammation or infection noted at the skin swelling site. Chest X-ray posterior-anterior (PA) and lateral views were normal. Provisional diagnosis made as dislodged zip fix and the patient admitted electively for zipfix removal under general anaesthesia. Intra-operative finding was the implant in the distal end of the sternum was loosened(implant which inserted into the locking head opened up).The other end, locking part of the zipfix was buried at the deep tissue close to the lateral edge of the sternum. The zipfix was easily removed without any complication and the sternum was healed. The patient was well post-procedure and was discharged the next day.

Fig. 1. Sternal zipfix after removal

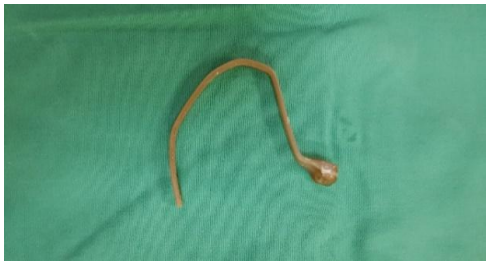

Fig. 2. The material became stiff to bend appropriately into the mechanism

3. DISCUSSION

The basic principles of fracture management, which includes re-approximation, stabilization, and immobilization, remains the key to optimal bone healing. The same principles apply to the sternotomy. Heavy breathing, coughing, weight lifting and vigorous body movement of a patient post operatively can affect bone approximation and stabilization and therefore lead to failure of sternal closure [4]. It is impeccable that any sternal closure techniques, devices, plates or implant must provide and maintain sufficient stabilization and immobilization for a duration long enough to allow bone healing. There has been mixed opinion as to how much rigidity and fixation is desirable from implants. Later, it is found that elimination of all motion is not necessary as it will prevent callus formation. It also fosters poor bone quality and give rise to secondary complication like re-fracture.

Therefore, micro-motion between two bone fragments is permissible. Recent studies showed that there is micro-motion in sternal closure by zipfix compared to sternal plate which will provide good callus formation. Load sharing by implants like zipfix is also thought to promote healthier and stronger bone. The locking mechanism of the system is the core of the device. If the mechanism fails, there will be no tension to hold and fix the sternum causing the system to fail. Complications may arise from any loose system such as bleeding, persistent pain, infection and non-union.

For this case, the extracted zipfix were reported to the company. Based on the company's analysis, a minor mark was seen on the ridge of the implant. A small amount of wear was observed on the latch within the locking mechanism. A functional test could not be performed, as the returned part was too small to reinsert into the locking mechanism to test the tightening ability of the implant. The material became too stiff to bend appropriately into the mechanism. This could be due to use within the patient's body. No other design defect was detected. Based on the analysis, no manufacturing defect was detected.

It is important to use the applicator to trigger tension of the implant fixing the sternum in place, while preventing over tension. Applicator lever able to cut the redundant end of implant avoiding undercut or overcut near the locking mechanism. All the above technique is vital for the longevity of the device. From the report, it was recommended to refer to surgical techniques. Few caution reminded, especially when securing the sternal zipfix, the cut end must not be inserted at an angle. Excessive force when tightening the implant must be avoided and must ensure the zipfix is properly orientated prior to insertion into the locking head.

Wrong technique may result into failure of the implant. We were strictly adhering to the above technique. However, the locking mechanism of the device had failed most probably due to the wear and tear component.

4. CONCLUSION

We concluded that the loosen zipfix in this patient most probably attributed to the isolated wear and tear after excluding all the other possible causes. We believe this is the first report of such faulty. Although it is an isolated case, surgeons should be aware that such failure can happen despite all measures taken. Long term studies, wide range of cohort and more incidence reports must be obtained to understand his type of failure rate. Although this may be an isolated case, one must aware, be vigilant and keep an open discussion for such possibility.

CONSENT AND ETHICAL APPROVAL

As per international standard or university standard guideline participant consent and ethical approval has been collected and preserved by the authors.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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