11º CONGRESSO NACIONAL DE BIOMECÂNICA
A. P. G. Castro, C. Pina, P. R. Fernandes, C. Santos, J. Folgado & A. Amaro (Eds)
Sesimbra, Portugal, 21-22 de Fevereiro, 2025

DEVELOPMENT OF A 3D-PRINTED EAR SPLINT FOR MICROTIA SURGICAL TREATMENT

Nuno Gomes [1], Carolina de Deus Guerreiro[1], Sérgio B. Gonçalves[1], Diogo A. Guimarães[2], Ana Soudo[3], Alexandra Morais e Castro[3]e Miguel Tavares da Silva[1]

[1] IDMEC, Instituto Superior Técnico, Universidade de Lisboa, Portugal

[2] ULS de São José, Departamento de Cirurgia Plástica Reconstrutiva e Estética, Portugal

[3] Hospital de D.ª Estefânia, ULS de S.José, Especialidade de Medicina Física e de Reabilitação, Portugal

{nuno.s.gomes, carolina.deus.guerreiro, sergio.goncalves,miguelsilva}@tecnico.ulisboa.pt;

diogoandradeguimaraes@gmail.com; {ana.soudo, alexandra.castro}@ulssjose.min-saude.pt

KEYWORDS: Ear Splint, Additive Manufacturing, 3D printing, Microtia, Otoplasty

1 INTRODUCTION

Ear reconstruction in microtia is a surgical challenge. The patient is born with remnant of cartilage instead of an ear. The most accepted surgical technique is to create an ear with rib cartilage in two stages. In the first, the cartilage framework is inserted under the skin. In the second, the ear must be elevated form the scalp. While the surgery itself can result in significant aesthetic improvements, the postoperative period is critical for ensuring the desired outcomes.

A common challenge during recovery is maintaining the newly shaped ear cartilage in its corrected position as it heals [1]. Ear splints are medical devices that are typically placed behind the operated ear to support and stabilize the cartilage following the second stage repair of microtia. These devices help to maintain the ears in the desired position during the post-operative period. By holding the ears in place, the splints preserve the surgical results while reducing the risk of complications such as adhering to scalp skin or asymmetry. Additionally, ear splints protect the surgical site from external forces, such as accidental pressure during sleep or sudden movements, which could interfere with healing [2]. Traditional methods for producing tailored ear splints involve using molded casts and thermoplastic materials or handcrafted solutions with plastic or foam frames [2]. Recently, with the advent of additive manufacturing (AM), several studies have begun to explore the potential of this technology to produce custom ear splints. However, the implementation of AM for this purpose is still in its early stages, and few studies have investigated the use of 3D printing with soft materials to develop these solutions [3]. Hence, this collaborative project aims to develop a methodology for designing and producing customized ear splints using AM techniques with soft materials.

2 METHODOLOGY

To develop the methodology, a structured design process tailored for the development of medical devices was implemented. Consequently, the design of the methodology was divided into four main stages: 1) Clarification – identification of needs, definition of product specifications, and concept generation; 2) Conceptual design – development of a methodology for acquiring the ear geometry, processing the 3D meshes, designing the custom ear splint, and producing the concept using 3D printing with soft materials; 3) Embodiment – optimization of the protocol and validation using a control population; 4) Detailed design – Refinement of the concept through an

iterative approach, followed by a validation of the methodology on a pathological case. To enhance the fit and comfort of the solution for the user, the methodology was designed to incorporate specialized methodologies, equipment, and software for the acquisition and manipulation of 3D geometric meshes. This includes 3D scanning, mesh processing, CAD software, and 3D printing.

From the needs analysis, it was determined that the solution should be compact, comfortable, discreet, and biocompatible. It should allow for easy placement and removal without risking injury to the user and be robust enough to withstand external forces, such as supporting the head's weight during sleep or accidental impacts. The first step of the methodology involves acquiring the geometry of the user's head and ear prior to surgery using a 3D scanner (EinScan Pro HD). The 3D meshes are then processed to correct any inconsistencies using open-source software for editing triangular meshes (e.g., MeshLab). Afterward, the processed mesh is imported into 3D CAD software (e.g., SolidWorks) to design the ear splint, considering the user's anatomy and the surgeon's specifications. Finally, the solution is produced using AM techniques with soft materials. In this case, a flexible elastomer, specifically TPU95A with a nude color, was chosen due to its balance of elasticity and rigidity.

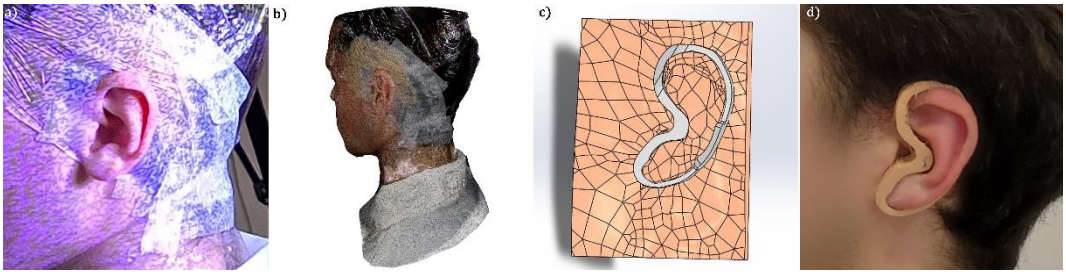

Figure 1 – Project methodology: a) 3D scanning; b) Mesh processing; c) CAD modelling; d) Validation

3 RESULTS AND DISCUSSION

Preliminary results conducted with a control group suggest that the methodology can produce customized solutions with a good fit (see Fig. 1), supporting its potential for clinical applications. The solution can be worn easily without folding the ear and is compact enough to occupy only the space between the head and ear without being noticeable bulky. It is important to note that the use of TPU not only enhances comfort but also eliminates the need for structures that must be inserted into the ear canal to support the splint. This material choice allows for easy placement and removal without additional components, enables a more compact design, and provides the option to match the splint color to the user's skin tone. The next steps of the project involve testing the methodology in a real case and comparing with one made using traditional methods.

ACKNOWLEDGEMENTS

The authors acknowledge Fundação para a Ciência e a Tecnologia (FCT) for its financial support via the projects LAETA Base Funding (DOI: 10.54499/UIDB/50022/2020) and LAETA Programmatic Funding (DOI: 10.54499/UIDP/50022/2020).

REFERENCES

[1] J. E. Janis, R. J. Rohrich, and K. A. Gutowski, "Otoplasty," Plast Reconstr Surg, vol. 115, no. 4, p. 1142, 2005, doi: 10.1097/01.PRS.0000156218.93855.C9.

[2] H. Vercruysse, J. I. J. Green, G. Osman, B. Harrison, K. Miyagi, and N. W. Bulstrode, "Splinting after Ear Reconstruction: A Stepwise and Inexpensive Workflow Protocol," Ann Plast Surg, vol. 80, no. 4, pp. 356–358, Apr. 2018, doi: 10.1097/SAP.0000000000001212.

[3] A. Argyropoulos and P. N. Botsaris, "Modern Applications of 3D Printing: The Case of an Artificial Ear Splint Model," Methods and Protocols 2021, Vol. 4, Page 54, vol. 4, no. 3, p. 54, Aug. 2021, doi: 10.3390/MPS4030054.