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ORIGINAL ARTICLE

Mechanical simulation study of reapproximated sternum rigidity comparing sternal fixation devices

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Abstract

Background A reliable sternal fixation is one of the most basic parts of cardiac surgery requiring sternotomy for preventing wound complications and promoting early recovery. Although various products have been released to the markets, the characteristics of each device are still unclear.

Methods A simulation study was conducted to compare the properties of two sternal fixation device: a commonly used monofilament stainless-steel wire and a newly designed cable comprised of several titanium alloys strands. Sternum models made of monomer casting nylon were tied with each material and displaced in longitudinal, antero-posterior, and horizontal directions. Resistance against each directional external force was measured and compared.

Results The titanium cable showed a higher resistance to every directional displacement since slight deviations and a twofold higher maximum strength than the stainless wire.

Conclusion An in vitro simulation study revealed the titanium cable system provide stronger sternum fixation than stainless-steel wire

Keywords Sternal fixation · Mechanical simulation · Titanium cable

Introduction

Sternal fixation is one of the most basic and critical part of cardiac surgery requiring sternotomy for reducing postoperative pain and preventing wound complications including mediastinitis [1]. Various procedures and products have been developed for a rigid sternum reapproximation. A stainless-steel wire is a conventional and commonly used product. Usually, 6 to 10 of stainless-steel wires are passed through the manubrium and through or around the body of the sternum. Then, the wires were tied to reapproximate the separated sternum with a twister. The tightness of the sternum is adjusted manually. There are some controversies in the sternum fixation method. Simple wire cerclage is known to have certain risk of complication of sternum dehiscence and resulting in mediastinitis which can be lethal, not strong enough against displacement in antero-posterior or superoinferior directions. To overcome the weakness of the wire cerclage, absorbable insertions such as pins [2] and a corrugated sheet have been invented [3]. External fixation devices including rigid plate fixation are also developed for offering stronger sternum fixation [4]. However, these are inferior in points of expense for each patient.

The wire cerclage as a basic procedure is comfortable for many surgeons. A newly developed cable which comprised of several titanium alloys strands can offer surgeons to obtain certain sternum reapproximation with similar procedures with the conventional wire cerclage. The cable also has a feature of higher resistance against traction. The manufacture component contains a specially designed crimp accompanied by a dedicated crimper for anchoring each end of the cable. The cable cerclage can be made without twisting knots which could be the most fragile point of the wire cerclage. The tightness of the cable cerclage can be controlled with a special tensioner (Fig. 1).

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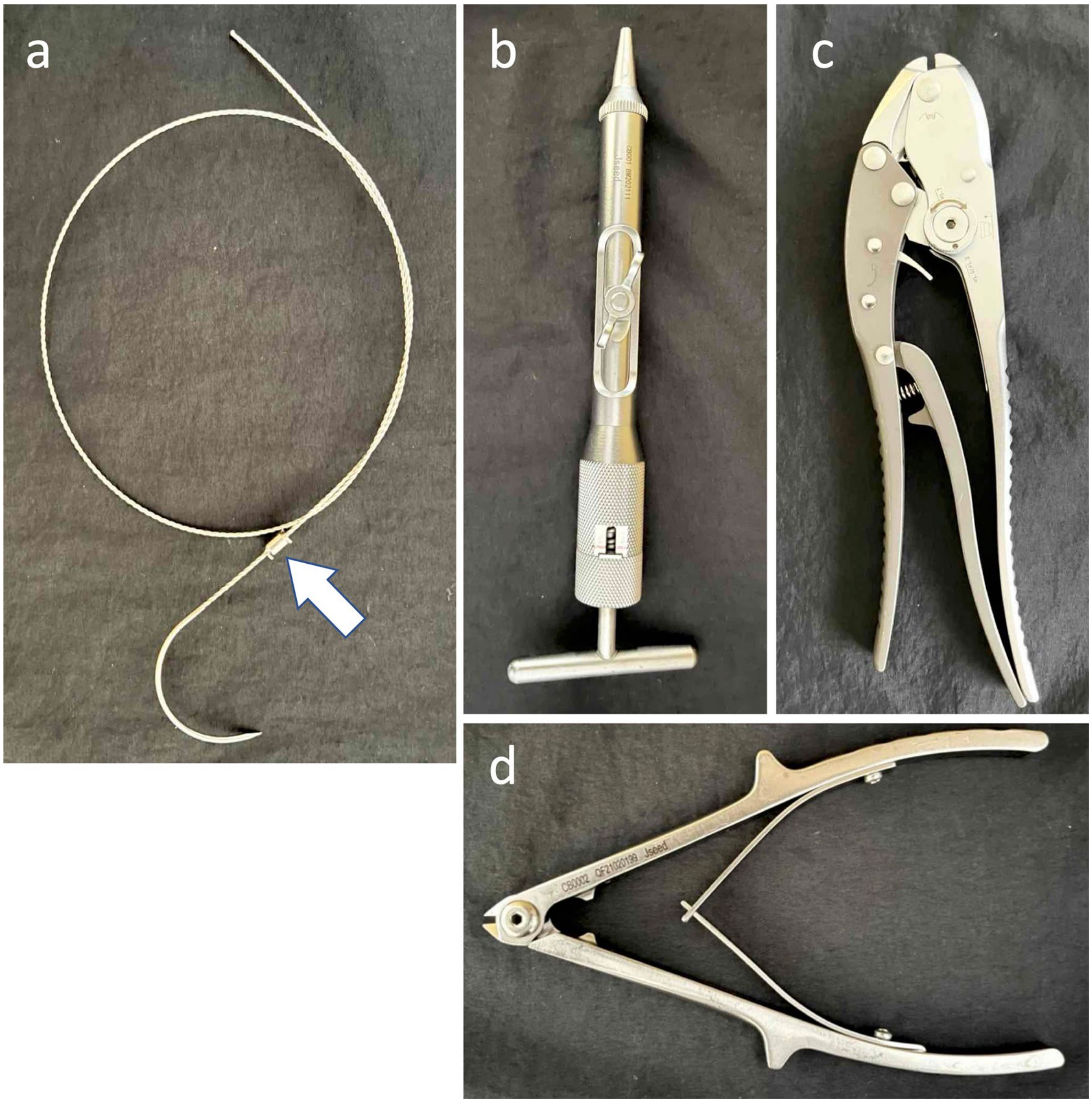

Fig. 1 **a** Titanium cable, **b** tensioner; enables quantitative tightening, **c** crimper, **d** cutter; designed to cut with fine tip. White arrow indicating attached crimp

The mechanical characteristics of each device are still unclear. The aim of present study is to compare the physical characteristics of conventional wire cerclage and titanium cable system.

Methods

Experimental model

To exclude biological variability, mock sternums which are made of monomer casting nylon (Standard, Misumi Group Inc., Tokyo, Japan) was used for this study as a previous study [3]. The mock sternums were approximated with either stainless wire or titanium cable piecing through a hole made on the mock sternums (Fig. 2).

A number 6 of stainless wires (M649G, Surgical steel, Ethicone) were tied with torque wrench which is designated to release the force at 27 N cm. The knot of the wire was trimmed at the 1 cm length and pushed down along the mock sternum surface to imitate clinical closure technique.

Diversity cable (J-seed Co., Ltd, Chiba, Japan) was engaged with the manufacture-defined maneuver which consist of tugging each side of the cable across through a specially designed crimp with traction device which enables quantitative traction. Then, the crimp was bit by a crimper. Excess cables were trimmed lastly.

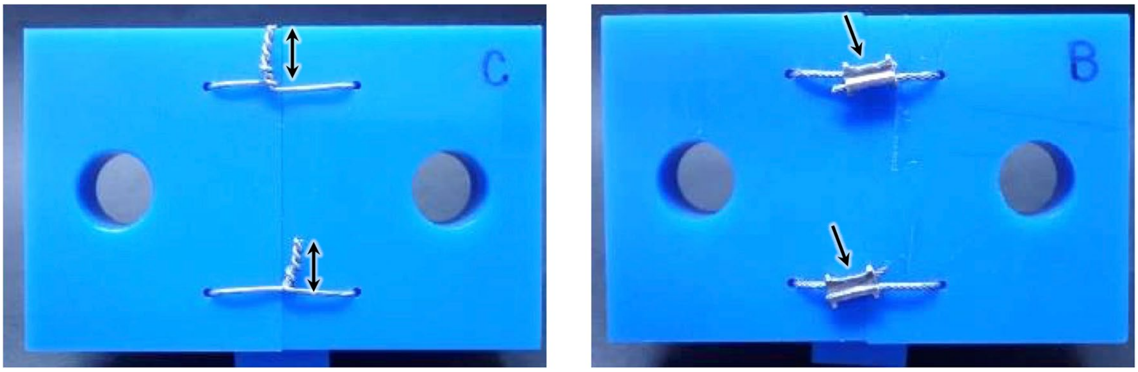

Fig. 2 Fixed mock sternums made of monomer casting nylon. Left: stainless-steel wire cerclages, right: titanium cables' system fixation. Double arrow: length of twisted knots which trimmed at 10 mm. Black arrow: crimper used to anchor each end of the titanium cable

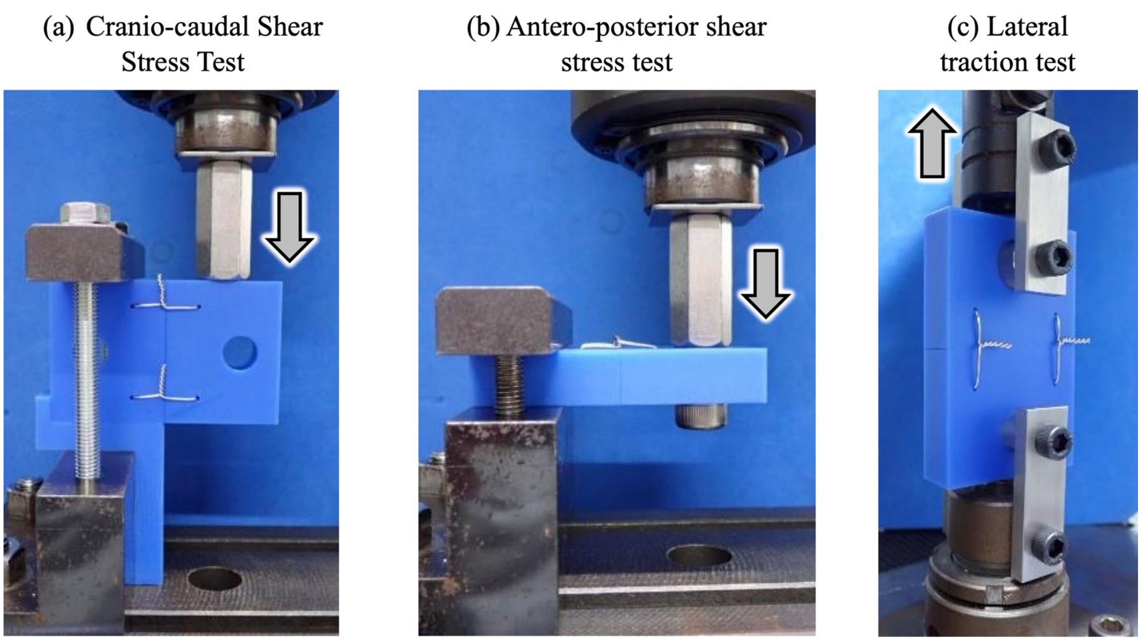

Fig. 3 Fixed sternum model and three tests showing each direction. Grey arrows show directions in each test. Velocity of each external force was applied in 10 mm/min. **a** Cranio-caudal shear stress test, **b** antero-posterior shear stress test, **c** lateral traction test

One side of the coupled mock sternum was fixed to the testing machine (Autograph AG-20kNXD, Shimadzu Co., Kyoto, Japan), and the other side of the sternum was pushed down or pulled by a rod attached to a load cell (Fig. 3). The machine can relocate the load cell at a defined constant speed without being affected by the force to move the load cell. Shear force or resistance power were measured along with the length of the displacement of the coupled sternum. Three samples tied with each cerclage materials for three directional displacements were prepared to perform statistical analysis.

All the experiments except sternal model fixation were performed in the Medical Research Laboratory of Teijin Medical Technologies Co., Ltd.

Statistical analysis

Continuous values were expressed as mean plus-minus standard deviation. Mann–Whitney test was used to compare unpaired non-parametric values. A p value less than 0.05 was identified as statistical difference.

Results

The resistance scatter-plotted against displacement showed higher resistance due to the small displacement in titanium cables than in stainless-steel wire (Fig. 4). In every

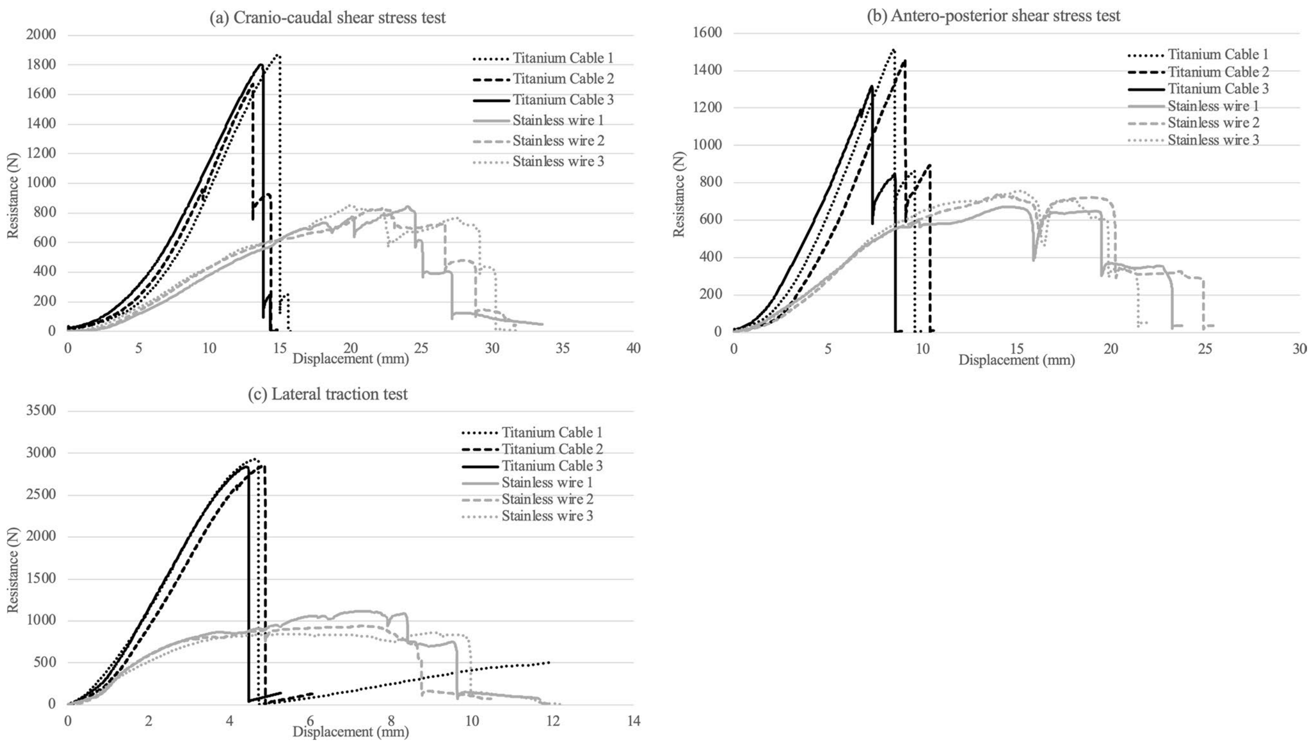

Fig. 4 Resistances plotted against each directional displacement. **a** Cranio-caudal shear stress. **b** Antero-posterior shear stress, **c** lateral traction

directional displacement, the titanium cable system showed significantly higher resistance than the stainless-steel wire. 1 mm lateral displacement and 2 mm antero-posterior displacement did not show statistical significance.

At the peak resistance, the displacement lengths are significantly shorter in the titanium cable system (Table 1). The stainless wires were gradually untied with external forces by the displacement rather than torn with external forces (Supplemental Video 1).

Discussion

Adamant sternal fixation is one of the most essential parts of heart surgeries requiring sternotomy to prevent postoperative wound complications including mediastinitis and pulmonary complications caused by wound pain from sternum instability [1]. The rigidity of the reapproximated sternum is decided by three factors: firmness of the sternum, the fixation method, and fixation material. The firmness of sternum depends on patient factors; age, physical status, and bone metabolisms, which surgeons would not address. However, the other two factors can be improved. Especially, the material can be easily changed if the alternative material is available and known to be superior. As far as the physical strength, the new titanium cable system is superior to the stainless wire cerclage.

This study was conducted to prove a hypothesis in which the newly developed titanium cable system would not be physically stronger as advertised in the setting of sternum cerclage than the stainless-steel wire. The results denied the hypothesis. The novel titanium cable system showed considerably higher resistance compared to conventional stainless-steel wire. The test was conducted in the setting of a simple comparison of single cerclage with each material. The other cerclage methods (e.g., a figure-of-eight) can be compared with same experiment model in future experiment.

The previous studies [4, 5] reported considerable cases after sternum wire cerclage showed sternal displacement or dehiscence since early postoperative phase according to the computed tomography scans. This phenomenon possibly can be explained by the characteristics of the stainless-steel wire found in the presenting study. The stainless wires were gradually untied with external forces by the displacement rather than torn off. This phenomenon corresponds with the clinical sternum displacement. Substantial external force to sternum occurs during postoperative convalescence and the force can make the wire loosen. McGregor et al. reported that a considerable amount of external force (200 to 350 N)

Table 1 Resistance at each displacement and maximum resistance with each fixing material

Stress direction	Cranio-caudal			Antero-posterior			Lateral		
Fixation device	Titanium cable	Stainless wire	*p* value	Titanium cable	Stainless wire	*p* value	Titanium cable	Stainless wire	*p* value
Resistance $\pm$ SD [*N*]									
1 mm displacement	35.1 $\pm$ 6.7	8.1 $\pm$ 4.0	0.007	49.9 $\pm$ 8.0	28.3 $\pm$ 7.1	0.026	344.8 $\pm$ 80.5	219.7 $\pm$ 15.6	0.110
2 mm displacement	64.1 $\pm$ 12.4	20.8 $\pm$ 8.7	0.010	111.2 $\pm$ 54.4	73.4 $\pm$ 16.5	0.353	1067.6 $\pm$ 119.7	566.4 $\pm$ 43.3	0.011
Maximum	1779.9 $\pm$ 102.2	842.2 $\pm$ 11.7	0.004	1456.5 $\pm$ 103.3	723.2 $\pm$ 45.3	0.002	2875.0 $\pm$ 48.9	973.2 $\pm$ 132.4	0.001
Displacement at maximum resistance [mm]	13.1 $\pm$ 0.9	22.1 $\pm$ 2.0	0.009	9.1 $\pm$ 0.9	14.5 $\pm$ 0.5	0.001	4.6 $\pm$ 0.2	7.9 $\pm$ 1.0	0.027

Displacement at maximum resistance are also shown

SD standard deviation

could be applied to sternum in physiological mechanical stress [5]. The titanium cable system will resist the external force more than the stainless wire cerclage. The cable anchored with the crimper will not be loosened unless the sternum splits. If the crimp can secure the stainless wire in place, the wire may also be strong enough to achieve rigid sternum fixation. However, because the crimp was designed to secure the titanium cable, the crimp should not be used to secure the wire. The wire would break at the crimped point if the crimp was used on the wire.

Although the titanium cable system showed significantly higher resistance than the stainless-steel wire. In 1 mm lateral displacement and 2 mm antero-posterior displacement did not show statistical significance. This might be result from fluctuations of the fixation procedures. The sharp edge of the mock sternum made materials difficult to slide smoothly. Especially, the cables which has a rough surface could be easily caught the sharp edge of the mock sternum. The dynamics of the cable in clinical use should be examined in future studies.

It may be confusing that the titanium cable showed the greatest resistance at shorter displacements on the graph (Fig. 4) and that the titanium cable broke faster than the wire on the video (Supplemental Video 1). However, the testing machine can displace the object at a constant speed, and the titanium cable is hardly elongated or loosened by the external force. Therefore, the titanium cable showed the greatest resistance at shorter and faster displacement and tore.

The rigid plate fixation is an alternative method of sternal fixation. Multiple randomized controlled trials showed the superiority of plate fixation over the conventional wire cerclage [6–8]. The clinical superiority of plate fixation is supposed to be a result from enhanced sternum healing with the rigid fixation. The issues of the rigid plate fixation are expenses during initial hospitalization and longer procedure time. Furthermore, many surgeons hesitate to use the system for concerning drilling into a sternum which is just in front of heart or great vessels. Although the titanium cable system also costs 40 thousand yen which is much expensive compared to conventional wire cerclage, procedural time and comfortability is supposed to be comparable to the conventional wire cerclage because of its similar closure technique. Moreover, the titanium cable system can provide more rigid sternal fixation than the stainless-steel wire. The property and the cost-effectiveness including long-term total medical cost suppression by reduced sternal complications must be well informed before its use.

The limitation of the presenting study is that the mock models are non-biological and not representing in vivo sternum behavior. However, a mock test is ideal and essential to eliminate biological variation. Further biological tests, including cadaver tests and clinical trials, would be necessary to confirm the results.

Conclusion

The titanium cable system has a feature of higher resistance to any directional external forth in sternal fixation when compared to the conventional stainless-steel wire fixation.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s11748-022-01856-w.

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Declarations

Conflict of interests Eiki Nagaoka received a research Grant from J-seed Co., Ltd.

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