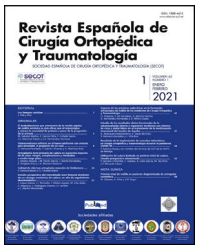
Revista Española de Cirugía Ortopédica y Traumatología 67 (2023) T81–T82

Revista Española de Cirugía Ortopédica y Traumatología

www.elsevier.es/rot



EDITORIAL

[Translated article] PERSONALISED MEDICINE: HOSPITAL-BASED ACADEMIC MANUFACTURING OF CUSTOMISED MEDICAL DEVICES IN ORTHOPAEDIC SURGERY AND TRAUMATOLOGY

[Artículo traducido] MEDICINA PERSONALIZADA: FABRICACIÓN ACADÉMICA HOSPITALARIA DE PRODUCTO SANITARIO A MEDIDA EN CIRUGIA ORTOPÉDICA Y TRAUMATOLOGÍA

The personalised and precision medicine paradigm is usually associated with genetics or advanced therapies, but this field also includes the manufacture of custom-made medical devices (CMD) and use of high biomedical technology in interventions with a high patient-specific planning burden. A CMD is understood as any instrument, device, equipment, software, implant, or material intended for use in humans for medical purposes (diagnosis, prevention, prediction, prognosis, or treatment) and which has been manufactured under medical prescription to be used only by a specific patient to meet particular needs.[1]

Orthopaedic Surgery and Traumatology is a specialty that can most benefit from hospital manufacturing of CMD with a wide range of possibilities from anatomical replicas or biomodels for planning, to the manufacture of surgical instruments or custom-made implants. It is also important to note that the prescribing surgeon is responsible for the specific design features of these products.[2]

With these premises in mind, technologies such as 3D printing have burst onto the medical market and have grown exponentially in recent years, partly due to the lower cost of components and new biocompatible printing materials. These are set of additive manufacturing tools that involve radiological image acquisition, digital segmentation, and 3D design stages, as well as manufacturing in multiple technical materials. This industrial process allows full freedom of design and geometries, while reducing manufacturing times and waste; however, its main advantage for the medical sector is that each product can be custom made without significantly increasing production costs.

Because of its potential advantages and the risks involved, the manufacture of personalised products is beginning to be championed in hospitals as a clear example of healthcare innovation. Hence the concept of the manufacturing hospital, not as competition to the traditional medical industry but as a new healthcare and academic model to create value in personalised medicine by bringing together the professional team and the resources necessary to integrate the process of personalising the healthcare product as a natural part of the hospital ecosystem, with maximum guarantees of quality and safety for patients, generating knowledge based on each individual experience and thus enabling a qualitative leap in exponential, patient-centred, medicine.

Integrating this technology within hospitals helps scalability and cost optimisation, moving towards new production models in which manufacturing hospitals are identified as hubs within a networked operation that combines in-house manufacturing with external outsourcing-type services, based on collaborative work and the creation of alliances. This is encompassed by the point-of-care (POC) manufacturing model,[3,4] which encourages the inclusion of engineers in clinical teams and investment in new infrastructures. Orthopaedic surgery and traumatology services in the midst of digital transformation can increase their service portfolio by committing to these new processes in which technological hybridisation allows the convergence of different imaging technologies for planning, surgical guidance, and manufacturing of custom-made solutions. This means implementing procedural changes in which a significant

DOI of original article: https://doi.org/10.1016/j.recot.2023.01.005

https://doi.org/10.1016/j.recot.2023.02.007
1888-4415/

part of the surgical stage is virtualised, fully entering the era of digital surgery. Using these technologies allows for the design of surgical tactics in multidisciplinary simulation settings where the surgeon's work is supported by that of the radiologist and the engineer. This is an organisational challenge that breaks with traditional role configurations and vertical task distribution to make way for process working, where the orthopaedic surgeon plays a critical role in the value chain. Thus, a circular workflow is fostered, where surgical planning and the design of the custom-made product itself merge in the same stage, and where experience with each patient feeds back into the knowledge generated in the team.[5] The methodology, known as design thinking, seeks to co-create through five stages: empathize, define, ideate, prototype, and test. It can be fully applied in healthcare when personalised clinical solutions based on this type of technology are implemented.

The hybrid operating theatre concept traditionally met the needs of image-based interventional procedures, and is now evolving towards advanced surgical practice, including highly complex reconstructive surgery, multi-approach open procedures, and oncology. An exponential leap can be made in these hybrid theatres in terms of quality of care, laying the foundations to integrate different imaging technologies, navigation, AR guidance, automation, robotics, and 3D manufacturing.

This integration into the flow of care requires the different stakeholders to be aware of the scope of application and the regulatory frameworks that define it.[6] The European Regulation 745/2017 on medical devices was published in 2017, and is about to be transposed into a Royal Decree, where the manufacture of CMDs by hospitals themselves is a real regulatory challenge. The Spanish Agency of Medicines and Medical Devices (AEMPS) establishes two possible scenarios for hospital manufacturing: in-house and under licence. For the former, the requirement is to be manufactured and used in-house and is limited to the manufacture of class I products (e.g., biomodels) or class IIa (instruments or surgical guides), whereas for the manufacture of implants (class IIb and III) a manufacturer's licence is essential and working under a solid quality management system that prioritises traceability and biomonitoring. Some centres already have an CMD manufacturer's licence and certification under international standard ISO 13485, which applies to the validation and verification of the life cycle of a medical device.[7]

The future of personalised medicine involves a paradigm shift through process working in multidisciplinary units. Daily working between radiologists, surgeons, and engineers, among others, is essential. This builds a common language and a shared vision that greatly facilitates and enriches daily work. These units must be guarantors of the process from and to the patient, knowing the real application of the different emerging technologies, working with innovation and quality management methodologies, and always prioritising patient safety.

References

1. Legislación sobre productos sanitarios. Agencia Española de Medicamentos y Productos Sanitarios (AEMPS). https://www.aemps.gob.es/productos-sanitarios/legislacion-sobre-productos-sanitarios/.
2. Reglamento (UE) 2017/745 del Parlamento Europeo y del Consejo, de 5 de abril de 2017, sobre los productos sanitarios. https://eur-lex.europa.eu/legal-content/ES/ALL/?uri=celex:32017R0745.
3. [3D] Printing Medical Devices at the Point of Care: Discussion Paper. U.S. Food and Drug Administration (FDA). https://www.fda.gov/medical-devices/3d-printing-medical-devices/3d-printing-medical-devices-point-care-discussion-paper.
4. Calvo-Haro JA, Pascau J, Asencio-Pascual JM, et al. Point-of-care manufacturing: a single university hospital's initial experience. 3D Printing in Medicine. 2021 Apr;7(1):11. DOI: 10.1186/s41205-021-00101-z. PMID:;1; 33890198; PMCID: PMC8061881. https://threedmedprint.biomedcentral.com/articles/10.1186/s41205-021-00101-z.
5. Calvo-Haro JA, Pascau J, Mediavilla-Santos L, Sanz-Ruiz P, Sánchez-Pérez C, Vaquero-Martín J, Perez-Mañanes R. Conceptual evolution of 3D printing in orthopedic surgery and traumatology: from ''do it yourself'' to ''point of care manufacturing''. BMC Musculoskelet Disord. 2021 Apr 16;22:360, http://dx.doi.org/10.1186/s12891-021-04224-6. PMID:;1; 33863319; PMCID: PMC8051827. https://bmcmusculoskeletdisord.biomedcentral.com/articles/10.1186/s12891-021-04224-6.
6. Andrés-Cano P, Calvo-Haro JA, Fillat-Gomà F, Andrés-Cano I, Perez-Mañanes R. Role of the orthopaedic surgeon in 3D printing: current applications and legal issues for a personalized medicine. Rev Esp Cir Ortop Traumatol (Engl Ed). 2021 Mar-Apr;65:138−51, http://dx.doi.org/10.1016/j.recot.2020.06.014. English, Spanish. Epub 2020 Dec 6. PMID:;1; 33298378. https://www.sciencedirect.com/science/article/pii/S1888441520301223.
7. Unidad de Planificación Avanzada y Manufactura 3D. Hospital General Universitario Gregorio Marañón. https://www.comunidad.madrid/hospital/gregoriomaranon/profesionales/unidades-multidisciplinares/unidad-3d-upam3d.

R. Pérez-Mañanes[a,b,c,d,*,1], J. Calvo-Haro[a,b,c,d,2]

[a] *Servicio de Cirugía Ortopédica y Traumatología. Hospital General Universitario Gregorio Marañón, Spain*

[b] *CSUR de Sarcomas y Otros Tumores Músculo Esqueléticos del Adulto. Red europea EURACAN, Spain*

[c] *Universidad Complutense de Madrid, Spain*

[d] *Unidad de Planificación Avanzada y Manufactura 3D (UPAM3D), Spain*

[*] Autor para correspondencia.
E-mail address: ruben.perez@salud.madrid.org (R. Pérez-Mañanes).

[1] Cirujano ortopédico oncológico. Coordinador de UPAM3D. Spain

[2] Jefe de Sección de Oncología Músculo-Esquelética. Spain