

CURRENT AND POTENTIAL APPLICATIONS OF 3D PRINTING IN A GENERAL HOSPITAL

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ABSTRACT

3D printing is widely touted as a game changer in medicine and surgery, paving the way for point-ofcare production of personalised medical devices. Nonetheless, to date, most reported applications of 3D printing in healthcare are restricted to specific scenarios in a few surgical disciplines, and little research exists on how 3D printing can be deployed more systematically beyond pioneer surgical departments. To understand the potential for 3D printing at a hospital level, we report the results of an interview study in a French general hospital. We analyse the current use of 3D printing and estimate the potential for new applications. We explore what share of these applications could be internalised, and what would be the organisational implications and the key success factors for an internal 3D printing unit. We find a large untapped potential for internal production of 3D printed products, spanning a much broader range of applications and hospital departments than what currently exists in the hospital. We then discuss important criteria to develop in-house 3D printing.

Keywords: Additive Manufacturing, 3D printing, Organizational processes, Biomedical design

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1 INTRODUCTION

With 3D printing, the fabrication of small series of objects can become economical. As a result, 3D printing has been extensively used for prototyping in multiple industries. In healthcare, it is seen as a way to produce personalised devices based on each patient's characteristics. With progress in technology and mounting evidence that 3D printed medical devices are clinically effective, 3D printing could become a key enabler of personalised healthcare. Promises, and expectations, are huge (Maruthappu and Keogh 2014). Applications range from printing simple, cheap products at the point-of-care, to making artificial bio-printed tissues and organs that could not be obtained otherwise (Lee 2016).

Reports of 3D printing in the healthcare literature mostly focus on a single category of application of 3D printing, such as preoperative planning or training, often in a single medical speciality. Yet, introducing 3D printing in a hospital is a decision that could open new opportunities for the whole hospital. Case studies of the use of 3D printing at the institutional level could help us understand what affects the decision to set up a 3D printing unit in a hospital. Aside from success stories and case series, we also lack the perspective of non-adopters in hospitals. Many questions remain unanswered: What do hospital professionals expect from 3D printing? Who is aware of the possibilities offered by this technology? Who uses it today? What for? What do non-users expect? Beyond what is possible, useful and desirable, what are the organisational implications of operating internally a 3D printing workshop? Such topics are important to support the development of 3D printing in healthcare.

After providing an overview of the current state of knowledge on the use of 3D printing in hospitals, we report the results of an interview study in a French general hospital. Our aim was to understand current applications of 3D printing, and to assess the potential for further developing the technology.

2 3D PRINTING IN HOSPITALS

2.1 Applications of 3D printing in hospitals

2.1.1 Surgical and clinical applications

3D printing is well established in surgery (Martelli *et al.* 2016). The most frequent application of 3D printing is surgeons using 3D-printed models to prepare and plan for an operation (Martelli *et al.* 2016). The models help surgeons appreciate the specific anatomy of the patient, in a way that 3D computer images cannot (Zheng et al. 2016). Surgeons also use 3D printing to make patient-specific implants and prostheses. This is common in dentistry, orthopaedics, and maxillofacial surgery. Outside of surgery and dentistry, 3D printing can be used to obtain personalised braces and orthoses (Daryabor *et al.* 2022), rehabilitation devices (Urquhart *et al.* 2022), or personalized supports for immobilising patients during delicate operations like radiotherapy (Robar *et al.* 2022).

In all medical fields where they have been used, 3D-printed devices were found to be clinically effective (Diment *et al.* 2017). In the disciplines where most research has been conducted, oral and maxillofacial surgery and musculoskeletal disciplines, 3D-printed devices often outperformed traditional options.

Producing 3D-printed models and devices requires additional preoperative time, and it comes at a cost (Martelli *et al.* 2016). However, it is hoped that better preparation and patient-specific devices could reduce operating time, which would reduce the cost of the surgery itself and balance the cost of 3D printing (Serrano *et al.* 2020).

2.1.2 Training applications

3D printing can be used to produce realistic models for training healthcare professionals. Simple models can be printed with desktop 3D-printers. With better equipment, more realistic imitations of human tissues can be produced, including dissectible models for surgical practice (Lemarteleur et al. 2021).

Studies of 3D printing in healthcare education are generally of low quality, but their results point towards better knowledge acquisition and retention when 3D-printed models are used instead of cadaveric models or computer images (Langridge *et al.* 2018; Ye *et al.* 2020).

2.1.3 Other applications

3D printing can be used outside of training and clinical practice, for research and development and problem-solving purposes. In particular, 3D printing is often a key technology in makerspaces. Little research exists on hospital makerspaces, but existing evidence indicates that healthcare professionals can take advantage of this infrastructure to solve routine problems that would otherwise be left unaddressed (Marshall and McGrew 2017; Svensson and Hartmann 2018; Scarmoncin et al. 2022). The return on investment is quick (Svensson and Hartmann 2018).

3D printing can also support the production of routine items when commercial alternatives are unsatisfactory or unavailable. For example, during the Covid19 crisis, 3D printers were used to produce facemasks, nasopharyngeal swabs, connectors, and even experimental ventilators (Aydin *et al.* 2021).

2.2 Operational model and impact of 3D printing in hospitals

Hospitals who want to start developing their own 3D printing capacity need to think carefully. Depending on their activity, different business and operational models are possible (Lanzarone *et al.* 2019). In terms of competences, various skills are needed to set-up, maintain and sustain 3D printing in a hospital: radiologists are needed to handle patient images, specialist physicians or surgeons to provide specifications, and technicians or engineers to handle the production and maintain the equipment (Sheikh et al. 2017). These competences can be internalised, or outsourced, leading to different operational, organisational and business models (Lanzarone *et al.* 2019):

- 3D printing could be done inside the hospital, or in another location. Even inside the hospital, production could be centralised or not, and this choice of location can make the service credible or not as a commercial operation (Polykarpou 2020).
- Regardless of the location, production could be managed by hospital personnel, or by a supplier.
- Similarly, the hospital could handle equipment maintenance, subcontract it, or let the equipment supplier manage it.
- The machinery could be owned by the hospital, by its supplier, or by a third party.
- The hospital could use the equipment only for its own needs, or it could also use this capacity to produce for other hospitals (and create a new economic activity).
- Finally, finding the right design process for 3D printed devices is important, since physicians do not have engineering training (Peel and Eggbeer 2016).

These choices need to be made with costs and benefits in mind. In surgery, the benefit of 3D printing is often derived from time saved during operations thanks to better preoperative planning and improved devices, making the operating theatre more efficient (Ballard *et al.* 2020). Developing highend 3D printing inside a hospital can also enable it to participate in innovative research and development projects (Calvo-Haro et al. 2021).

Finally, costs depend on applications. A Spanish hospital with a large in-house 3D printing operation reports that anatomical models, i.e. non implantable products, are the most demanded products (Calvo-Haro et al. 2021). Since these are not intended to be implanted, the constraints on the materials used are low, and in many cases, low-cost desktop 3D printers can be used (Kamio *et al.* 2018). With all these parameters, and a range of applications that evolves quickly, assessing the variety of actual benefits of 3D printing in an hospital is not straightforward.

2.3 3D printing in French hospitals

In France, in 2016, nine departments in eight hospitals reported that they possessed 3D printing equipment (Pierreville *et al.* 2018). Eight of these departments were maxillofacial surgery and one was orthopaedic surgery. Overall, they all estimated that running their 3D printing equipment cost them less than 15,000 euros per year.

3 CASE STUDY: 3D PRINTING IN A GENERAL HOSPITAL

We conducted a study of the use of 3D printing in a private, non-profit, general hospital in France. This hospital provides secondary care as well as specialised services. It participates in research programs and has a clinical research department. It is considering creating an in-house 3D printing unit.

Between May and June 2021, we conducted interviews with 18 people from 15 different departments (Table 1). We aimed for maximum variety (Cash *et al.* 2022) in departments, and were pointed to the

person most suitable and available to answer our questions in each. We asked interviewees about their knowledge of 3D printing, their current use of this technology and the potential they saw for it in their practice, what criteria they would use to assess the use of 3D printing (price, quality, mechanical properties, delivery lead time, regulatory conformity), and who they collaborated (or would collaborate with) for 3D printing. We also met prospective suppliers of 3D printing services or technology, and visited a makerspace in another hospital. We analysed the number of acquired medical devices produced through 3D printing. We counted the number of interventions per department that were compatible with 3D-printed devices and their proportion against the total number of interventions.

Finally, we estimated how in-house production could replace current uses. For maxillofacial surgery and a few other products (e.g., otorhinolaryngology implants), we used past orders of 3D-printed devices and made hypotheses on how many could be internalised. For other departments, we used the annual number of interventions and made hypotheses on how many devices used in these interventions could be produced through 3D printing, and of those, how many could be produced inhouse. Where statistics were not easily available (e.g., orthoses used by physiotherapists), we estimated the potential for 3D-printed devices through discussions with members of the corresponding departments.

Department	Interviewees								
Maxillofacial surgery and stomatology	Head of department								
Orthopaedic surgery	Surgeon								
Vascular and endovascular surgery	Surgeon								
Otorhinolaryngology (ear, nose, and throat)	Surgeon								
Physiotherapy	Head of department, neurological physiotherapist, orthopaedic physiotherapist								
Pneumology and thoracic oncology (2 sites)	Sleep technicians, pneumologist								
Gastroenterology and endoscopy	Physicians								
Vascular medicine and phlebology	Nurse coordinator								
Accidents and emergencies	Engineer								
Hospital administration	Chief operating officer								
Biomedical engineering	Head of department								
Anaesthesia	Head of department, anaesthetist								
Pre-clinical research	Head of department								
Extracorporeal circulation	Technician								

Table 1. List of interviewees.

4 **RESULTS**

4.1 Knowledge and current use of 3D printing

In most departments, interviewees did not know about 3D printing and its application to healthcare. The only departments where interviewees had previous knowledge of 3D printing were the R&D department, maxillofacial surgery, otorhinolaryngology, and orthopaedics.

Three departments ordered 3D-printed products from external suppliers between 2019 and 2021 (Table 2). 91% of orders came from maxillofacial surgery, with orthopaedics and otorhinolaryngology accounting for 2% and 7% of orders, respectively. Surgical guides (devices used to indicate where to incise or drill during a surgery) and implants constituted the bulk of the orders (90% combined).

		2019	2020	2021 (January to June)	Total
Number of products per year		125	75	36	236
Material	Silicone	28	6	0	34 (14%)
	Resin	31	3	4	38 (16%)
	Metal	38	32	20	80 (34%)
	Polymer	27	24	12	73 (31%)
	Other	1	10	0	11 (5%)
Product	Surgical guides	57	25	20	102 (43%)
category	Anatomical models	9	2	0	11 (5%)
	Implants	30	24	12	66 (28%)
	Prostheses	28	12	4	44 (19%)
	Moulds and others	1	12	0	13 (6%)
Department	Orthopaedics	0	4	0	4 (2%)
	Maxillofacial surgery	119	64	32	215 (91%)
	Otorhinolaryngology	6	7	4	17 (7%)

Table 2. Current uses of additively manufactured products used by the hospital's departments (printed in-house and externally sourced), between January 2019 and June 2021. Percentages were rounded and therefore do not always add up to 100%.

Table 3 shows how many interventions per year we found were compatible with the use of 3D-printed devices, per department (i.e., interventions that *could* have used 3D printed devices, where Table 2 shows how many were *actually* used in the hospital). Note that it is not possible to combine Tables 2 and 3 to calculate how many eligible interventions did use 3D-printed devices. Indeed, table 2 is a count of devices, whereas Table 3 is a count of interventions, and one intervention can require more than one device. We would need to dissect interventions more precisely to provide this finer-grained analysis.

Table 3. Number of interventions compatible with 3D-printed devices, and total number of	
interventions per department, per period. $N/A = data not available.$	

	2019		2020		2021 (January to June)				
	Compatible with 3D- printed	Total	Compatible with 3D- printed	Total	Compatible with 3D- printed	Total			
	devices (%)		devices (%)		devices (%)				
Orthopaedics	N/A	N/A	327 (12%)	2800	N/A	N/A			
Maxillofacial surgery	272 (42%)	644	256 (38%)	673	179 (41%)	436			
Otorhinolaryngology	64 (6%)	1103	50 (6%)	854	45 (8%)	594			

Two departments owned 3D-printers, but we do not know how many objects they produced with these machines. The maxillofacial surgery department had a stereolithography printer and a polyjet printer. The orthopaedics department had a fused deposition modelling printer. These machines were used to print anatomical models for training and preoperative planning. Indeed, these products represent a small portion of external orders (only 5%) whereas the literature suggests that they are a common product in surgical practice. They do not need to be qualified as medical devices, and therefore can be produced by anyone, using any type of technology. The machines were also used to produce surgical guides, which qualify as medical devices and require specific oversight.

4.2 Potential applications

4.2.1 Projected quantities of products obtained through 3D printing

Table 4 illustrates our estimation of the yearly number of products that could be additively manufactured. This accounts for existing demand (Table 2) and for products that are currently bought off-the-shelf but could be replaced by an internal 3D printing production. Depending on the application, we estimated that between 5% and 80% of the devices used in the hospital could be produced through

3D printing. Low ratios like 5% correspond to very technical and heavily regulated products, like metal implants. High ratios like 80% correspond to simpler products, like custom-made heel cushions.

Table 4. Projection of potential annual consumption of additively manufactured products. ^{*i*}: in-house prototyping, ^{*p*}: in-house production by the pharmacy, ^{*e*}: external production by subcontractor. +: potential application suggested, but not quantified.

											-	-		-	
	Maxillofacial surgery and stomatology	Orthopaedic surgery	Vascular and endovascular surgery	Otorhinolaryngology (ear, nose and throat)	Physiotherapy	Pneumology (2 sites)	Digestive endoscopy	Vascular medicine and phlebology	Accidents and emergencies	Biomedical engineering	Anaesthesia	Pre-clinical research	Extracorporeal circulation	Others	TOTAL
Clinical and surgical															-
applications															•
Surgical guides	25 ^p	+		3 ^p											28 +
Guides for															6 +
preforming	6 ^p														
prostheses		+													48
Implants	19 e	29 ^e		a n		0.0		a n							
Prostheses	6 ^p			2 ^p		8 ^p		3 ^p							19
Surgical		3 ^p													3
instruments Models for		31													56 +
preoperative															30 +
planning	6 ⁱ	50 ⁱ	+												
Respiratory mask	0	20													5
fitters										5 ⁱ					
Orthoses and					138			176						7 ^p	321
braces					р			р							
Cannulas						+					10 ^p				10 +
Training applications															
Visualisation and															
manipulation			+		8 ⁱ	1 ⁱ	1 ⁱ	+							10 +
Simulation				1 4 -				0.5			<u> </u>				25 +
training				14 ^p				8 ⁱ			3 ⁱ				
Other															
applications															2 .
Spare equipment					3 ⁱ										3 +
parts Custom non-	+				3	+			+			+			53
medical objects						5 ⁱ			16 ⁱ			4 ^e		28 ⁱ	33
Research			1 ⁱ			5			10			4 16 ⁱ		20 3 ⁱ	20
			1									10		5	+
Patient education					+		+								+

TOTAL	62	82	1	19	149	14	1	187	16	5	13	20	0	38	607
Total external I	19	29	0	0	0	0	0	0	0	0	0	4	0	0	52
Total in-house															154
prototyping (ⁱ)	6	50	1	0	11	6	1	8	16	5	3	16	0	31	
Total in-house															401
pharmaceutical														7	
(^p)	37	3	0	19	138	8	0	179	0	0	10	0	0		

In total, we estimate that 3D printing could be used for around 590 products per year. Many departments outside of maxillofacial surgery could benefit from it, e.g. physiotherapy (149 products, 25% of the total) or vascular medicine (187 products, 32%).

Examples of clinical and surgical applications include:

- Patient-specific surgical guides, implants and prostheses for maxillofacial surgery, otorhinolaryngology, and orthopaedic surgery
- Task-specific tools for orthopaedic surgeons
- Patient-specific support and braces for vascular medicine; cannulas for intensive care; foot, ankle, and wrist braces for physiotherapy; facemask fitting connectors

Examples of training applications include:

- Models for surgical training, e.g., for endovascular aortic aneurysm repair
- 3D-printed models for training advanced nurses in vascular medicine, bronchial and tracheal models for training pneumologists, realistic organ models (e.g., pancreas) for training endoscopists, complex cases for intubation training in anaesthesia
- Models of disabled patients for simulation training in physiotherapy (where most simulators today represent unaffected people)

Examples of other applications include:

- Spare parts or one-off prototypes for test benches for research
- Cannulas for extracorporeal blood circulation devices
- Replacing animal models with more realistic models, e.g., models for testing coronary stents that would reproduce the effect of calcification
- Spares for non-medical equipment (e.g., for exercise bikes used by physiotherapists), for medical equipment (e.g., valves and connectors for sleep apnoea equipment, spares for medical beds)

4.2.2 Technological and regulatory constraints

The needs of the departments correspond to different technologies. The exact technology for each application would require further investigation, but our current estimates are:

- Fused deposition modelling for surgical guides, braces, spare parts...: 324 to 437 units per year
- PolyJet for organ models: 33 units per year
- Selective laser sintering for organ models, orthoses, surgical tools...: 29 to 85 units per year
- Stereolithography for surgical guides, braces, and prostheses: 9 to 153 units per year
- Material jetting for prostheses, training models and cannulas: 27 units per year
- Silicone printing for organ models or prostheses: 0 to 19 units per year
- Powder bed fusion / selective laser melting for metallic implants: 2 units per year

The needs expressed by the departments also correspond to different levels of certification. From a regulatory perspective, some products would be medical devices (427 units, 72%), whereas others would not (163 units, 28%). Because of the combination of technological constraints (e.g., high investment for a small production on some technologies, like for titanium objects) and regulatory constraints, even if an in-house 3D printing unit was set-up, a small fraction of products would still need to be acquired externally (35 units, 6%). These products are mostly implants (along with a few very specific items, like cannulas for extracorporeal blood circulation). The rest could be produced in house. These products can be split between those that qualify as medical devices, which current regulations mandate must be produced under pharmaceutical supervision (401 units, 68%), and other products that do not require such supervision and could be produced directly in clinical departments (154 units, 26%).

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4.2.3 Performance criteria

When asked what added value 3D printing could bring, responses varied between departments. The most recurring performance criterion was to propose devices that better fit patient needs, and to improve patient comfort through better adjusted devices.

Interviewees also proposed economic criteria. The use of 3D printing for preoperative planning and surgical guides and tools could reduce the duration of surgeries, and therefore improve the efficiency of the operating theatre. Producing patient-specific devices would also save time on the adaptation of standard products. Some also hoped that internally produced devices would be cheaper than externally-sourced equivalents. Finally, one department mentioned patentable innovations as a key outcome of an in-house 3D printing unit, showing a drive to make this a revenue-generating activity.

Most units mentioned lead-time as a key performance criterion. If internal 3D printing is to be competitive, then products must be made available quickly. If it is quicker to adapt a standard product or order from an external supplier, then doctors might prefer these options.

From a quality perspective, some interviewees hoped that moving to an in-house production would enhance the mechanical and material properties of some products, as well as their fidelity in reproducing human organs and tissues. Nonetheless, others insisted than anything produced in-house had to be at least as safe as external options, and should be able to obtain CE marking.

On a less tangible level, some proposed that 3D printing could enhance communication between disciplines, by providing artefacts to support discussions.

5 DISCUSSION

5.1 Main findings

The use of 3D printed products is currently limited to few departments. Our study confirms that maxillofacial surgeons are the main users, as noted previously by Pierreville *et al.* (2018). Outside of maxillofacial surgery, orthopaedics and otorhinolaryngology, most specialties expressed curiosity and interest, but their limited knowledge made it hard to go beyond replicating current products or speculating about possible applications.

Nonetheless, and while we must remain cautious on this estimate, we think it would be possible to sharply increase the use of 3D printing, with up to 94% of the products made through in-house 3D-printing and the remaining 6% procured from external suppliers. Many departments could benefit from the technology. Still, key questions need answering.

First, which technologies should be internalised? The range of applications proposed by the interviewees requires multiple 3D printing technologies. Some technologies would be used for many products, e.g., fused deposition modelling. Others would be more marginal. For these low-quantity technologies, the investment would need careful evaluation.

Second, a decision would need to be made on the extent of centralisation of production. 68% of the products would require pharmaceutical supervision. For these products, there is no alternative but to set up a centralised 3D printing unit in the pharmacy. However, for the 26% of products that do not require pharmaceutical supervision and could be internalised, a decentralised strategy could be explored. This is important, because reactivity and delivery lead time were key performance criteria for many interviewees. Point-of-care manufacturing offers this flexibility. Yet, it would require skilled professionals in each department setting up a 3D printing capacity. Full centralisation could enable economies of scale, but if it was not reactive enough, a centralised unit may lose part of the demand.

Third, most interviewees considered 3D printing as a way to answer their own needs. Yet, at the hospital level, it makes sense to also consider the possibility to develop this activity into a business in its own right, by supplying other hospitals (Pourabdollahian and Copani 2017). Some hospitals already prepare chemotherapy doses for other hospitals (Dobish *et al.* 2018): one hospital bears the high cost of developing and maintaining a heavily regulated activity, and sells its excess capacity as a service.

Finally, most interviewees focused on using 3D printing to replace off-the-shelf products with locally produced, personalised devices. Yet, if innovation is also to be an ambition, more attention needs to be paid to design. Printing could be outsourced, but innovation really happens at the design stage. In this kind of applications, partnerships with engineering teams would be useful to codesign new products.

5.2 Strengths and limits of study, and perspectives for future research

We provide a case study of the development of 3D printing in a hospital, at the institution level. This has so far been poorly studied. Nonetheless, our study included a single hospital. Besides, our estimates have potentially large uncertainty.

It would be interesting to follow-up on this initial study, to produce a longitudinal case study of 3D printing deployment. Only few of these have been published, and they have yielded interesting insights on the key success factors of 3D printing deployment in hospitals (e.g., (Polykarpou 2020) on the importance of political factors and location decisions in sustaining a 3D printing initiative). Additionally, a cross-sectional study of practice would be useful. The last national study of 3D printing in French hospitals is 5 years old (Pierreville *et al.* 2018), so things may have changed. A new survey could include non-adopters, to better understand expectations of, and barriers to, using 3D printing.

Finally, a detailed financial evaluation would be useful to understand what a hospital could gain by setting up a 3D-printing unit. The set-up is likely to be expensive, and recurrent items like raw materials, software licenses, specialised staff and maintenance will cost as well. With stringent regulatory constraints on some products, interested organisations must carefully evaluate the cost-benefit balance. Observational studies of current organisational setups, using in-depth data collection, or even an experimental approach with some organizations using centralized, per department, outsourced, or no additive manufacturing could be interesting (notwithstanding the practical difficulties of organizing such a trial). Future studies could also investigate to what extent the possibilities of additive manufacturing affect the reasoning of healthcare professionals and patients in designing solutions to medical issues.

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