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Biodegradable fixator for sternum closure after median sternotomy

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Annotation. This article discusses the solutions to manufacture fixator for the osteosynthesis of the sternum from biocompatible and biodegradable material to prevent reopening.

Introduction

Currently, more than one million cardiac surgeries are performed worldwide and their number is growing due to an increase in the incidence of cardiovascular diseases in the population. Most operations are performed using a sternum dissection or sternotomy.

Standard closure after median sternotomy repeats approximation of the sternum using steel wires and simple suture technique. However, this closure technique was associated with several serious complications that prompted surgeons to look for new closure methods. These complications include instability of the sternum, dissection, and mediastinitis, as a result of bone compaction or destruction caused by steel wire. These conditions represent the main causes of morbidity and mortality after heart surgery.

The search for a convenient and optimal method for fixing the sternum, the main feature of which is universality, reliability and affordability, was carried out with the beginning of the development of cardiovascular surgery. The most common method of osteosynthesis of the sternum in our days for more than 50 years has been the fixation of fragments of the sternum with steel wire with many variations of suturing. Despite the entire duration of use, traditional methods do not exclude the possibility of complications in the postoperative wound.

Various methods of closure of the sternum, known to our days:

1. Steel wire closure (standard technique). The most common way to close the sternum is to use alternating trans and peristernal techniques.
2. Staples. Clips, which consist of the same material as the wire, prevent cutting the wire into the bone because of their larger contact area thus reduce the risk of deep wound infections.
3. Nitinol brackets with shape memory effect. Centofanti introduced a new technique for closing the sternum clamps. The material in the clips is called NITINOL (NITINOL - Nickel Titanium Naval Ordinance Laboratory) and consists of nickel and titanium. The clamps are implanted in the sternum.



4. Zipfix. Closing technology is called Zipfix, consisting of an implant similar to cable ties. This implant is made from PEEK (polyetheretherketone), which is biocompatible.
5. Sternal Talon. Sternal Talon is a new technique used to close the sternum after a sternotomy.
6. Kryptonite glue - bone glue for improved biocompatible closure of the sternum.
7. Posthorax Support Vest. Posthorax Support Vest is a vest designed for use around the chest after a heart operation.

One of the relatively new and reliable ways to close the sternum is the use of polymeric clamps of the "collar" type, the usefulness of which has been appreciated by cardiac surgeons.

The main disadvantage of all existing methods of connecting the sternum is that the materials with which the osteosynthesis was performed remain in the human body even after successful fusion of the sternum and no need to further support the bones. The use of clamps for osteosynthesis of the "collar" type allows to reduce the level of postoperative pain in patients due to reliable stable fixation of the sternum, reduce the clicking of the sternum in patients and its crepitus, and thus improve their quality of life and reduce the period of rehabilitation after surgery. A multicenter study with a large sample and long observation periods will further confirm the effectiveness and safety of this technique.

Therefore, the improvement of closure methods and the development of methods for osteosynthesis of the sternum after median sternotomy are promising tasks of modern cardiothoracic surgery.

The aim of the work is to develop a technology for manufacturing individual medical sternal fixers of the sternum from a biodegradable material.

Main part

Based on all methods of closure of the sternum, taking into account the experience of cardiac surgeons "University Hospital (RCH 2)" and taking into account their preferences, the design of the fixer of the "clamp" type with the most reliable geometry was modeled.

As a prototype of the offered fixer Zipfix sternum closure technology was chosen, which has an implant similar to cable ties, fig. 1. This implant is made from PEEK (polyetheretherketone), which is biocompatible. The closure technique uses cable ties wrapped around the open sternum with a needle. The number of cable ties varies, but usually these are five cable ties that are located around the sternum. Then the needle is removed, the cable ties are tightened and all excess valves are cut off. The reduced risk of bone eruption is due to the fact that implants have a relatively large contact width of 4.2 mm. Cable ties are wider than those used in steel wire closures. The contact area between the sternum and cable ties is then larger than the contact area between the sternum and steel wire, which results in lower pressure on the sternum. Implants are wrapped around the sternum in the intercostal space, which makes the risk of bleeding less than the standard technique in which wire can cut through the sternum in the transverse direction. Zipfix provides a lower offset than standard technology, which implies that the number of repetitive operations can also be reduced if Zipfix is used. It was actually shown at the Karolinska University Hospital, Sweden, that repeated operations were reduced when using Zipfix instead of standard equipment. The change was studied over a six-month period, and the total number of repeated operations changed from ten repeated operations for steel wires to two repeated operations for Zipfix implants.



Figure 1 – ZipFix

After examining all the advantages and disadvantages of ZipFix, the following changes were included in the developed model:

1. The fastener-lock shown in Fig. 2. The reliability of fixing the fastener is due to its change, namely, the second clove is added to the lock to form a double point of contact with the teeth located on the main surface of the fixture, which will increase the adhesive strength of the lock and prevent the likelihood of the lock opening.



Figure 2 – Fastener-lock

2. Cogs are shown in figure 2. Cogs are enlarged over the entire surface of the fixer to fix it more firmly in the chest, similar teeth are made in the clasp-lock.
3. Needle in figure 3. To facilitate the technological production of the fixer model, it was decided to make a needle from the same material as the fixer web. The needle cross-section is made round for smooth expansion of the opening of soft tissues, which will ensure free passage of the retainer web. Needle diameter increased, starting from the tip (3 mm) to the base (5 mm).

The new design of the model clamp type "clamp" shown in Fig. 4, provides a rigid fixation for use in the primary closure of the sternum due to the new lock, which allows increasing fatigue strength. In addition, due to the large contact area of the implant with the bone, which leads to an optimized stress distribution, the effort to achieve bone dissection should be much higher. The fixer is easy to handle when the surgeon works, and it does not require additional equipment for its installation.



Figure 3 – Fixer needle

The main advantage over the ZipFix model is the creation of a fixative from biodegradable material. Polymers are used as biodegradable materials. The following table 1 shows the three types of material that are suitable for the manufacture of biodegradable fixatives.

The optimal material for the developed fixative was chosen polycaprolactone. This material is used for a long time in surgical practice. The following characteristics of polycaprolactone for biomedical application are known:

- does not cause allergic reactions;
- long resolved (completely resorption occurs within 12-24 months);

- loss of physical properties by 40-50% occurs in 2-3 months, which will allow the thorax to coalesce in time after the median sternotomy;
 - leaves behind a skeleton of newly formed young connective tissue.
- In fig. 5 drawing of the designed clamp with indicated dimensions is presented.

Table 1. Biodegradable materials

Properties	Material		
	PCL polycaprolactone [-(CH ₂) ₅ -CO-O-] _n	Poly lactide (C ₃ H ₄ O ₂) _n	Polyoxyalkanoates (ΠOA)
Type	thermoplastic	thermoplastic	thermoplastic
Biodegradability, dissolving	yes	yes	yes
Melting temperature, °C	63	190-195	177
Flexural strength (23 °C), MPa	29	55,3	38
Tensile strength (23 °C), MPa	18	57,8	40
Density, g / cm ³	1,021	1,25	1,26
Stretching at break (23 °C), %	11	3,8	43
Young's modulus, GPa	7,4	0,384-0,481	1,4-3,5
Glass transition temperature, °C	-60	-60	(-50) - 4



Figure 4 – Polycaprolactone fixator

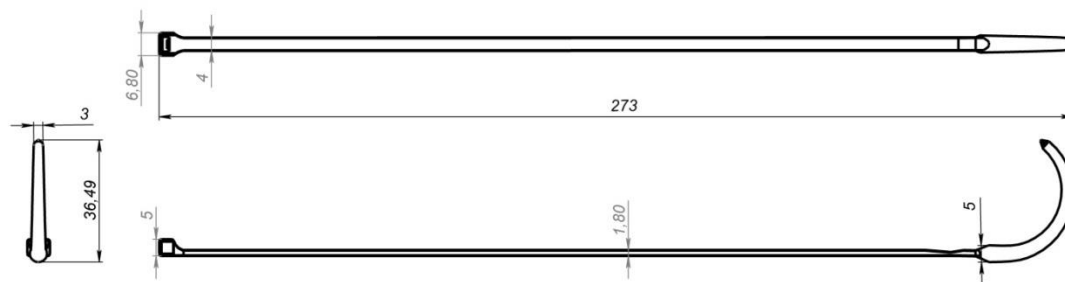


Figure 5 - Drawing developed fixator

Conclusion

The results of our study indicate that the fixers currently used require refinement and changes. The design of the fixer provides a rigid fixation for use in the primary closure of the sternum due to the new lock, which allows increasing fatigue strength. In addition, due to the large implant contact area with the bone, which leads to an optimized stress distribution, the effort to achieve bone dissection should be much higher. The fixer is easy to handle when the surgeon works, and it does not require additional equipment for its installation. The known biodegradable materials are analyzed and the most suitable polycaprolactone is selected.

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