



## Reverse engineering and 3D additive manufacturing from research to the clinical assistance.

Fabrizio Clemente,<sup>a,\*</sup> Mario Formisano,<sup>b</sup> Luigi Iuppariello.<sup>c</sup>

### 1 Introduction

This contribution aims to present the design and implementation of an innovative image treatment and 3D printing lab for the production of customized medical devices within a hospital facility.

### 2 Methods and Materials

In 2016 a charity from Bank of Italy to Fondazione Santobono Pausilipon (active in assistance, research, training and improvement of the quality of life of pediatric patients) was spent in a project to create in reverse engineering and 3D printing personalised plastic casts to be experimented at Orthopaedics and Traumatology Dep. of the Santobono Pediatric Hospital. To develop this study the know-how and multidisciplinary competences from different CNR Institutes (IC now ICCSB, IBB, IPCB) has been involved to produce the proof of concept and the consequent clinical application. Following the design phase<sup>1</sup> in 2017 the Ethics Committee authorized a clinical trial of the developed device on 40 patients<sup>2</sup>. In the meanwhile the project was awarded by Italian Convention of Public Health (ForimPA Sanità). The success of clinical trial<sup>3</sup> brought researcher and hospital management to awareness that the scientific outcomes are ready to be transferred to the real clinical use.

This led to the establishment of an innovative company (Santobono Innovatin srl) operating within the Santobono-Pausilipon Foundation in which CNR was consultant to optimize manufacturing workflow. The company structured two models of 3D printed devices and submitted itself to the certification process for the production of medical devices. In June 2019 the ISO 13485 certification and the exposure on market of public companies (MEPA).

### 3 Conclusion

The collaboration between researcher from CNR and clinical practitioners inside a health facility produces real innovations and represent a great opportunity to promote new collaborations and research projects among stakeholders. Indeed the introduction of image processing, reverse engineering and 3D printing techniques is rapidly spreading to exploit the advantages given by the design flexibility and low-cost production of prostheses, medical devices and anatomical models.

### References

- 1 F. Clemente, F. Colella, M. D'albore, A. Gloria, P. Guida, A. Casaburi, Esoscheletri prototipali personalizzati in materiale plastico per immobilizzazioni prolungate. applicazioni cliniche in pediatria., 1° Congresso Nazionale IDBN, Bologna (2017), abstract n. IDBN 8001-08.
- 2 Ethics Committee AA.OO.R.N "A.Cardarelli/Santobono Pausilipon, clinical trial: FSP1/2016 and Italian Ministry of Health, clinical trial: 0002535-13/01/2017-DGDMF-MDS-P.
- 3 P. Guida, A. Casaburi, T. Busiello, D. Lamberti, A. Sorrentino, L. Iuppariello, M. D'Albore, F. Colella, F. Clemente, An alternative to plaster cast treatment in a pediatric trauma center using the cad/cam technology to manufacture

<sup>a</sup> CNR - Istituto di Cristallografia, Strada Provinciale 35d n.9, Montelibretti (RM), Italy

<sup>b</sup> Santobono Innovation srl

<sup>c</sup> AORN Santobono - Pausilipon

Creative Commons Attribution - Non commerciale - Condividi allo stesso modo 4.0 Internazionale

† oral communication at 1 st Conference on Crystallography, Structural Chemistry and Biosystems, (Catania) 04-06/10/2021

customized three-dimensional-printed orthoses in a totally hospital context: a feasibility study, *Journal of Pediatric Orthopaedics B* 28 (3) (2019) 248–255. [doi:10.1097/BPB.0000000000000589](https://doi.org/10.1097/BPB.0000000000000589).