BIOMECHANICAL STUDY ON ADDITIVELY MANUFACTURED NITINOL PATIENT-MATCHED DEVICE FOR UNICORONAL CRANIOSYNOSTOSIS

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Introduction

Unicoronal Craniosynostosis (UC) is the second most-common form of non-syndromic craniosynostosis and occurs when one of the coronal sutures ossifies prematurely in the newborn [1]. Reconstructive surgery is required to expand and remodel the skull. Spring Assisted Cranioplasty (SAC – consisting in using spring distractors to guide cranial remodelling) is a promising minimally invasive surgical treatment mainly adopted for the treatment of craniosynostosis of the sagittal suture [2]. It consists in positioning a spring-shaped steel distractor to guide cranial remodeling. A first objective of this project is to substitute steel with NITINOL, a NiTi alloy, to exploit its superelastic behaviour [3]. Superelasticity consists in a material's ability to recover large deformations upon unloading: this is supposed to allow for constant force distraction and therefore improved cranial adaptation. The second aim of the work consists in designing a patient-matched spring-shaped distractor. Both the design complexity and device customization are addressed and overcome by means of Additive Manufacturing (AM) technology.

Method

A previous study established a UC population average skull shape by statistical shape modelling (fig.1a). Surgical cuts were simulated on a CAD model (fig.1b).

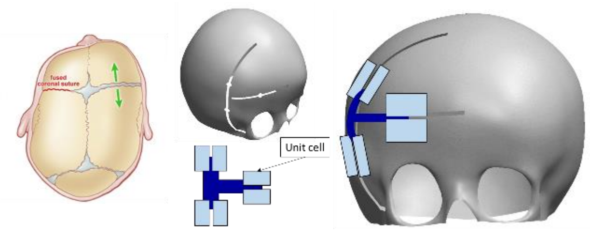

Figure 1: Representative UC skull (a). Optimized positioning of osteotomies and representation of the device (b). Device customized on UC skull shape (c).

A novel device was designed, consisting in 3 pairs of unit spring cells (i.e. spring-shaped distractors) (fig.1b). The expansion of 3 spring unit cells, whose behaviour was based on existing distractors adopted in SAC, was simulated using FEA software (Ansys, 2020): surgical cut length and position, spring unit stiffness and spring notch location were optimized to minimize the model Cranial Vault Asymmetry Index (CVAI-a measurement of head asymmetry) by means of Design of Experiments (DoE). Spring expansion forces, spring opening distance and cranial remodeling were quantified. With this information, a number of optimized spring-shaped unit cell designs were created using SolidWorks, 2021 and the mechanical response was modelled in Ansys.

NiTi dogbone specimens were realized by laser powder bed fusion (LPBF) with optimized process parameters and mechanically tested to assess the material's mechanical behaviour. Afterwards, a preliminary spring unit prototype was produced by means of LPBF process. Finally, the spring-shaped unit cells was mechanically tested in compression. The results were compared with the FEA model analysis for validation.

Results

DoE allowed to estimate and optimize surgical parameters and localized distraction forces (ranging from 24N to 32N), required to correct the UC model shape and minimize CVAI. NiTi tensile specimens confirmed the AMed material superelastic behaviour. Experimental NiTi parameters were implemented in the spring unit model to simulate its behaviour in compression. Experimental tests on the AMed spring validated the computational model (fig.2).

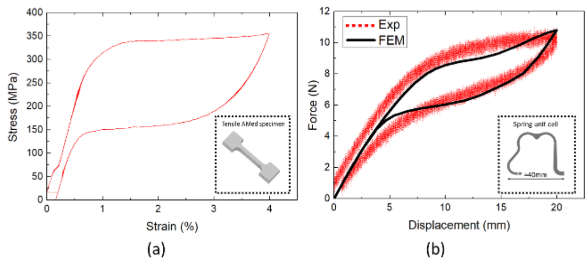

Figure 2: experimental σ-ϵ curve for NiTi AMed specimens (a). Comparison between F-d curves of AMed device and simulated one (b).

Discussion

In this work a design process for the development of a novel NiTi AMed spring-shape distractor for UC correction was proposed and validated. Next steps aim to finalize the spring unit design according to the required distraction forces. Upon design realization, the full AMed device will be prototyped tested in-vitro using a 3D printed skull replica.

References

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2. Borghi et al., J. of Neurosurgery Pediatrics, 20:400–409, 2017.
3. Biffi el al., Shape memory and superelasticity, 6:342–353, 2020.