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# Practical Validation of Personalized Biomedical Devices Using Low-Cost 3D Printing

## Validación práctica de dispositivos biomédicos personalizados mediante impresión 3D de bajo costo.

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**PALABRAS CLAVE**
Realidad aumentada; impresión 3D; dispositivos biomédicos personalizados; diseño y validación industrial; innovación tecnológica.

**RESUMEN**
Este estudio aborda la aplicación de la realidad aumentada (RA) como herramienta complementaria en el diseño y la validación de dispositivos biomédicos personalizados mediante impresión 3D, destacando su papel en los procesos de innovación tecnológica en biomedicina. La investigación analiza la interacción entre lo digital y lo físico para comprender cómo la superposición de modelos tridimensionales sobre el entorno clínico contribuye a una validación anatómica más precisa y a una mejor toma de decisiones durante el desarrollo de dispositivos. La integración de la RA en este contexto permite observar, ajustar y validar los modelos antes de su fabricación, optimizando el flujo de trabajo y fomentando la colaboración interdisciplinaria entre profesionales del diseño, la ingeniería y la medicina. Además, se examinan los factores técnicos, humanos y organizativos que condicionan su implementación, como la interoperabilidad del hardware y el software, la curva de aprendizaje y los costes de adopción. Finalmente, reflexiona sobre el potencial de esta herramienta para transformar los procesos tradicionales de diseño biomédico, promoviendo un enfoque más eficiente, participativo y centrado en el paciente, que consolida la realidad aumentada y la impresión 3D como pilares en la transición hacia tratamientos personalizados e interactivos.

**KEY WORDS**
Augmented reality; 3D printing; Personalized biomedical devices; Industrial Design and Validation; Technological innovation

**ABSTRACT**
It addresses the application of augmented reality (AR) as a complementary tool in the design and validation of personalized biomedical devices using 3D printing, highlighting its role within the processes of technological innovation in biomedicine. The research analyzes the interaction between the digital and the physical to understand how the overlay of three-dimensional models on top of the clinical environment contributes to more accurate anatomical validation and better decision-making during device development. The integration of AR in this context makes it possible to observe, adjust and validate models before they are manufactured, optimizing the workflow and fostering interdisciplinary collaboration between design, engineering and medical professionals. In addition, the technical, human and organizational factors that condition its implementation are examined, such as hardware and software interoperability, the learning curve and adoption costs. Finally, it reflects on the potential of this tool to transform traditional biomedical design processes, promoting a more efficient, participatory and patient- centered approach, which consolidates augmented reality and 3D printing as pillars in the transition to personalized and interactive treatments.

## 1. INTRODUCTION

The development of immersive and digital fabrication technologies has significantly transformed contemporary biomedical practice, driving new methods of diagnosis, simulation, and computer-aided design [1]. Among these innovations, augmented reality (AR) has emerged as a key tool for integrating digital environments with physical spaces, facilitating anatomical understanding and direct interaction with three-dimensional models during clinical and design processes [2].

In a complementary way, 3D printing has enabled the production of personalized biomodels and patient-specific medical devices, contributing to the development of precision medicine and user-centric approaches [3],[4]. The convergence of both technologies poses an interdisciplinary scenario where engineering, industrial design and medical sciences converge to improve the effectiveness of validation, ergonomics and clinical communication processes [5],[6].

This article addresses the use of an augmented reality tool applied

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to the design and validation of personalized biomedical devices using 3D printing, based on a documentary review of recent research. The objective is to analyze its application, principles and relevance in current biomedical processes, highlighting the technological and human factors that condition its adoption. This review seeks to
offer a comprehensive vision of the opportunities and challenges that accompany the incorporation of these technologies in contemporary clinical practice, contributing to strengthening the link between technological innovation and health [7],[9],[12].

## 2. STATE OF THE ART AND CONTEXT

### 2.1. AUGMENTED REALITY IN THE HEALTHCARE SECTOR

In the context of biomedical design, augmented reality (AR) has been positioned as an essential tool to optimize the creation and validation of personalized devices; by allowing the superimposition of three-dimensional information on the clinical environment or on physical models generated by 3D printing. This interaction between the digital and the tangible makes it possible to simulate, adjust and accurately evaluate the geometry and behavior of implants, prostheses or surgical guides before their final manufacture. The principle of integrating AR into the biomedical design process seeks to reduce positioning errors, reduce times, improve interdisciplinary communication, and facilitate early validation of patient-centered customized solutions [1].

### 2.2. APPLICATION CASES

Several studies have demonstrated the submillimeter precision achieved with this technology; in cranio-orbit facial reconstruction procedures assisted by Microsoft HoloLens 2, errors of less than 1mm were reported, and 1° which confirms the usefulness of AR to guide placement and alignment during surgical [2] planning. Similarly, validation experiments such as 3D printed phantoms showed navigation 1.71 times faster than that obtained with conventional methods, maintaining a margin of error within the clinically acceptable range. [3] Other work focused on neuronavigation based on printed 3D markers recorded average errors of 1.56 mm, demonstrating the compatibility between AR and 3D printing for intraoperative guidance [4].

In spinal interventions, the use of AR with 3D intraoperative imaging improved the accuracy of pedicle screw placement compared to traditional neuro- navigated techniques [5] . Beyond the surgical setting, AR has proven its effectiveness in medical education and clinical communication, enabling immersive anatomical visualization and spatial analysis of complex structures using mixed environments and physical biomodels [6].

### 2.3. IMPLEMENTATION REQUIREMENTS

The effective implementation of an augmented reality (AR) tool for the design and validation of personalized biomedical devices requires the balanced integration of technological, human and organizational components, which can be classified into four areas: hardware, software, training, human factors.

**Hardware:** The most successful configurations combine high-resolution optical viewers such as Microsoft HoloLens or HoloLens 2, along with devices capable of running real-time three-dimensional visualization. [2] Some workflows included printed 3D markers that acted as anatomical landmarks and allowed for accurate spatial recording of the digital model about the patient[4]. Other advanced settings. These devices must ensure minimal latency and submillimeter resolution to maintain the correct alignment between the virtual model and the physical environment, and compatibility between the viewer and the 3D modeling and printing stations is critical to avoid scaling or anatomical matching errors. [7], [8].

**Software:** The programs used must include segmentation, anatomical registration, surface modeling and direct export to 3D printing functions, in addition to allowing integration with rendering engines compatible with mixed reality, in addition, computer security and the management of sensitive data are necessary conditions to ensure compliance with ethical standards and clinical confidentiality. [1], [9] Some references mention the use of custom mobile applications that operate on Android or iOS systems to plan surgical trajectories and display anatomical overlays in real time [10].

**Training:** Various studies agree that the adoption of AR systems and 3D printing require structured training for medical personnel, designers and engineers, focused on the spatial interpretation of 3D models, manipulation of interfaces and calibration of equipment [1]. The learning curve may represent an initial barrier, but practical experience significantly improves the user's accuracy and confidence after the sessions; training programs interdisciplinary learning between students from different areas demonstrate that joint learning increases acceptance and innovation in the hospital environment [11].

**Human Factor:** Perception studies highlight that users positively value visual clarity, the ability to interact and the fluid integration with existing clinical protocols [1]. However, challenges are identified such as institutional resistance to new technologies, the need for broader clinical validation, and implementation costs, factors that still limit their massification in health centers [12].

## 3. METHODOLOGY

### 3.1. WORKFLOW USED

**Anatomical capture:** The process begins with obtaining the patient's medical data by means of computed tomography (CT) or magnetic resonance imaging (MRI), which will be converted into DICOM files for subsequent segmentation. This stage allows the extraction of the morphological information necessary for the precise anatomical reconstruction, an essential condition in the design [6].

**3D processing and modeling:** Medical images are processed with specialized software capable of segmenting anatomical structures and generating three-dimensional models in STL or OBJ format. During this phase, the cut points, contact edges and dimensional tolerances are defined, optimizing the geometry to ensure compatibility with 3D printing processes [10] .

**Visualization and adjustment with augmented reality:** Once the digital models were obtained, they were integrated into the projection in the physical environment, devices such as Microsoft HoloLens 2 and tablets with 3D overlay software were used, which allow real-time evaluation of the fit of the model on the anatomical biomodel or on the corresponding body region [2].

**3D printing of the biomedical component:** Once the model has been digitally validated, the device or biomodel is 3D printed, compatible materials such as photopolymeric resins and medical or commercial PLA polymers are used, this is selected according to the application (surgical guides, prostheses, supports or reference markers) This stage allows the generation of physical models with proven dimensional accuracy ready for validation tests [3].

**Experimental validation and precision measurement:** The manufactured device is compared with the digital reference data to verify dimensional deviations and positioning accuracy. The results obtained previously report mean errors of 1.5 to 1.8 mm, remaining within the clinically acceptable range, in addition the implementation of AR allowed to reduce surgical time by 25-30%, equivalent to 45- 90 min less per intervention [10].

### 3.2. UNIVERSITY EXPERIMENTAL CASE

As a practical validation of the workflow described, an experimental exercise was carried out within the Technical University of Ambato, in the Faculty of Design and Architecture, in which the stages of digital modeling, lamination, 3D printing and anatomical verification of a personalized biomedical device in the cervical region were applied.

This example allowed us to verify the technical feasibility of the proposed methodology, from digital planning to the physical validation of the prototype, evidencing the precision of fit and the ergonomics of the design generated.

During the process, PLA filament was used as the base material, configuring optimized printing parameters for organic geometries and low-density perforated structures, which facilitate ventilation and user comfort, the result was a functional printed model that was evaluated directly on the body surface, verifying the morphological adaptation of the design.

The following figures document the most relevant phases of this procedure.

Figure 1 shows the initial configuration of the three-dimensional model in the laminating software, where the 3D printing parameters were defined, such as layer height, fill percentage, model orientation, and structural support layout. This stage allowed for optimization of manufacturing and prevention of deformation during the printing process.

**Fig .1.**

Configuration of the three-dimensional model in laminating software, showing the arrangement of supports and 3D printing parameters.

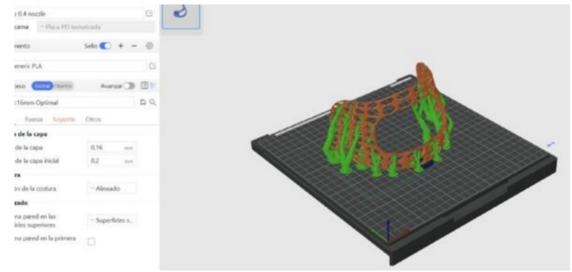


Figure 2 shows the complete simulation of the customized biomedical model with structural support, ready for physical printing. In this phase, the estimated manufacturing times, material consumption, and total volume of the model were validated. The prototype was planned to be manufactured in PLA thermoplastic material, selected for its rigidity, dimensional stability, and ease of printing, ideal for physical validation of the design.

**Fig .2.**

Simulation of the customized biomedical model with structural support, ready for physical printing on PLA material.

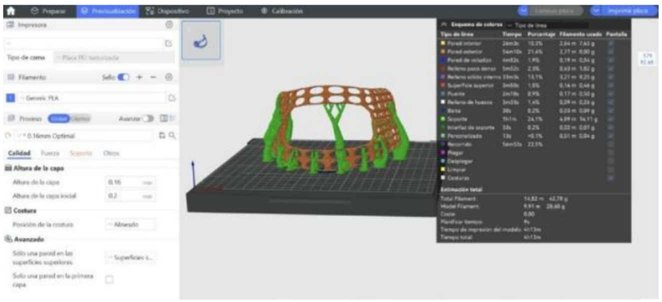


Figure 3 shows the physical model freshly printed in PLA, prior to the removal of the structural supports. This result allowed us to verify geometric fidelity with respect to the digital design and the correct execution of the printing process.

**Fig .3.**

Physical model newly printed in PLA, prior to the removal of structural supports.

Subsequently, Figure 4 shows an overview of the biomedical device once the supports have been removed, highlighting its ergonomic geometry and structural flexibility. These characteristics are essential to ensure comfort and correct morphological adaptation in the user's cervical area.

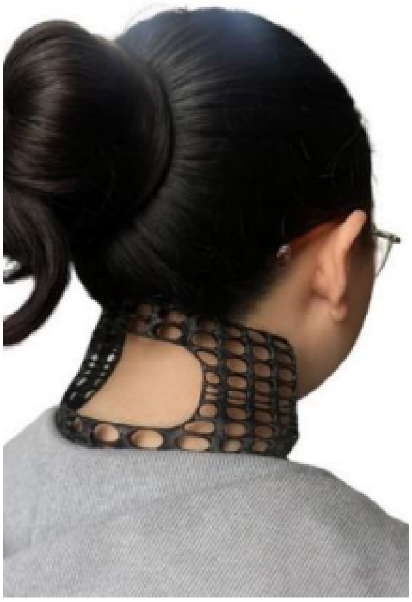
**Fig .4.**

General view of the finished biomedical device, showing its ergonomic geometry.

Finally, Figure 5 shows the application of the model on the user, highlighting the accuracy of fitness, comfort, and ergonomics of the design. This result confirms the feasibility of the proposed methodological flow, from digital modeling to physical validation, demonstrating the potential of 3D printing and augmented reality in the development of customized biomedical devices.

**Fig .5.**

Application of the model on the user, evidencing the flexibility, ergonomics and precision of attachment in the cervical area.



## 4. RESULTS AND DISCUSSION

### 4.1. BENEFITS AND IMPACT

The integration of augmented reality (AR) and 3D printing in the design and validation of personalized biomedical devices has demonstrated direct benefits in the accuracy, visualization, and efficiency of clinical procedures. In terms of visualization, AR allowed anatomical structures to be observed with greater clarity and precision, achieving alignment errors of less than 1mm in cranioorbitofacial reconstructions [2] and 1.56 mm in neuro-guided navigation using 3D printed markers [4].

In decision-making, personalized models accelerated surgical planning; in orthopedic oncology, a reduction in operative time of 25 to 30% was recorded, maintaining an average accuracy of 1.7 mm[10].

Remote collaboration was strengthened through the use of mixed environments with motion sensors (IMUs), which enabled simultaneous interaction between physicians, designers, and engineers during the planning and adjustment of surgical guides [7].

In terms of efficiency, trials with 3D printed phantoms showed that the increased navigation was 1.71 times faster than conventional methods, reducing costs and the need for additional prototypes [3].

### 4.2. CHALLENGES AND LIMITATIONS

Several studies point to the difficulty of linking AR systems with medical imaging equipment and 3D modeling stations, which can lead to scale mismatches or loss of spatial accuracy during data transfer. [8]. In addition, interoperability between platforms remains limited, forcing the use of hybrid configurations that require manual calibrations and constant validations [4].

In terms of cost, the acquisition of both specialized machinery, software, and biocompatible materials represents a considerable investment for hospitals, laboratories and for the user himself [9].

## CONCLUSIONS

The integration of the Augmented Reality (AR) with the 3D printing represents a significant advance in the field of Design and validation of personalized biomedical devices, by allowing the digital environment to be linked to the physical environment through interactive anatomical models [1], [4], [5]. Its application makes it possible to visually and dimensionally verify devices before they are manufactured, improving the accuracy, interdisciplinary communication and efficiency of clinical and design processes [2], [3]. This technological convergence between industrial design and biomedical engineering constitutes methodological support for contemporary medical practice, by offering tools that integrate precision, ergonomics and adaptability in patient care [6], [10].

Beyond the technical benefits, the implementation of AR in biomedicine shows the need to strengthen the processes of training and technological adoption, considering human, economic, and organizational factors that condition its application [9], [11]. Overcoming limitations such as interoperability between systems, equipment costs and the learning curve will consolidate this tool as an essential part of the clinical flow and the development of medical products. Together, AR and 3D printing are emerging as strategic pillars of biomedical innovation, guiding the transition towards a more precise, participatory and patient-centred medicine [7], [9], [12].

## REFERENCES


[1] A. Taghian, M. Abo-Zahhad, M. S. Sayed, and A. H. Abd El-Malek, "Virtual and augmented reality in biomedical engineering", Biomed Eng Online, vol. 22, no. 1, pp. 1–25, Dec. 2023, doi: 10.1186/S12938-023-01138-3/FIGURES/12.

[2] A. Pose-Díez-de-la-Lastra et al., "Microsoft HoloLens 2 vs. tablet-based augmented reality and 3D printing for fronto-orbital reconstruction of craniosynostosis: a case study", 3D Print Med, vol. 11, no 1, Dec. 2025, doi: 10.1186/s41205-025-00251-4.

[3] H. H. Glas, J. Kraeima, P. M. A. van Ooijen, F. K. L. Spijkervet, L. Yu, and M. J. H. Witjes, "Augmented Reality Visualization for Image-Guided Surgery: A Validation Study Using a Three-Dimensional Printed Phantom", Journal of Oral and Maxillofacial Surgery, vol. 79, no 9, pp. 1943.e1-1943.e10, sep. 2021, doi: 10.1016/J.JOMS.2021.04.001.

[4] G. Yavas, K. E. Caliskan, and M. S. Cagli, "Three-dimensional–printed marker– based augmented reality neuronavigation: a new neuronavigation technique", Neurosurg Focus, vol. 51, no 2, p. E20, Aug. 2021, doi: 10.3171/2021.5.FOCUS21206.

[5] F. Müller, S. Roner, F. Liebmann, J. M. Spirig, P. Fürnstahl, and M. Farshad, "Augmented reality navigation for spinal pedicle screw instrumentation using intraoperative 3D imaging", Spine Journal, vol. 20, no 4, pp. 621–628, Apr. 2020, doi: 10.1016/j.spinee.2019.10.012.

[6] H. W. Goo, S. J. Park, and S. J. Yoo, "Advanced Medical Use of Three-Dimensional Imaging in Congenital Heart Disease: Augmented Reality, Mixed Reality, Virtual Reality, and Three-Dimensional Printing," Korean J Radiol, vol. 21, no. 2, pp. 133–145, Feb. 2020, doi: 10.3348/KJR.2019.0625.

[7] E. Kabuye, · Philip Leduc, and J. Cagan, "A mixed reality system combining augmented reality, 3D bio-printed physical environments and inertial measurement unit sensors for task planning," vol. 27, pp. 1845–1858, 2023, doi: 10.1007/s10055-023-00777-0.

[8] R. Moreta-Martinez, D. García-Mato, M. García-Sevilla, R. Pérez-Mañanes, J. Calvo- Haro, and J. Pascau, "Augmented reality in computer-assisted interventions based on patient-specific 3D printed reference", Healthc Technol Lett, vol. 5, no. 5, pp. 162–166, Oct. 2018, doi: 10.1049/HTL.2018.5072.

[9] Cardenas Navarro Yesly Dayana and Lozano Melgarejo Loreta Marcela, "Innovation In Biomedical Use Equipment For Treatments In Surgical Specialties Systematic Review", 2024.

[10] R. Moreta-Martinez, A. Pose-Díez-De-La-Lastra, J. A. Calvo-Haro, L. Mediavilla- Santos, R. Pérez-Mañanes, and J. Pascau, "Combining Augmented Reality and 3D Printing to Improve Surgical Workflows in Orthopedic Oncology: Smartphone Application and Clinical Evaluation", 2021, doi: 10.3390/s21041370.

[11] Y. H. Yun, D. H. Shin, and H. J. Choi, "Perspectives of Medical Students and Developers Regarding Virtual Reality, Augmented Reality, Mixed Reality, and 3D Printing Technologies: Survey Study," JMIR XR Spatial Comput 2024; 1:e54230 https://xr.jmir.org/2024/1/e54230, vol. 1, no 1, p. e54230, May 2024, doi: 10.2196/54230.

[12] Karageorgos F, Karolos I, Pettas T, Tsioukas V, Pikridas C, and Tsoulfas G, "The Role of 3D Printing and Augmented Reality in the Management of Hepatic Malignancies," Technology in Cancer Research and Treatment. Accessed: October 20, 2025. [Online]. Available in: https://journals.sagepub.com/doi/epdf/10.1177/15330338251323138?src=getftr& utm_source=mendeley&getft_integrator=mendeley