Reviewer's report

Title: A new cable-tie based sternal closure system: Description of the device, technique of implantation and first clinical evaluation

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Reviewer: Carlos - A. A Mestres

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In this submission authors are describing a new system for sternal closure in patients undergoing cardiac surgery through median sternotomy. They present the Sternal ZipFixTM System that is based on the cable-tie principle. The material is a biocompatible ketone and the method includes pericostal implant. The authors included 50 patients in which they used two different techniques for closure. Out of them 44 were considered at high risk. One patient died from unrelated causes. No sternal instability was observed despite two presented with mediastinitis requiring reintervention and removal of material. Their initial evaluation suggests that this system may be safe and effective. Authors consider it as an alternative to standard wire closure.

A number of comments should be made.

Structure. The paper is well written, it is correctly presented. It can be easily read and the information incorporated.

The pages are not numbered.

Introduction. At the end of this section author state that “…This article presents a very reliable technique...”. This is simply a speculation as reliability must be proved. They use this word “reliable” in the introduction, before the study is done. Talking on reliability means that there is proof of this and the study was design to test the device in a short series of patients. This term must be eliminated. Reliability will rely on experience and this paper just present some initial data and the paper has a number of limitations.

Furthermore, the authors also state that “…The device is optimized in design and material that makes it applicable…”. To state that this device is “optimized” entails a comparison with something else. In this submission there is no comparison at all with any other device. Authors only describe their initial experience. Therefore, the optimization needs to be demonstrated and this paragraph needs rephrasing in any way.

Clinical experience and results. The mention to how data were collected is inappropriately placed here. Everything regarding the way of doing this must be described in the methods section including approvals, etc. Therefore, in methods authors need to confirm the design of the study, etc.
Which was the actual study design? It is not clear from what is described here. If this was a well defined protocol, the protocol, that seems to be approved by the ethics committee, must be described in full. The protocol is not described herein. The reader understands that this is not a randomized study. Therefore, the authors should at least provide in the methods section with a minimum list of inclusion criteria.

The reason to why to choose a given technique must be clearly depicted here. The problem in the 13/50 cases in which authors used additional wires is that this groups cannot be used for analysis due to the coincidence of different materials.

Apparently, 2 patients had “mechanical resuscitation”. This needs a very thorough description.

Discussion. Authors refer to “…due to a large implant to bone contact area…”. How does the reader know that there is “large” contact area. “Large area” must have a true and clear definition and entails also the comparison with something else as the reader does not know with a “small” contact area is. In the absence of accurate definitions, some issues are not to be accepted.

Another problem is that 2 patients had a mediastinitis that required a reintervention to remove the material. This means that the device does not protect against mediastinitis despite sternal stability. On the other hand it is not easy to understand that the patients had mediastinitis with a stable sternum. Which was the definition of mediastinitis? Which criteria were used for this diagnosis? Which were the pathogens isolated in these cases?

At the end of this section authors refer to “high-risk patients”. However these “high-risk” patients have not been accurately described in the methods section.

Authors must elaborate a full list of limitations of the present study, which are many, under a separate subheading.

The conclusions might not be acceptable in terms of safety and effectiveness as two patients had mediastinitis in any way. This means 4/50 patients or 8%, far above the regular figures confirmed by the authors in the introduction section.

Tables. In Table 1, authors refer to “Osteoporosis” but this is a vague term that may need a definition in the methods section.

Authors also refer to operative time but it is more appropriate that they show cross-clamp and cardiopulmonary bypass times, too.

**Level of interest:** Reject as not of sufficient priority to merit publishing in this journal

**Quality of written English:** Acceptable

**Statistical review:** Yes, but I do not feel adequately qualified to assess the
statistics.

Declaration of competing interests:
No conflict of interest declared