3D Printing in Medicine

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Point-of-care additive manufacturing: state of the art and adoption in Spanish hospitals during pre to post COVID-19 era

Arnau Valls-Esteve[1,2,3*], Rubén I. García[4,5,6], Anna Bellmunt[7], Harkaitz Eguiraun[5,10], Ines Jauregui[4], Cristina del Amo[4], Nuria Adell-Gomez[1,2], Lucas Krauel[2,3,9] and Josep Munuera[8,11]

Abstract

Background 3D technologies [Virtual and Augmented 3D planning, 3D printing (3DP), Additive Manufacturing (AM)] are rapidly being adopted in the healthcare sector, demonstrating their relevance in personalized medicine and the rapid development of medical devices. The study's purpose was to understand the state and evolution of 3DP/AM technologies at the Point-of-Care (PoC), its adoption, organization and process in Spanish hospitals and to understand and compare the evolution of the models, clinical applications, and challenges in utilizing the technology during the COVID-19 pandemic and beyond.

Methods This was a questionnaire-based qualitative and longitudinal study. Data on 3DP and AM activities in Spain were collected from 73 hospitals/institutions falling under the ITEMAS (Platform for Innovation in Medical and Health Technologies) and the Plataforma ISCIII Biomodelos y Biobancos from January 2019 to May 2020 for the first study, and at the end of 2022 and 2023 for the second study.

Results A total of 23 (31.5%) hospitals during the first study, while 30 (41.09%) during the second study reported having at least one 3DP/AM initiative. Post-covid, the majority of hospitals had onsite 3DP/AM services with a well-defined, structured, and centralized system. Traumatology and maxillofacial surgery services were found to be the most involved in 3DP projects for the production of custom-made surgical guides, prostheses and orthoses. Bio-printing initiatives were also noted to be expanding. Human resources, cost, and regulatory compliance were the key hurdles in introducing 3D/AM in hospitals.

Conclusions In-house 3DP/AM units, with Mixed-Model is the most common model in Spain; The COVID-19 pandemic influenced the 3D planning activity and adoption. Further research and clinical trials, and improvements in resources, reimbursement and regulatory compliance are critical for the Point-of-care hospital growth of this break-through technology.

Keywords Additive manufacturing, 3D printing, Bioprinting, Surgical planning, Point-of-Care manufacturing, Anatomical models, Surgical education

*Correspondence:
Arnau Valls-Esteve
arnau.valls@sjd.es
Full list of author information is available at the end of the article

Background

Additive Manufacturing (AM) or three-dimensional printing (3DP) are transforming healthcare by providing novel and personalized solutions for complex clinical treatments and surgical procedures [1, 2]. Orthopedic, ophthalmology, dentistry, pediatric surgery, and maxillofacial surgery are just few of the specialties that are utilizing the 3DP/AM technology to optimize their operations [3–8]. The technology has gained an increasingly important role in applications including medical education and teaching through simulation models [9–13], and tissue engineering and regeneration through bioprinting [14]. Additionally, the technology aids in the development of patient-specific medical devices such as prosthetics and orthotics [9, 15, 16], human skin [17], cardiac tissue [18], surgical guides, implants, and drugs [14, 19–24].

One of the first and most widespread implementation of AM in healthcare has been in pre-surgical planning. Unlike traditional two-dimensional imaging, 3D models provide an identical copy of patient's anatomical structures and an understanding of spatial relationships, allowing the surgeon to customize the surgical approach prior to beginning the operation [25, 26]. This has resulted in a significant improvement in clinical and economic outcomes, such as a reduction in second interventions, risks and complications, surgery time, and potential improvements in operating room efficiency [27–29]; benefits well recognized by scientific societies. 3DP/AM is therefore becoming a tool for personalized medicine by providing tactile feedback as well as tangible depth information about anatomic and pathologic conditions.

The process of 3DP/planning in hospitals usually involves the following 7 steps as shown in Fig. 1.

The advantages of AM in clinical practice, as well as the rapid evolution of 3DP, have prompted the healthcare industry to seek out the best models for adopting this new technology. As a result, the emergence of in-house 3DP laboratories in hospitals and medical institutes has escalated in recent years. In the United States, there was an expansive growth in the number of hospitals with 3DP capabilities from three in 2010 to 99 in 2016 [30]. In line with this trend, the U.S. Veterans Health Administration (VHA) reported to increase the number of 3D printers from 3 in 2017 to 60 in 2020 [31].

Individual patient-specific models and tools, which may be expensive when outsourced to a 3DP service, can be produced at a lower cost and in a shorter possible time by utilizing hospital-based manufacturing and implementing 3DP at the point-of-care (PoC) [30, 32, 33]. However, in-house 3DP service requires an established infrastructure, facilities, workflow processes, employees, safety, quality, and regulatory compliance, resources that not all hospitals can afford [29, 30].

During the COVID-19 pandemic, the exponential demand for human resources and the reduction in business activity due to a lack of essential medical supplies due to supply-chain cuts challenged public health, healthcare organizations, and hospitals, bringing many countries' health systems to the verge of collapse [34]. This has shown the value of having certain manufacturing capabilities within the organization itself for the production and fair supply of products at the point and time of demand, saving lives and minimizing the socio-economic damage [35, 36]. Furthermore, 3DP has a potential to change the manufacturing paradigm by enabling decentralized productions, moving the digital design instead of the physical product [37].

The present longitudinal and qualitative study was therefore undertaken to investigate the state of the art, maturity, adoption, applications, model and challenges of 3DP and AM technology in Spanish hospitals during the COVID-19 pandemic (2019–2020), as well as the impact on the technology post-pandemic (end of 2022 and 2023).

Materials and methods

Study design and population

This was a qualitative, descriptive, longitudinal and structured questionnaire-based study. The current study included all the hospitals, health centers and clinical foundations in the Spanish territory (N=73) that fall under the ITEMAS (Platform for Innovation in Medical and Health Technologies) and the Plataforma Instituto de Salud Carlos III (ISCIII) Biomodelos y Biobancos.

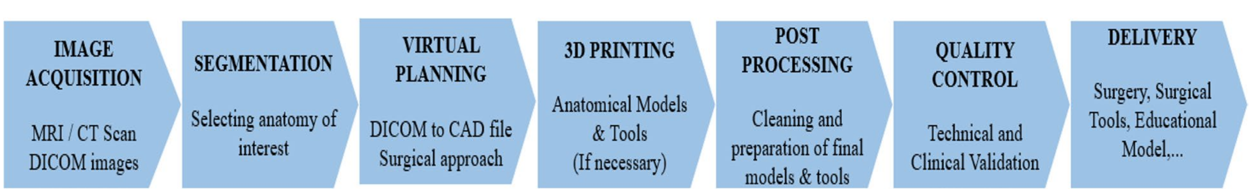


Fig. 1 3DP workflow in hospitals

Three reference hospitals led the study's design: Cruces U. Hospital-Osakidetza/BioBizkaia HRI (HUC), Hospital Clinic Barcelona/Instituto de Investigaciones Biomédicas August Pi i Sunyer (HCB/IDIBAPS), and Hospital Sant Joan de Déu Barcelona (HSJD).

Data collection

Data collection using a study specific questionnaire (about 3DP and AM activities in Spanish hospitals) was performed from January 2019 to May 2020 for the first study, and thereafter in the end of the year 2022 and during 2023 for the second study. Data was gathered via email or semi-structured phone-call interviews with medical professionals, technical specialists, and financial experts in-charge of the 3DP/AM and bioprinting initiatives from each hospital.

Setting and assessment tool

For the years 2019–2020 data, this study required the completion of 2 different questionnaires containing 21 and 12 questions respectively (as given in Annex 1). The questionnaire 1 was divided into 5 parts to collect data on (A) organization and process, (B) equipment, (C) clinical applications of 3D activities (including types of profiles involved, types of products produced (anatomical models, surgical guides and implants) and bioprinting), (D) research, and (E) activity. The questionnaire 2 was divided into 4 parts; (A) organization and process (including new questions to obtain information regarding the challenges faced in its implementation), (B) equipment, (C) clinical applications of 3D activities and (F) activity and future prospects.

For the year 2022 and 2023, there was only 1 questionnaire with 31 questions related to the same parts of the previous questionnaires and adding some specific questions related to the COVID-19 impact. The 5 parts were: (A) organization and process, (B) equipment, (C) clinical applications of 3D activities, (D) research, (E) activity, and the impact of COVID-19 pandemic on the 3D manufacturing activities in the hospitals/institutes included (given as questionnaire 3 in Annex 2).

Google forms were set to complete the questionnaires online. Four types of answers were considered: multiple-choice, Yes / No / NA, calendar date, and open answer.

Finally, all the responses were evaluated after removing the 'NA' and blank entries (for open-ended answers).

The longitudinal view of the state of 3DP and AM in Spanish hospitals was studied by comparing the data obtained during the year 2019–2020 (COVID-19 era) and during the end of 2022 and 2023 (post-covid pandemic).

Statistical analysis

The data obtained were analysed using the Statistical Package for the Social Sciences (SPSS) (IBM Corp, NY, USA) version 26. Categorical variables were represented as frequencies and percentages.

Results

The findings have been divided into two studies: study 1 (2019–2020) and study 2 (2022–2023). Out of 73 institutes/hospitals/foundations, 23 (31.5%) during the first study and 30 (41.09%) during the second study reported having at least one initiative running related to 3DP, bioprinting or 3D planning. The questionnaires (1–3) were completed in Spanish language by all participants.

Data from the questionnaires have been categorized into seven groups: 1.Organization and Process, 2.Profiles Involved, 3.Clinical Applications, 4.Equipment, 5.Research, 6.Activity, and 7.Future Prospects.

Organization and process

3DP models in Spanish hospitals

According to the current processes identified for the implementation of 3DP activities, the following five different models have been identified among Spanish hospitals:

1. Full in-house/PoC/Onsite service: Completely internal, with a significant investment in internal resources.
2. Outsourcing: Direct subcontracting of services to suppliers (commodity).
3. External company implemented in the center/hospital.
4. Center spin-off: Set up of a company dedicated to providing 3DP services to the hospital and other institutions.
5. Mixed Model: In-house service, with some services outsourced to third-party providers. This can have 3 sub-models:

    a. In-house service implemented and outsourcing of some products to external providers.
    b. External company implemented in the center and some products outsourced to external providers.
    c. In-house service and an external company implemented in the center.

The implementation of 3DP in participated hospitals in Study 1 (2019–2020): Majority of hospitals ($n=10$; 45%) used a mixed type of 3DP model (in-house service + outsourcing some products to external providers). Moreover, 2 cases of "an external company implemented in the center" were observed during this period (Fig. 2a).

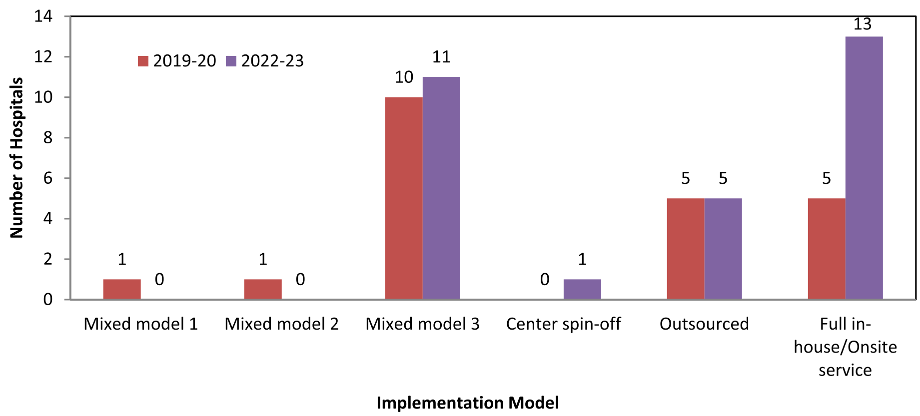


Fig. 2 3DP models in hospitals in (**a**) 2019–2020; (**b**) 2022–2023. Mixed model 1 (In-house service and an external company implemented in the center), Mixed Model 2 (External company in the center and some products outsourced to external providers), Mixed model 3 (In-house service implemented and outsourcing of some products to external providers)

Study 2 (2022–2023): Full onsite/in-house service model was observed in most of the hospitals ($n=13$; 43.3%). Eleven hospitals (36.7%) also used a mixed service model (in-house and outsourcing some products to external providers). No external company was reported to be implemented in the center; however, there appeared a case of a center spin-off (Fig. 2b).

How 3DP initiatives were born

To understand the adoption pathway of 3DP in hospitals, it is necessary to first understand how AM initiatives were born.

Study 1: According to the survey results, the majority of cases ($n=18$; 67%) of 3DP entered a bottom-up strategy from specific clinical services, leading to first proof-of-concept projects in 2019. Only one case originated from the infrastructures/engineering department. Finally, 15% ($n=4$) stated that the use of 3DP in their hospitals was a top-down initiative promoted by hospital leadership, while the remaining 15% ($n=4$) were promoted by the research institute.

Study 2: In the majority of institutes ($n=5$; 16.7%), AM/3D services were implemented in the years 2018 and 2019 respectively. These services emerged as an original investment from a specific clinical service in 46.7% ($n=14$) of the institutes, while it was an organizational commitment of the institute/hospital in 20% ($n=6$, respectively).

According to the results of the study, all hospitals that implemented a 3D service (either internal, mixed or external) started with the first 3DP initiatives almost 3 years (mean of 2,7 years) before implementing a 3D Lab.

Figure 3 shows the distribution of 3D Point-of-Care initiatives implemented at the Spanish hospitals and the year of implementation. As can be seen, there have been a growth from 2011 to 2022, especially since 2018. The Autonomous Communities of Catalonia, Andalusia, Basque Country and Madrid are the ones showing more initiatives.

Coordination and prioritization of 3DP/AM cases or projects

Hospital 3DP can be coordinated by autonomous units or as a consolidated strategy at the corporate level. There are various models of coordination and during the studied years there have been an evolution of the coordination models. The following are the results of the various strategies used by the participating entities:

> Study 1: Majority of 3DP/AM projects in hospitals were led by a specific service or researcher ($n=11$; 50%) (Fig. 4a).
> Study 2: In 17 cases (56.7%), the coordination of the 3D planning initiatives of all the hospital's clinical services was defined, structured, and centralized in one department or unit. Notably, in approximately 10 cases (33.3%), there were specific initiatives led by an specific service or researcher (Fig. 4b).

Prioritization of 3DP/AM cases or projects and 3D planning services in Spanish hospitals have a very varied structure. There was no prioritization process for new 3DP cases in majority of the hospitals surveyed in 2019–20 (32%) and 2022–23 (36.7%). However, in the second study, approximately 26.7% of the hospitals presented a prioritization criterion defined by a specific commission in the absence of a catalogue, while in 20%, the head of the clinical department requesting the provision of a 3D service decided the priority of a new case.

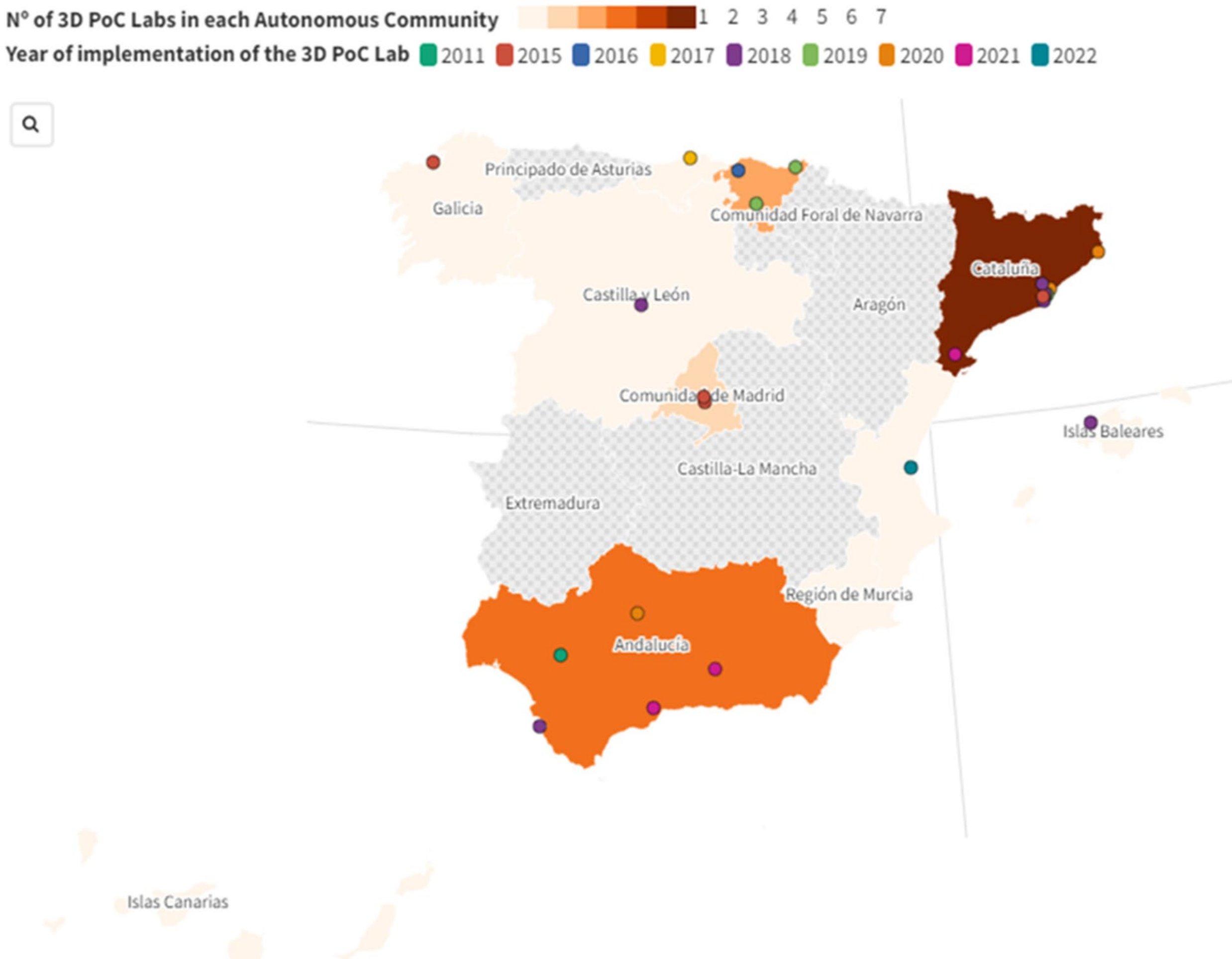


Fig. 3 Distribution of 3D Point-of-Care initiatives implemented at the Spanish hospitals per Autonomous Community and the year of implementation

Profiles involved in the 3D/AM process

Study 1: Clinical specialist was the most common profile involved in 3DP projects in 2019–20 as observed in 21 (95%) of the Spanish hospitals/institutes included in our study. Additionally, 16 (73%) hospitals had the support of the Innovation Department (Fig. 5a).

Study 2: In 2022–23, data revealed that clinicians were mostly involved in 3D simulation/AM processes in 19 hospitals (63.3%), similar to 2019, with surgeons in about 17 hospitals (56.7%). Bioengineers and other profiles from the Innovation Department had also taken active participation in the process in approximately 16 (53.3%) and 15 (50%) of the hospitals respectively (Fig. 5b). More profiles participated in the 3DP process in 2022–23, than in 2019–20.

The process of 3DP and planning often begins with a DICOM (Digital Imaging and Communications in Medicine) file obtained from a CT scan or an MRI. Despite the fact that radiologists and image technicians are the specialists in hospitals who provide imaging and anatomy knowledge, image segmentation was never performed through the radiology department in 24% (study 1) and 43.3% (study 2) of the surveyed hospitals. Alternatively, radiology department specialists in 48% and 36.7% of hospitals, in 2019–20 and 2022–23 respectively, only performed segmentation in complex cases.

Clinical applications

Clinical specialties

Studies 1 and 2: Bone-related services such as orthopaedics and traumatology ($n = 15$; 68% in 2019–20, $n = 21$; 70% in 2022–23) and maxillofacial surgery ($n = 15$; 68% in 2019–20, $n = 16$; 53.3% in 2022–23) were found to be

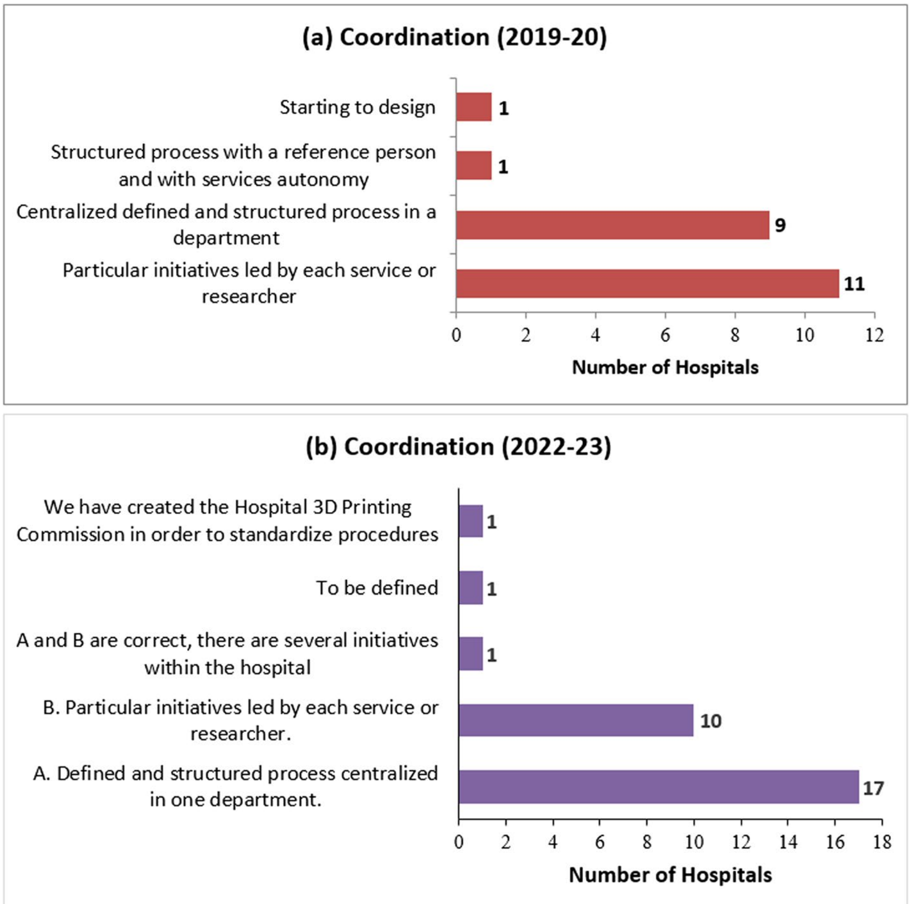


Fig. 4 Coordination of 3D simulation/AM projects in (**a**) 2019–20; (**b**) 2022–23

involved in 3D/AM initiatives in the majority of hospitals. General surgery, neurosurgery, radiology, cardiology, angiology and vascular surgery, and urology services showed a growing interest in 3D/AM initiatives across the surveyed hospitals when results from the two studies were compared (Fig. 6).

3DP applications

Studies 1 and 2: Surgical training, planning and pre-surgery simulation was found to be the most prevalent application among the Spanish hospitals surveyed in 2019–20 ($n=17$; 77%) and 2022–23 ($n=22$; 73.3%) (Fig. 7).

3D/AM technologies were also used for other applications such as guiding tools during surgery ($n=15$; 68% in 2019–20 and $n=15$; 50% in 2022–23); R+D+i prototypes ($n=12$; 55% in 2019–20 and $n=20$; 66.7% in 2022–23), anatomical biomodels for visualization ($n=17$; 77% in 2019–20 and $n=19$; 63.3% in 2022–23), and teaching ($n=15$; 68% in 2019–20 and $n=17$; 56.7% in 2022–23) (Fig. 7).

Surgical guides/instruments

Studies 1 and 2: Approximately 22 hospitals in 2019–20 and 19 in 2022–23 declared to use 3DP/AM surgical guides. These were most commonly used by the bone-specialty services such as orthopaedics and traumatology ($n=12$; 55% in study 1 and $n=16$; 84.2% in study 2) and maxillofacial surgery ($n=11$; 50% in 2019–20 and $n=12$; 63.2% in 2022–23) (Fig. 8). Other specialties that used surgical guides included neurosurgery, plastic surgery, general surgery, cardiovascular surgery and others.

Furthermore, according to the 2022–23 data, out of 19 (63.3%) hospitals that declared to be using surgical guides by AM, 52.6% subcontracted the services directly to external providers, while 21.1% manufactured them in-house and another 21.1% used mixed services, subcontracting most of the cases to external providers, but producing some in-house. One case declared to acquire the surgical guides from a spin-off of the same center.

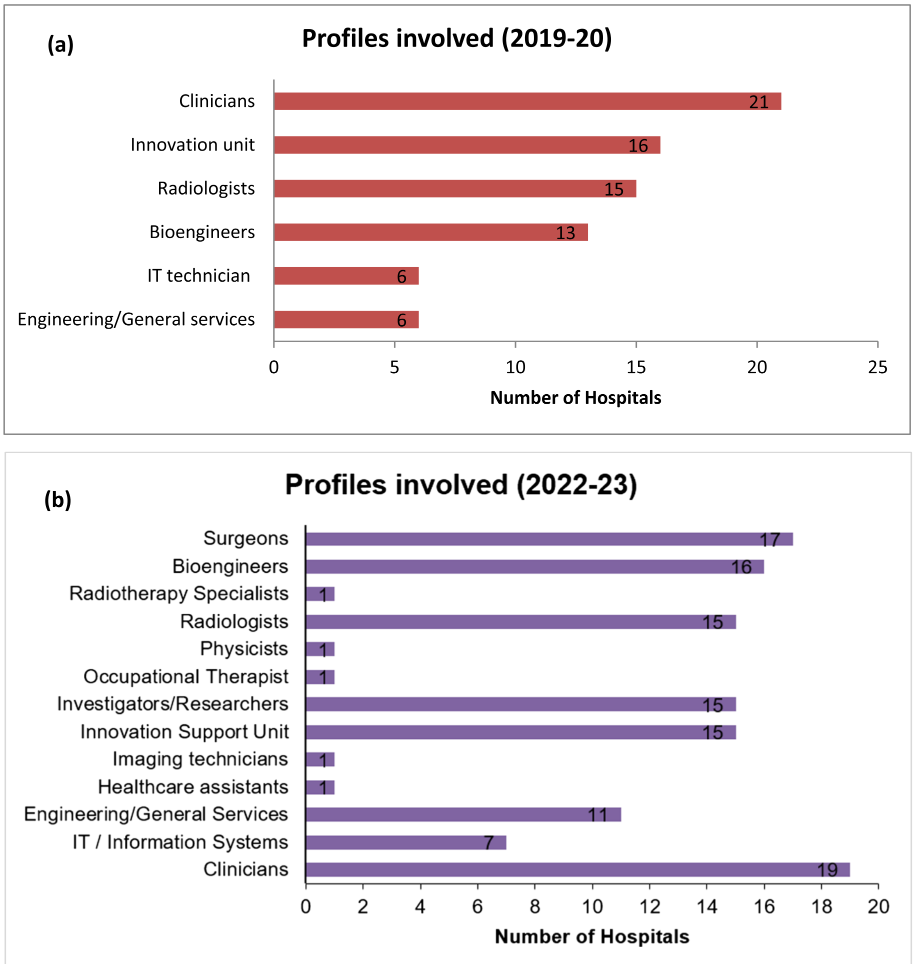


Fig. 5 Profiles involved in the 3DP process in Spanish hospitals in (**a**) 2019–20; (**b**) 2022–23

Custom implants

Study 1 and 2: In 2019–20, half of the hospitals ($n = 11$) reported to make use of custom implants manufactured in 3D/AM technologies. In 2022–23, the number of hospitals using custom implants increased to16 out of 30 hospitals (53.3%). In both surveys, most of the cases ($n = 10$) were subcontracted to external providers. However, in 2019–20, 4 hospitals reported to manufacture them in-house; with 1 out of these 4 cases done through an external company implemented in the center. While in 2022–23, 4 institutions reported to manufacture the cases in-house; 1 reported to do it through a spin-off and not through an external company implemented in the center.

Both orthopaedics and traumatology (45% in 2019–20 and 73.3% in 2022–23) and maxillofacial (45% in 2019–20 and 53.3% in 2022–23) services were found to be the leaders in the use of customized implants (Fig. 9).

Bioprinting

Study 1: By 2019–20, 13 hospitals (59.1%) declared to have at least one bioprinting initiative at their institution. Bioprinting initiatives were mainly in research stage and was most commonly used in cardiology (18% of hospitals), and orthopaedics and traumatology (14%). Other initiatives existed in services such as oncology, dermatology and plastic surgery in the hospitals surveyed.

Study 2: By 2022, 16 (53.3%) hospitals had declared to have at least one initiative in bioprinting. In 15 of

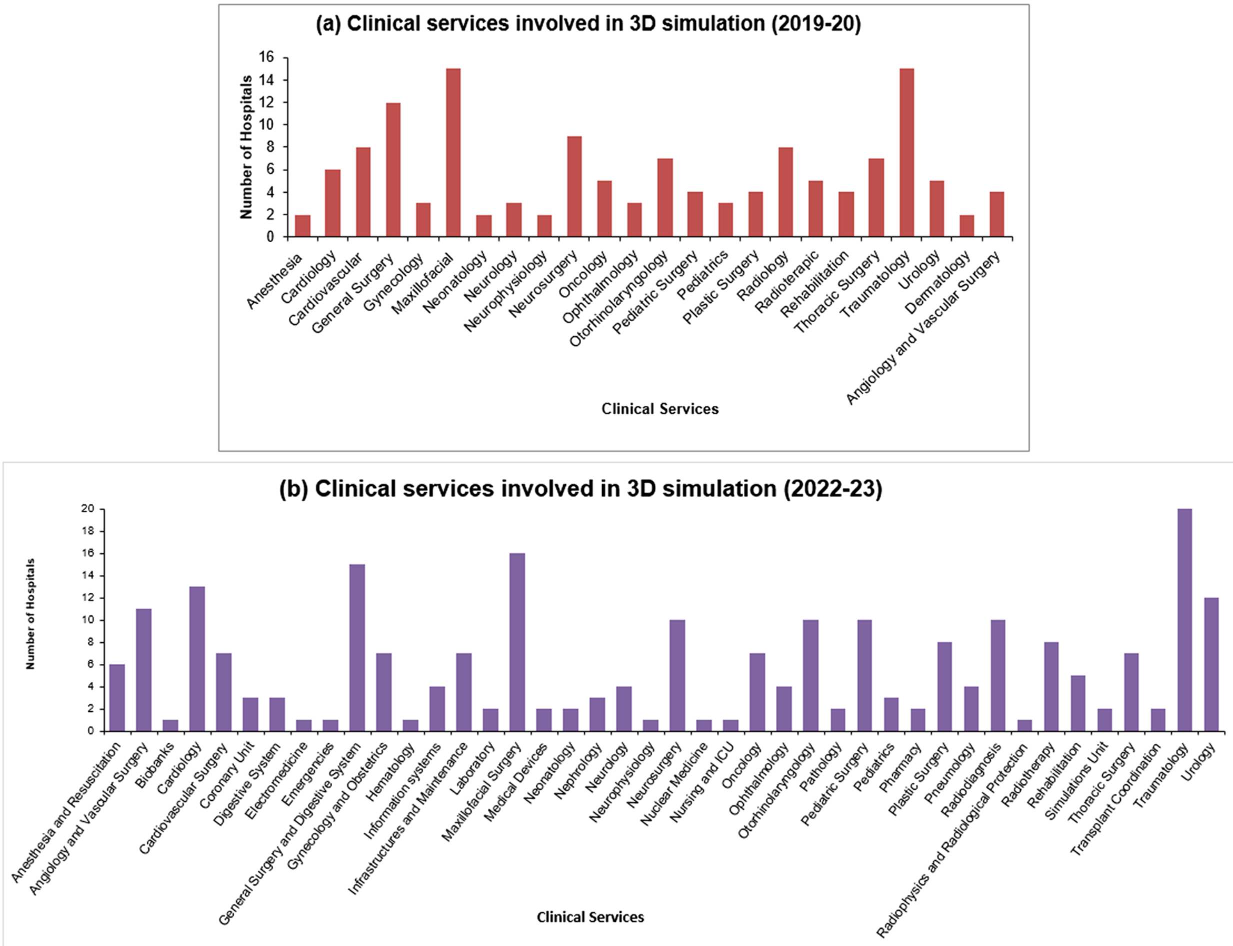
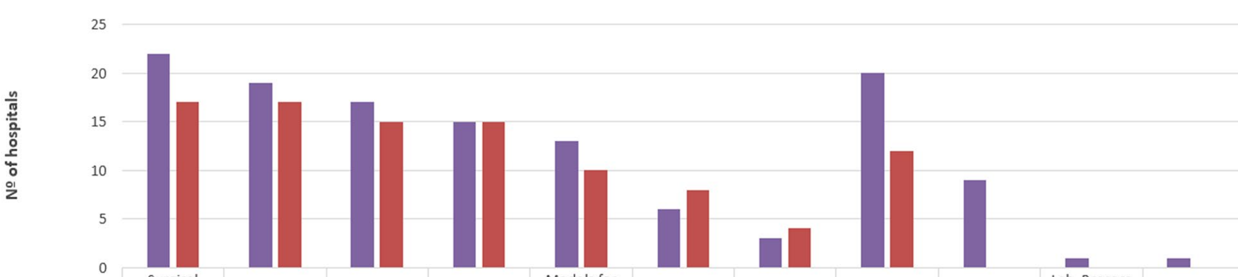


Fig. 6 Clinical Specialties involved in 3D/AM activities in Spanish Hospitals in (**a**) 2019–20; (**b**) 2022–23



	Surgical Training / Simulation	Visualization	Teaching	Guiding tools	Models for pre-forming plates	Bio-printing	Rehabilitation devices	R+D+i prototypes	EPIS	Lab. Process and product improvement	Brachytherapy molds
Count 2022-23	22	19	17	15	13	6	3	20	9	1	1
Count 2019-20	17	17	15	15	10	8	4	12	0	0	0

Activity

Fig. 7 3D/AM healthcare applications used in Spanish Hospitals in 2019–20 and 2022–23

them, the bioprinting initiatives were in research stage, while 1 (3.3%) was already in production. These bioprinting initiatives were most frequently used in the manufacture of structural tissue (bone; 31.3%), cartilage fabrication (31.3%), skin fabrication (25%) and organoid manufacturing (25%).

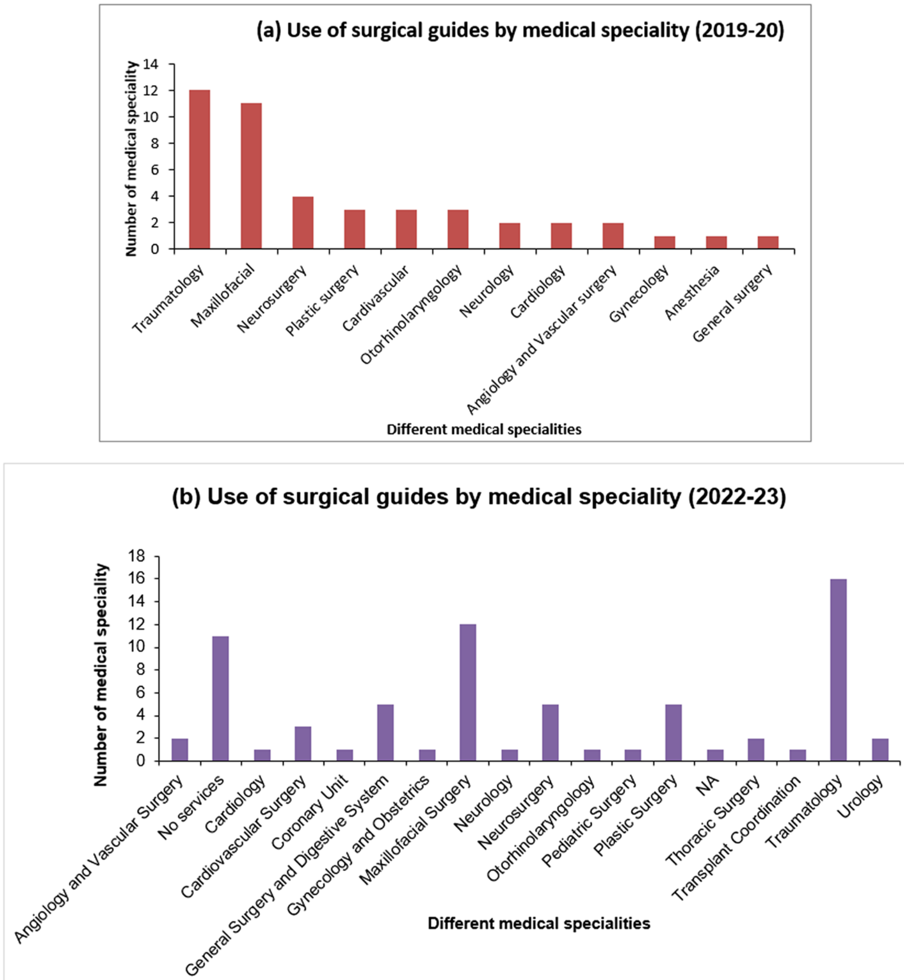


Fig. 8 Use of surgical guides by clinical specialty in Spanish hospitals in (**a**) 2019–20; (**b**) 2022–23

3D printed medicines/pharmaceutical products

In 2022–23, 4 institutions reported to have initiatives in additive manufacturing of pharmaceuticals at their institution, with 3 in research stage and 1 case already in production.

Equipment

Additive manufacturing equipment

Study 1: There were 23 Fused-Deposition-Modeling (FDM) printers spread across 12 hospitals, followed by 5 Stereolithography (SLA) printers in 5 different hospitals and a Material Jetting (PolyJet®) printer in 4 different hospitals (Fig. 10a).

Study 2: 3D printers were mostly of FDM technology in 25 (83.3%) hospitals, followed by SLA in 17 (56.7%) hospitals (Fig. 10b). There was no increase in Polyjet printers, whereas 1 hospital had acquired a Digital Light Processing (DLP) printer. An increase in bioprinting technologies was also reported.

Software integration for imaging segmentation

Study 1: For imaging segmentation and post-processing, approximately 41% ($n = 9$) of the hospitals used an open-source software (3D Slicer (Brigham and Women's Hospital (BWH), Massachusetts), OsiriX (Pixmeo SARL, Geneva) or other). In few hospitals ($n = 6$; 27%), radiology software was used integrated into hospital systems, whereas in few others ($n = 3$, 14%), software was a standalone solution; a commercial proprietary software such as Dolphin (Patterson Dental Holdings, Inc, Saint Paul) or Materialise Mimics (Materialise, Leuven, Belgium) that was not integrated into hospital electronic health record (EHR) was another option. Few hospitals had mixed software structures (Fig. 11a).

Study 2: Open-source software was most commonly used for performing image segmentation in 11 (36.7%) hospitals while 6 hospitals (20.0%) declared to use commercial software integrated into radiology and only 5

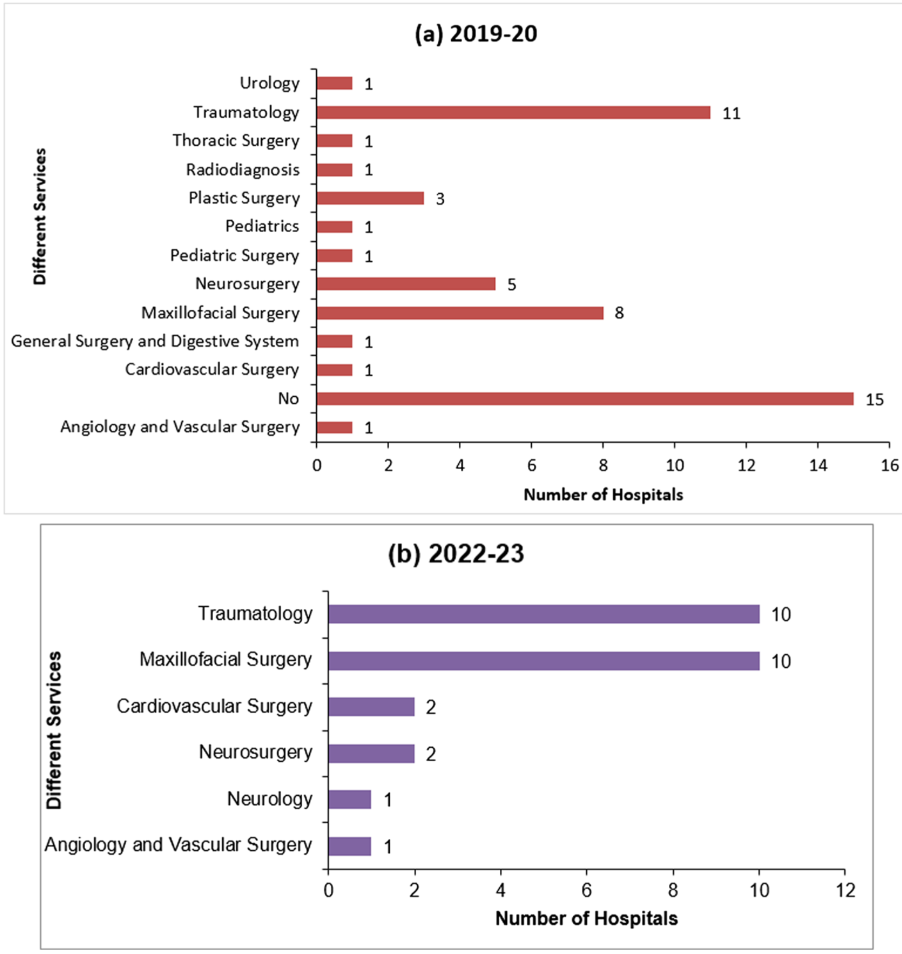


Fig. 9 Use of patient-specific implants by clinical specialty in Spanish hospitals in (**a**) 2019-20; (**b**) 2022-23

declared to use commercial proprietary certified software not integrated into radiology (Fig. 11b).

Open-source and proprietary software coexisted with only a few options certified for clinical use. There were two types of software used: those for image acquisition and segmentation (converting DICOM images to Standard Tessellation Language (STL) or Computer-aided design (CAD) files) and those for 3D design and post-processing.

Active research and development projects using 3D and AM

Study 1: Out of 23 hospitals that declared to have 3DP/AM initiatives, majority of them (54.5%) had between 2 and 5 active research projects. Two hospitals reported having more than 5 research projects.

Sixteen (70%) hospitals declared that they did not have any clinical trials in interventions utilizing 3DP/AM technologies. Six (26.1%) hospitals reported participation in at least one 3DP clinical trial (Fig. 12).

Study 2: Out of 30 hospitals, 13 (43.3%) had between 2 and 5 active 3DP/AM projects, and 8 hospitals (26.7%) reported to have more than 5 ongoing research projects. Twenty-two (73.3%) hospitals stated that they had not participated in any clinical trials related to AM, while 8 (26.7%) hospitals stated that they had (Fig. 12).

Activity

Activity in hospitals is an important indicator of maturity, adoption capability, demand and growth of 3D/AM technologies. Therefore, the questionnaires included information regarding the volume of 3D surgeries they planned or simulated each year.

Study 1: In 2019–2020, the majority of the hospitals ($n = 11$; 36.7%) had an annual volume of cases ranging between 0 and 5. Five (16.7%) hospitals reported having more than 60 cases per year (Fig. 13).

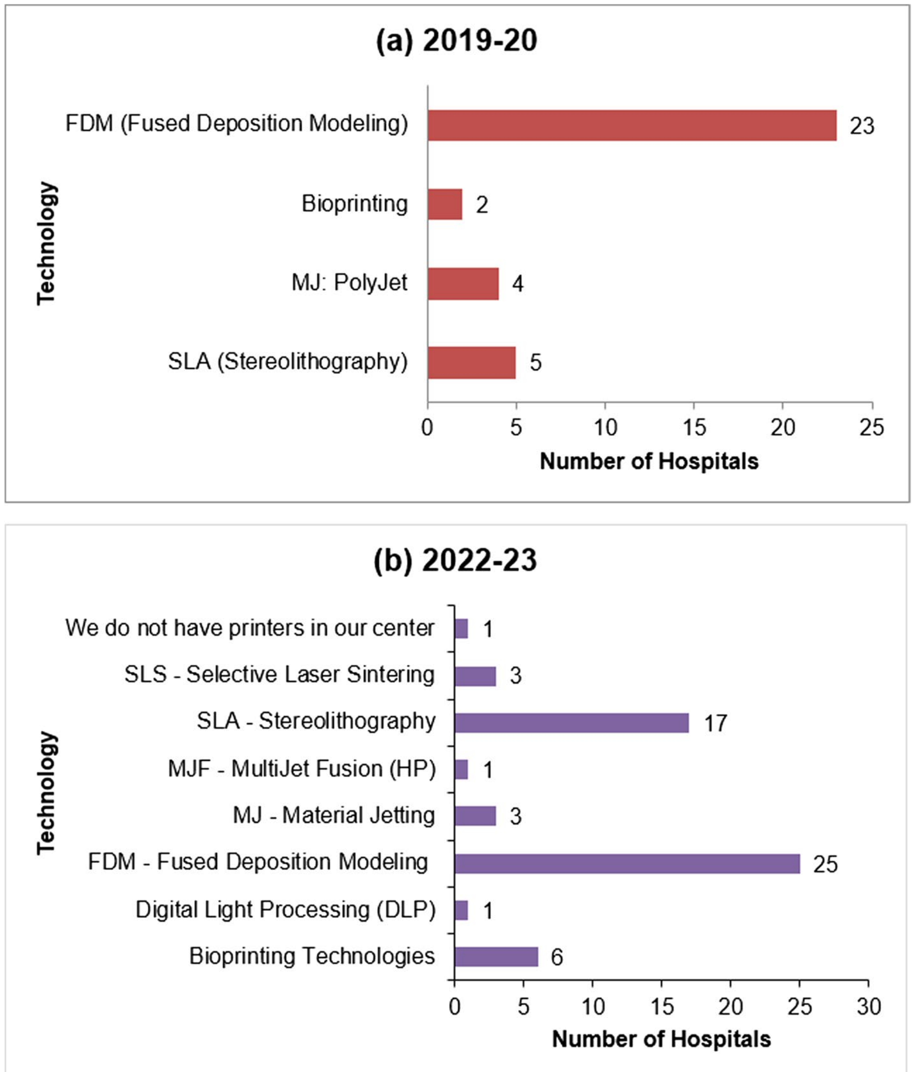


Fig. 10 3DP technologies in Spanish hospitals in (**a**) 2019–20; (**b**) in 2022–23

Study 2: In 2022–23, the majority of hospitals had either 0–5 ($n=7$, 23.3%) or 10–30 ($n=7$; 23.3%) 3D simulation/AM surgical planning cases yearly. Three (10%) hospitals reported 60–100 cases and four hospitals reported to have more than 100 annual cases (Fig. 13).

Effect of COVID-19 on the 3D manufacturing activity

Out of 30 hospitals surveyed in the year 2022 and 2023, 18 (60%) hospitals indicated that COVID-19 pandemic did not favor the creation of a 3D unit in their institution, while 12 reported it did.

Twelve (40%) hospitals reported a decrease in AM activity in general, while 13 reported to maintain or increase the surgical planning activity, 16 reported to decrease surgical planning activity and 6 (20%) reported to have increased surgical and device manufacturing activities (Fig. 14).

Future prospective

Challenges in expanding medical applications of AM

The majority of hospitals identified similar challenges in both studies. The question was structured as a multiple-choice providing respondents the opportunity to select all that apply for them. In Study 1, the three most voted challenges were: 1st.- Human resources with dedicated time to internal 3D service ($n=17$; 73.9%), 2nd.- Funding ($n=16$; 69.6%) and 3rd.- Regulation ($n=12$; 52.2%). While in 2022–23, in Study 2: 1st.- Regulation ($n=23$; 76.7%), 2nd.- Funding ($n=21$; 70%), and 3rd.- Human resources with dedicated time to internal 3D service

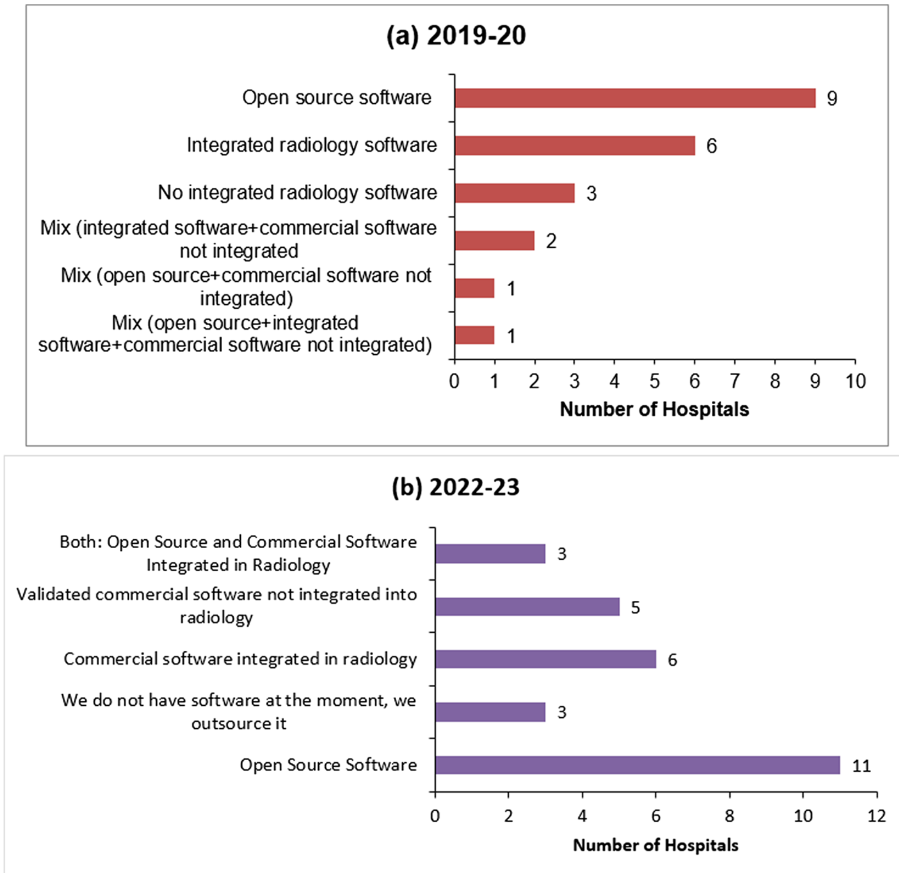


Fig. 11 Type of software used for imaging segmentation in (**a**) 2019–20; (**b**) 2022–23

($n = 21$; 70%) were the top three challenges reported by most hospitals. The 4th and 5th positions do not differ much from the two studies being in study 1, 4th.- Skilling of personnel dedicated to 3D/AM activities ($n = 8$) and 5th.- Lack of needed technology (printers) ($n = 8$) and in study 2, 4th.-Skilling of personnel dedicated to 3D/AM activities ($n = 16$) and 5th.- Availability of software for segmentation and 3D design ($n = 12$).

Manufacturing license

More than a third of the institutions ($n = 11$; 36.7%) stated that there was no plan to obtain a license for PoC manufacturing of medical devices in the near future and that they do not follow the research process in the 3D/AM clinical cases done. Ten hospitals (33.3%) in 2022–23 reported to follow clinical 3D cases under the guidelines of a research project. Only 2 hospitals reported to have the license for in-house and custom-made manufacturing of medical devices, but 6 hospitals reported to be in the process of obtaining it in the following year.

Best-fit future model for 3D technology implementation

Studies 1 and 2: Most hospitals anticipated implementing a Mixed Model in the following years ($n = 15$; 65% in 2019–20 and $n = 19$; 63.3% in 2022–23), with an in-house 3D lab providing services to the institution and some services being outsourced to external providers or suppliers (Fig. 15).

Discussion

3DP is a type of AM that involves a process of producing 3D objects from digital CAD modelling by joining raw materials, usually layer upon layer [38]. Advances in 3DP/AM technology with the capability to improve treatments of certain medical conditions have caught the attention of the global healthcare community. In fact, several hospitals in Spain have developed 3DP/planning initiatives up to various levels of maturity. In this paper, we investigated and compared the state of the 3DP/AM technology in Spanish hospitals during the COVID-19 pandemic (2019–2020; study 1) and post-covid (end of 2022–2023; study 2) to better understand the situation and adoption of this technology in Spanish healthcare system and how the pandemic impacted the overall situation of 3DP/AM in Spain.

We observed that out of 73 hospitals, 23 hospitals during the first study and 30 during the second study were actively using the 3D/AM technology, with the majority of them located in the Spanish Autonomous Communities or regions of Madrid, Euskadi, Andalusia, Catalunya and Valencia.

In Spain, the majority of hospitals ($n=12$; 52.17%) used a mixed type of 3DP model (in-house + outsourced services) during 2019–20, whereas post-covid, 43.3% ($n=13$) hospitals had implemented onsite (PoC) 3DP services and 36.6% ($n=11$) employed a mixed service model. Thus, although the adoption of a mixed model decreased only in 1 hospital from 2019–20 to 2022–23, the increase of in-house manufacturing services was remarkable growing from 5 in 2019–20 to 13 in 2022–23. Interestingly, while in 2019–20 there were two hospitals with external companies implemented within the hospital, in 2022–23, no case was reported. Remarkably, one case appeared of generation of a spin-off from the center that provides internal and external services.

Larger research hospitals with centralized 3DP facilities adopted in-house or onsite (PoC) services during the COVID-19 pandemic crisis, when the lack of available medical resources on a global level prevented universal supply and coverage. This is also visible with the reported increase in 46.67% of the cases in the manufacture of in-house medical devices.

Adoption of a defined, structured, and centralized petition system for 3D cases has become more common in the Spanish hospitals during these years. A standardized process ensures that 3DP/AM cases are prioritized fairly and quickly, which was not the case in Spanish hospitals in the first phase of this study. However, there is still a significant amount of hospitals with 3D Units/Labs depending on specific clinical services, instead of transversal hospital platforms, potentially reducing the capacity, fairness and equal provision to all cases in need.

In Table S1 (Annex 3), we highlight the main characteristics of four of the most active hospitals in 3D printing adoption in Spain in 2022–23. The chosen hospitals have more than 60 surgical cases per year (volume) with more than 10 different services (diversity) and 2 of the 4 have the manufacturing license (according to Medical Devices Regulation 2017/745/EU (MDR) requirements) at the time of the study. From the analysis of reference hospitals it seems that the success in the implementation of the technology does not depend on the size of the hospital or the capacity of the radiology service. On the contrary, a centralized, well-defined and integrated process with a request and prioritization system is necessary. All four hospitals share the implementation model being Mixed, doing most of the cases in-house and some outsourced.

Furthermore, a single clinical service or researcher spearheaded the vast majority of 3D initiatives in most of the cases.

Clinical specialists were the ones most involved in 3D/AM projects in 2019–20, according to the current study. New profiles are entering hospitals, resulting in the creation of new professions. That is the case of bioengineers and AM engineers, who have become increasingly important in 3D project launching and bringing new knowledge to the institution. Although, clinical imaging, diagnostic and segmentation of DICOM images are the starting points for the 3DP process, and radiology specialists should play a central role, in the majority of cases they were only involved in the most complex 3DP projects in Spanish hospitals. Post-covid, surgeons have encouraged institutions to implement a service or purchase 3DP/AM equipment, with hope for incorporating the equipment into their clinical services. 3D/AM technology has promoted collaboration primarily among 3 profiles: bioengineers, surgeons, and radiologists.

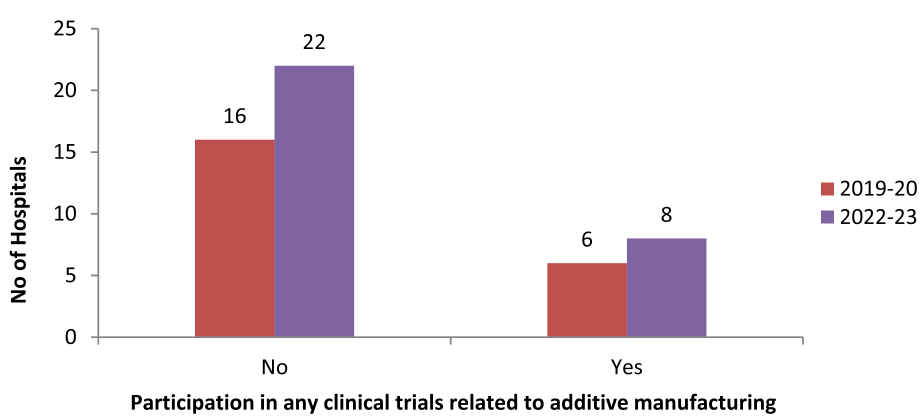


Fig. 12 Participation in clinical trials using 3D/AM according to the results of the 2 studies (study 1 in 2019–20 and study 2 in 2022–23)

Fig. 13 Volume of 3D simulation/AM surgical cases/year in (**a**) 2019-20; (**b**) 2022-23

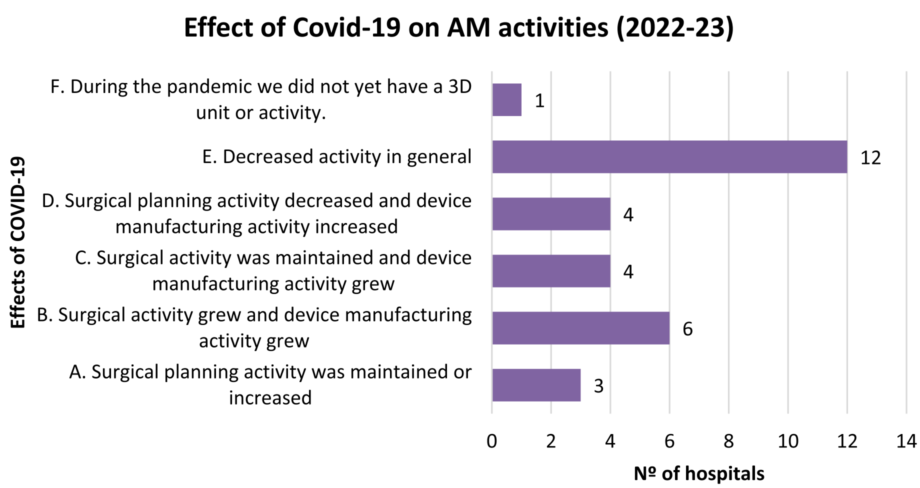


Fig. 14 Effect of COVID-19 pandemic on AM activities in institutes/hospitals

Orthopaedic, maxillofacial and dental applications in the medical and pharmaceutical industries have been the most favorable to embrace the 3DP technology [20, 39]. As expected, in our study, orthopaedics and traumatology and oral and maxillofacial surgery services were the most involved in 3DP initiatives for the manufacture of custom surgical guides, prostheses and orthoses in the majority of hospitals in Spain. This is in line with other studies [40–43]. The reason for this result may be multifactorial: first, orthopaedics and traumatology and maxillofacial specialties are bone-based specialties treating with complex bone osteotomies and malformation in which custom-made cutting and position guides play a key role as an aid for surgeons [44, 45]. Moreover, in Spain an important amount of dental clinical services are treated in private clinics, promoting the use of value-added services.

Hearing aids, dental crowns, bone tether plates, hip cups, spinal cages, knee trays, facial implants, screws, surgical instruments, and Invisalign® braces are among the few FDA and EMA approved 3D printed prostheses at the moment of the present study [46]. These 3D printed models that are specific to patient anatomy have been extensively used for surgical planning because they provide the surgeon good aid for adapting the treatments

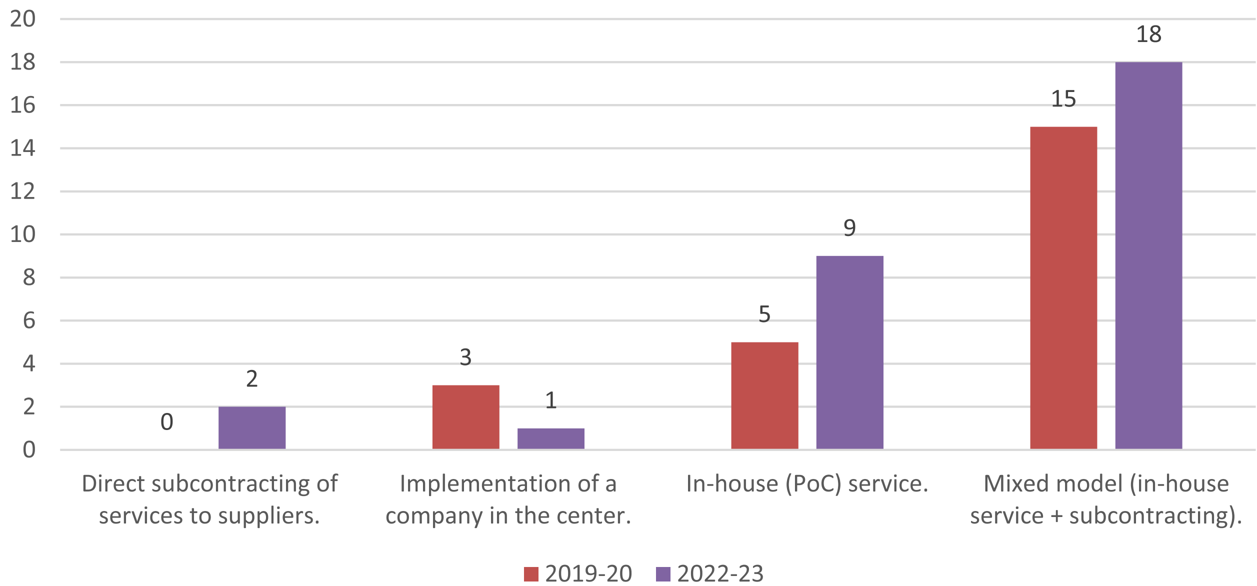


Fig. 15 Best-fit perceived future model for implementation of 3D technology in 2019–20 and 2022–23

to the complex anatomy, determining the best therapeutic intervention options for the patient [47, 48].

Additionally, 3DP has the potential to transform medical education. The findings from the present study revealed that 3DP technology was mostly used in Spanish hospitals for surgical planning, training/pre-surgery simulation, visualization, and teaching. High resolution 3D prints or models representing normal and pathologic anatomy are excellent tools for virtual surgical planning (including virtual, augmented and mixed reality technologies), simulation and hands-on training for medical students, fellows, and doctors because models are safe to handle, can be shared between institutions with limited infrastructure, and allow the practice of different surgical techniques without endangering patients [7, 10, 49, 50]. R + D + I (Research, Development and Innovation) was also observed as a significant application utilizing 3DP/AM in 2022–23 as a way to accelerate development of medical devices (between others). 3DP and research go hand-in-hand, acting as a catalyst for clinical development and innovation, enabling rapid prototyping, and shorter validation durations. Adaptation of surgical masks and breathing support devices for COVID-19 patients, by manufacturing within university hospitals, are the best instances of R + D + I application [51]. The supply chain cuts during COVID-19 pandemic and the capacity of decentralized medical device manufacturing at the point-of-demand allowed by the 3D/AM technologies accelerated the adoption of these technologies bringing new evidence of its value [52, 53].

Bioprinting is another field of 3DP technology with a promising future for regenerative applications. It involves the use of bioprinters to print with cells, biomaterials, and growth factors to create organ like structures [14, 22]. In our study, initiatives in bioprinting technology increased significantly from 2019–20 to 2022–23 and were mostly seen in cardiology, orthopaedics and traumatology, maxillofacial and dermatology clinical services and was most frequently used to manufacture organoids, structural tissue (bone), skin and cartilage.

According to this study, from 2019–2023, fused deposition modeling (FDM) for 3DP was the prevalent technology in Spanish hospitals.

Furthermore, Spain still has some room for development in terms of research. Only 43.3% of hospitals reported having 2–5 ongoing 3D/AM projects in 2022–23. However, most of the institutions reporting a high volume of 3D/AM research projects claimed to have at least one in bio-printing. Nonetheless, clinical trials are the most common structured research methodology for assessing the prospective safety and efficacy of new treatments. Therefore, more systematic research with comprehensive clinical trials is essential to generate enough evidence to incorporate new 3D medical technologies within clinical workflows having impact on patients. In this study, we found that there are very few clinical trials as compared to the amount of the reported research projects going on. The lack of clinical evidence, however, does not seem to slow down the adoption of 3DP/AM technologies in Spanish hospitals, as more doctors are convinced of their benefits (40% of hospitals reported to conduct more than 30 surgical cases utilizing 3D simulation/AM post-covid). Moreover, while 40% believed to have a decrease in total AM activities post-covid, results showed an increase in both activity and number of hospitals using 3DP. Moreover, 40% reported an increase in device manufacturing and 20% reported having increased surgical and device manufacturing activities.

Despite its numerous uses and applications in healthcare, 3DP/AM technology still poses significant obstacles. The main challenge for the future will be to integrate 3DP into hospital activity with a scalable and sustainable model, training and budget allocation. Typical 3DP costs include the printer, printing materials, software, high-powered computers with outstanding resolution screens, post-processing equipment, facility costs (with additional fume hoods or ventilation system) and skilled personnel [54]. Additionally, human resources with dedicated time to undertake modeling require technical expertise and training, as well as compensation to deliver such services. According to Javanet al. [55], institutions with low budgets can save money by outsourcing printing to external providers. However, the availability of expert personnel during critical times such as the COVID-19 pandemic is also essential. Currently, manufacturers (in-hospital or external) must define a structured process and obtain the manufacturing license following the regional regulation based on the MDR for the production of 3D printed products as medical devices [56]. This may further impact manufacturing costs and, as a result, technology implementation [57].

In view of this study, the best-fit future model for implementing 3DP/AM technology in hospitals throughout Spain would be a combination of an in-house service and supplier outsourcing, the Mixed Model. Nevertheless, most of 3DP services and products are still not recognized by the National Health System, lacking a reimbursement scheme. Without a structured and recognized reimbursement process, 3DP will limit its potential adoption and impact.

Limitations of the present study

This work focused on exploring the level of maturity and state of adoption of 3D/AM technologies in Spanish hospitals through a qualitative, longitudinal study conducted in 2019, 2020 and 2022 and 2023, exploring the effect of the supervening COVID-19 pandemic. Few limitations of this study include the difficulties of developing a research project during the COVID-19 pandemic. The impact of the pandemic on hospital investments, innovation, and research capability may have influenced the findings. In addition, clinical assistance and the scheduling of medical visits and surgeries were also affected by the pandemic. This work provided an overview of the state of 3D adoption in hospitals and the Spanish healthcare system, however, a more detailed study would be required to investigate the impact of the technology on implementation costs, cost-effectiveness and on specific patient outcomes and experience.

Future perspectives of the present study

This work was developed to understand the maturity and adoption of 3DP technologies at the PoC in Spain. We expect to continue this research updating the results on a regular basis in the future. During the development of the project, the new Spanish 3D at the PoC group has been created within the framework of the Plataforma ISCIII Biomodelos y Biobancos network. We hope that this framework will help to continue the activity carried out.

Conclusions

This paper presents a qualitative, descriptive analysis of the maturity of 3D technologies in the Spanish healthcare system and its evolution from 2019 to 2023, accounting for the influence of the COVID-19 pandemic. Based on the reported experience of Spanish hospitals, it also proposes a model for implementation of hospital PoC manufacturing through 3D labs. According to the current study, the success in the implementation of the 3DP/AM technology is contingent on a well-defined and integrated process within the hospitals that includes a prioritization system as well as a strategic plan to accelerate its utilization. 3DP/AM in healthcare is an innovative technology and in Spanish hospitals/institutes, it is in a phase of exponential growth and productivity, being rapidly adopted especially for surgery planning and fabrication of patient-specific implants and surgical guides and mainly in bone-based specialties such as oral and maxillofacial surgery, traumatology and orthopaedics. As public procurement, budget, software, hardware and materials continue to improve, and regulatory standards become clearer, in-house 3D labs may be strengthened in the coming years. Additionally, public–private and industry-hospital collaborations, as well as further clinical trials, will serve to generate strong evidence and foster innovation. Mixed models with in-hospital manufacturing and outsourcing of some services to external providers seems to become the standard of care in Spain.

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s41205-024-00244-9.

Supplementary Material 1.

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Authors' contributions
Study conceptualization and design: A. Valls-Esteve, Rubén I. García, A. Bellmunt. Design and methodological advice: Eguiraun Harkaitze, J. Munuera, L. Krauel. Study development: Inés Jauregui, Cristina del Amo, A. Valls-Esteve, Rubén I. García, A. Bellmunt, N. Adell-Gomez. Results analysis: A. Valls-Esteve, Rubén I. García. Study monitoring and evaluation: Eguiraun Harkaitze, J. Munuera, L. Krauel. Manuscript writing: Inés Jauregui, Cristina del Amo, A. Valls-Esteve, Rubén I. García, A. Bellmunt, N. Adell-Gomez. Manuscript review: A. Valls-Esteve, Rubén I. García, A. Bellmunt, N. Adell-Gomez, Inés Jauregui, Cristina del Amo, Eguiraun Harkaitze, J. Munuera, L. Krauel.

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Data availability
No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate
Not applicable.

Consent for publication
Not applicable, as the manuscript does not contain data from any patient or individual person, but a survey on the adoption of 3D printing and bioprinting within Spanish hospitals. However, all participants provided informed consent to participate in the survey voluntarily since the following text was enclosed within the survey:
"Participation in the survey is entirely voluntary. Participants implicitly consent to using the information they provide by filling out the survey. The data will be treated as confidential, and the names of participants will not be identified. Your responses will only be used for the purpose stated in the study."
This unstated consent was considered sufficient, given the nature of the research and the fact that the participants are professionals rather than patients.

Competing interests
The authors declare no competing interests.

Author details
[1]Innovation Department, Hospital Sant Joan de Déu, Santa Rosa 39-57, 08950 Esplugues de Llobregat, Spain. [2]3D Unit (3D4H), Hospital Sant Joan de Déu, Santa Rosa 39-57, 08950 Esplugues de Llobregat, Spain. [3]Medicina i Recerca Translacional, Facultat de Medicina i Ciències de la Salut, Universitat de Barcelona, Carrer de Casanova, 143, 08036 Barcelona, Spain. [4]3D Printing and Bioprinting Laboratory, Biobizkaia Health Research Institute, Plaza Crucess/N, 48903 Barakaldo, Spain. [5]Department of Graphic Design and Engineering Projects, Faculty of Engineering in Bilbao, University of the Basque Country UPV/EHU, Plaza Ingeniero Torres Quevedo 1, 48013 Bilbao, Spain. [6]Innovation and Quality Department, Cruces U. Hospital, Plaza Cruces S/N, 48903 Barakaldo, Spain. [7]Fundació de Recerca Clínic Barcelona-Institut d'Investigacions Biomèdiques August Pi i Sunyer, Carrer Rosselló 149-153, 08036 Barcelona, Spain. [8]Diagnostic Imaging Department, Hospital de la Santa Creu i Sant Pau, Sant Antoni Maria Claret 167, 08025 Barcelona, Spain. [9]Department of Pediatric Surgical Oncology, Pediatric Surgery Department, SJD Barcelona Children's Hospital, Universitat de Barcelona, Passeig Sant Joan de Déu, 2, 08950 Esplugues de Llobregat, Spain. [10]Research Centre for Experimental Marine Biology & Biotechnology, University of the Basque Country PiE-UPV/EHU, Areatza Pasealekua 47, 48620 Plentzia, Spain. [11]Advanced Medical Imaging, Artificial Intelligence, and Imaging-Guided Therapy, Institut de Recerca Sant Pau (IR SANTPAU), Sant Quintí 77-79, 08041, Barcelona, Spain.

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References
1. Fox M, Peregrin T. 3-D printing: revolutionizing preoperative planning, resident training, and the future of surgical care. Bull Am Coll Surg. 2016;101(7):9–18.
2. Meyer-Szary J, Luis MS, Mikulski S, Patel A, Schulz F, Tretiakow D, et al. The role of 3D printing in planning complex medical procedures and training of medical professionals—cross-sectional multispecialty review. Int J Environ Res Public Health. 2022;19(6):3331. https://doi.org/10.3390/ijerph19063331.
3. Eltorai AE, Nguyen E, Daniels AH. Three-dimensional printing in orthopedic surgery. Orthopedics. 2015;38:684–7. https://doi.org/10.3928/01477447-20151016-05.
4. Huang W, Zhang X. 3D printing: print the future of ophthalmology. Invest Ophthalmol Vis Sci. 2014;55:5380–1. https://doi.org/10.1167/iovs.14-15231.
5. Obregon F, Vaquette C, Ivanovski S, Hutmacher DW, Bertassoni LE. Three-dimensional bioprinting for regenerative dentistry and craniofacial tissue engineering. J Dent Res. 2015;94:143S–152S. https://doi.org/10.1177/0022034515588885.
6. Groth C, Kravitz ND, Jones PE, Graham JW, Redmond WR. Three-dimensional printing technology. J Clin Orthod. 2014;48:475–85.
7. Valls-Esteve A, Adell-Gómez N, Pasten A, Barber I, Munuera J, Krauel L. Exploring the potential of three-dimensional imaging, printing, and modeling in pediatric surgical oncology: a new era of precision surgery. Children. 2023;10(5):832. https://doi.org/10.3390/children10050832.
8. Pereira HR, Barzegar M, Hamadelseed O, Esteve AV, Munuera J. 3D surgical planning of pediatrictumors: a review. Int J Comput Assist Radiol Surg. 2022;17:805–16. https://doi.org/10.1007/s11548-022-02557-8.
9. Marconi S, Pugliese L, Botti M, Peri A, Cavazzi E, Latteri S, et al. Value of 3D printing for the comprehension of surgical anatomy. Surg Endosc. 2017;31(10):4102–10. https://doi.org/10.1007/s00464-017-5457-5.
10. Lim KH, Loo ZY, Goldie SJ, Adams JW, McMenamin PG. Use of 3D printed models in medical education: a randomized control trial comparing 3D prints versus cadaveric materials for learning external cardiac anatomy: Use of 3D Prints in Medical Education. Anat Sci Educ. 2016;9:213–21. https://doi.org/10.1002/ase.1573.
11. Yoo SJ, Spray T, Austin EH III, Yun TJ, van Arsdell GS. Hands-on surgical training of congenital heart surgery using 3-dimensional print models. J Thorac Cardiovasc Surg. 2017;153:1530–40. https://doi.org/10.1016/j.jtcvs.2016.12.054.
12. McMenamin PG, Quayle MR, McHenry CR, Adams JW. The production of anatomical teaching resources using three-dimensional (3D) printing technology. Anat Sci Educ. 2014;7:479–86. https://doi.org/10.1002/ase.1475.
13. Langdon C, Hinojosa-Bernal J, Munuera J, Gomez-Chiari M, Haag O, Veneri A, et al. 3D printing as surgical planning and training in pediatric endoscopic skull base surgery-systematic review and practical example. Int J Pediatr Otorhinolaryngol. 2023;168:111543. https://doi.org/10.1016/j.ijporl.2023.111543.
14. Tappa K, Jammalamadaka U, Ballard DH, Bruno T, Israel MR, Vemula H, et al. Medication eluting devices for the field of OBGYN (MEDOBGYN): 3D printed biodegradable hormone eluting constructs, a proof of concept study. PLoS One. 2017;12:e0182929. https://doi.org/10.1371/journal.pone.0182929.
15. Dall'Ava L, Hothi H, Henckel J, Di Laura A, Shearing P, Hart A. Comparative analysis of current 3D printed acetabular titanium implants. 3D Print Med. 2019;5(1):15. https://doi.org/10.1186/s41205-019-0052-0.
16. Jin Y, Plott J, Chen R, Wensman J, Shih A. Additive manufacturing of custom orthoses and prostheses– a review. Proc CIRP. 2015;36:199–204. https://doi.org/10.1016/j.procir.2015.02.125.
17. Pourchet LJ, Thepot A, Albouy M, Courtial EJ, Boher A, Blum LJ, et al. Human skin 3D bioprinting using scaffold-free approach. Adv Healthc Mater. 2017;6(4):1601101. https://doi.org/10.1002/adhm.201601101.

18. Borovjagin AV, Ogle BM, Berry JL, Zhang J. From microscale devices to 3D printing: advances in fabrication of 3D cardiovascular tissues. Circ Res. 2017;120:150–65. https://doi.org/10.1161/CIRCRESAHA.116.308538.
19. Decker S, Ford J, Ching J. Patient-specific jaw splint for edentulous and partially edentulous patients presenting with jaw fractures. Int J Comput Assist Radiol Surg. 2014;9(Suppl 1):S258–9.
20. Tack P, Victor J, Gemmel P, Annemans L. 3D-printing techniques in a medical setting: a systematic literature review. Biomed Eng Online. 2016;15:115. https://doi.org/10.1186/s12938-016-0236-4.
21. Goyanes A, Det-Amornrat U, Wang J, Basit AW, Gaisford S. 3D scanning and 3D printing as innovative technologies for fabricating personalized topical drug delivery systems. J Control Release. 2016;234:41–8. https://doi.org/10.1016/j.jconrel.2016.05.034.
22. Weisman JA, Nicholson JC, Tappa K, Jammalamadaka U, Wilson CG, Mills DK. Antibiotic and chemotherapeutic enhanced three-dimensional printer filaments and constructs for biomedical applications. Int J Nanomed. 2015;10:357–70. https://doi.org/10.2147/IJN.S74811.
23. Weisman JA, Tappa K, Nicholson JC, Ballard DH, Wilson CG, D'Agostino H, et al. 3D printing antibiotic and chemotherapeutic eluting catheters and constructs. J Vasc Interv Radiol. 2015b;2(26):S12. https://doi.org/10.1016/j.jvir.2014.12.040.
24. Highlights of prescribing information. [Prescribing-information]. In SPRITAM. Aprecia Pharmaceuticals. 1999. p. 1–3. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/207958s000lbl.pdf.
25. Talanki VR, Peng Q, Shamir SB, Baete SH, Duong TQ, Wake N. Three-dimensional printed anatomic models derived from magnetic resonance imaging data: current state and image acquisition recommendations for appropriate clinical scenarios. J Magn Reson Imaging. 2022;55:1060–81. https://doi.org/10.1002/jmri.27744.
26. Tejo-Otero A, Fenollosa-Artés F, Uceda R, Castellví-Fernández A, Lustig-Gainza P, Valls-Esteve A, et al. 3D printed prototype of a complex neuroblastoma for preoperative surgical planning. Ann 3D Print Med. 2021;2:100014. https://doi.org/10.1016/j.stlm.2021.100014.
27. Martelli N, Serrano C, van den Brink H, Pineau J, Prognon P, Borget I, et al. Advantages and disadvantages of 3-dimensional printing in surgery: a systematic review. Surgery. 2016;159:1485–500. https://doi.org/10.1016/j.surg.2015.12.017.
28 Morgan C, Khatri C, Hanna SA, Ashrafian H, Sarraf KM. Use of three-dimensional printing in preoperative planning in orthopaedic trauma surgery: a systematic review and meta-analysis. World J Orthop. 2020;11(1):57–67. https://doi.org/10.5312/wjo.v11.i1.57.
29. Bastawrous S, Wu L, Strzelecki B, Levin DB, Li JS, Coburn J, et al. Establishing quality and safety in hospital-based 3D printing programs: patient-first approach. Radiographics. 2021;41(4):1208–29. https://doi.org/10.1148/rg.2021200175.
30. Medical Manufacturing Innovations. Physicians as manufacturers: the rise of point-of-care manufacturing. Southfield: SME; 2018. p. 20.
31. Printing at VHA. U.S. Department of Veterans Affairs. 2020. https://www.va.gov/INNOVATIONECOSYSTEM/assets/images/covid-images/3D-Printing-Overview-HIMSS_v2.pdf.
32. Am WPOC. Considerations for Point of Care (POC) 3D Printing |Thought Leadership|Knowledge|Exponent. 2019. p. 8–10.
33. Olivieri LJ, Su L, Hynes CF, Krieger A, Alfares FA, Ramakrishnan K, et al. "Just-In-Time" simulation training using 3-D printed cardiac models after congenital cardiac surgery. World J PediatrCongenit Heart Surg. 2016;7(2):164–8. https://doi.org/10.1177/2150135115623961.
34. Nacoti M, Ciocca A, Brambillasca P, Fazzi F, Pisano M, Giupponi M, Pesenti A, Valoti O, Cereda M. A Community-Based Model to the COVID-19 Humanitarian Crisis. Front Cell Infect Microbiol. 2021;11:639579. https://doi.org/10.3389/fcimb.2021.639579.
35. Bayona E. The pandemic strips the Spanish industry and places the country before the hallenge of its reconversion. Diario Público. https://www.publico.es/economia/covid-19-pandemia-desnuda-industria-situa-pais-reto-reconversion.html.
36. Pons-Òdena M, Valls A, Grifols J, Farré R, Lasosa FJC, Rubin BK. COVID-19 and respiratory support devices. Paediatr Respir Rev. 2020;35:61–3. https://doi.org/10.1016/j.prrv.2020.06.015FDA.
37. Wall S. 3D printing: a manufacturing revolution. 2016. https://shanewallcto.com/2016/12/28/3d-printing-a-manufacturing-revolution/.
38. 3D Printing of Medical Devices Washington DC: US Food and Drug Administration; 2020. https://www.fda.gov/medical-devices/products-andmedical-procedures/3d-printing-medical-devices.
39. Markets and Markets. 3D printing market by offering, process, application, vertical, technology, and geography - global forecast to 2024. 2019. Retrieved from https://www.marketsandmarkets.com/Market-Reports/3d-printing-market-1276.html.
40. Di Rosa L. 3D printing in maxillofacial surgery. In: 3D printing in plastic reconstructive and aesthetic surgery: a guide for clinical practice. Cham: Springer International Publishing. 2022. p. 75–84.
41. Sharkh HA, Makhoul N. In-house surgeon-led virtual surgical planning for maxillofacial reconstruction. J Oral Maxillofac Surg. 2020;78:651–60. https://doi.org/10.1016/j.joms.2019.11.013.
42. Krauel L, Valls-Esteve A, Tejo-Otero A, Fenollosa-Artés F. 3D-printing in surgery: beyond bone structures. A review. Ann 3D Print Med. 2021;4:100039. https://doi.org/10.1016/j.stlm.2021.100039.
43. Longeac M, Depeyre A, Pereira B, Barthelemy I, Dang NP. Virtual surgical planning and three-dimensional printing for the treatment of comminutedzygomaticomaxillary complex fracture. J Stomatol Oral Maxillofac Surg. 2021;122:386–90. https://doi.org/10.1016/j.jormas.2020.05.009.
44. Rubio-Palau J, Prieto-Gundin A, Cazalla AA, Serrano MB, Fructuoso GG, Ferrandis FP, et al. Three-dimensional planning in craniomaxillofacial surgery. Ann Maxillofac Surg. 2016;6(2):281–6. https://doi.org/10.4103/2231-0746.200322.
45. Rubio-Palau J, Ayats-Soler M, Albert-Cazalla A, Martìnez-Padilla I, Prieto-Gundin A, Prieto-Peronnet N, et al. Accuracy of virtually planned maxillary distraction in cleft patients-an evaluative study. Ann Maxillofac Surg. 2021;11(1):49–57. https://doi.org/10.4103/ams.ams_331_20.
46. Ventola CL. Medical Applications for 3D Printing: Current and Projected Uses. P T. 2014;39(10):704–11.
47. Itagaki MW. Using 3D printed models for planning and guidance during endovascular intervention: a technical advance. Diagn Interv Radiol. 2015;21:338–41. https://doi.org/10.5152/dir.2015.14469.
48. Matsumoto JS, Morris JM, Rose PS. 3-dimensional printed anatomic models as planning aids in complex oncology surgery. JAMA Oncol. 2016;2:1121–2. https://doi.org/10.1001/jamaoncol.2016.2469.
49. Trace AP, Ortiz D, Deal A, Retrouvey M, Elzie C, Goodmurphy C, et al. Radiology's emerging role in 3-D printing applications in health care. J Am Coll Radiol. 2016;13:856–62. https://doi.org/10.1016/j.jacr.2016.03.025.
50. Adams JW, Paxton L, Dawes K, Burlak K, Quayle M, McMenamin PG. 3D printed reproductions of orbital dissections: a novel mode of visualising anatomy for trainees in ophthalmology or optometry. Br J Ophthalmol. 2015;99:1162–7. https://doi.org/10.1136/bjophthalmol-2014-306189.
51. El Gregorio Marañón adapta un aparato para la apnea del sueño como Soporte Respiratorio Para Pacientes covid-19. Europa Press Madrid. europapress.es. 2020. Available at: https://www.europapress.es/madrid/noticia-gregorio-maranon-adapta-aparato-apnea-sueno-soporte-respiratorio-pacientes-covid-19-20200407122245.html.
52. Tino R, Moore R, Antoline S, Ravi P, Wake N, Ionita CN, et al. COVID-19 and the role of 3D printing in medicine. 3D Print Med. 2020;6:11. https://doi.org/10.1186/s41205-020-00064-7.
53. Pons-Òdena M, Valls A, Grifols J, Farré R, Lasosa FJ, Rubin BK. COVID-19 and respiratory support devices. Paediatr Respir Rev. 2020;35:61–3. https://doi.org/10.1016/j.prrv.2020.06.015.
54. Mason J, Visintini S, Quay T. An overview of clinical applications of 3-D printing and bioprinting CADTH issues in emerging health technologies. 2019. https://www.cadth.ca/dv/ieht/overview-clinical-applications-artificialintelligence.
55. Javan R, Herrin D, Tangestanipoor A. Understanding spatially complex segmental and branch anatomy using 3D printing. Acad Radiol. 2016;23:1183–9. https://doi.org/10.1016/j.acra.2016.04.010.
56. Clemens N. The European medical device regulation 2017/745/EU: changes and impact on stakeholders. J Clin Res Best Pract. 2018;14(9):1–7 http://data.europa.eu/eli/reg/2017/745/2020-04-24.
57. Van der Maaden T, Dam-Deisz WD, Vonk R, Weda M. Horizon scan of medical technologies: technologies with an expected impact on the organisation and expenditure of healthcare. 2018. https://rivm.openrepository.com/handle/10029/622204.

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