In-house 3d printing: why, when, and how? overview of the national french good practice guidelines for in-house 3d-printing in maxillo-facial surgery, stomatology, and oral surgery

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In-house 3D printing: why, when, and how? Overview of the national French good practice guidelines for in-house 3D-printing in maxillo-facial surgery, stomatology, and oral surgery

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Abstract

3D-printing is part of the daily practice of maxillo-facial surgeons, stomatologists and oral surgeons. To date, no French health center is currently producing in-house medical devices according to the new European standards. Based on all the evidence-based data available, a group of experts from the French Society of Stomatology, Maxillo-Facial Surgery and Oral Surgery (Société Française de Chirurgie Maxillofaciale, Stomatologie et Chirurgie Orale, SFSCMFCO), provide good practice guidelines for in-house 3D-printing in maxillo-facial surgery, stomatology, and oral surgery. Briefly, technical considerations related to printers and CAD software, which were the main challenges in the last ten years, are now nearly trivial questions. The central current issues when planning the implementation of an in-house 3D-printing platform are economic and regulatory. Successful in-house 3D platforms rely on close collaborations between health professionals and engineers, backed by regulatory and logistic specialists. Several large-scale academic projects across France will soon provide definitive answers to governance and economical questions related to the use of in-house 3D printing.

Keywords

Printing; Three-Dimensional; Maxillofacial surgery; Medical devices; Recommendations; guidelines;

Introduction

3D-printing is part of the daily practice of maxillo-facial surgeons, stomatologists and oral surgeons. Additive manufacturing allows the production of custom-made medical devices (such as, among others, cutting guides for orthognathic surgery), anatomical models and various types of surgical simulators [1]. Thanks to the recent development of accessible computer-assisted design (CAD) software and the decrease in the price of professional 3D-printers, in-house 3D platforms are currently being settled in a large number of hospitals. Despite these encouraging initiatives, in the vast majority of cases, surgeons using 3D-printing still rely on external services provided by specialized companies. No French health center is currently producing in-house medical devices according to the new European standards [2] (regulation 2017/745, effective since May 2021, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745&from=EN).

A group of experts from the French Society of Stomatology, Maxillo-Facial Surgery and Oral Surgery (*Société Française de Chirurgie Maxillofaciale, Stomatologie et Chirurgie Orale*, SFSCMFCO), led by Dr Roman Hossein Khonsari (Paris, France) under the supervision of Pr. Christophe Meyer (Besançon, France) has brought together all the evidence-based data available on the in-house use of 3D-printing in 2021. Based on the results of this workgroup, we provide expert recommendations answering the following questions:

- What are the technical and logistic challenges faced when implementing in-house 3D-printing?
- What are the regulatory issues raised by in-house 3D-printing, in particular regarding the production of medical devices?
- What are the current indications of additive manufacturing in maxillo-facial surgery, stomatology and oral surgery? What are the expected clinical benefits?

- What are the economic questions related to the use of in-house 3D-printing?

The detailed analysis of the literature and the relevant references are provided in the full version of the guidelines [3]. The current article provides an outline of the main conclusions of the larger scale full-text recommendations of our Society.

1. Technical and logistic issues related to in-house 3D-printing: the first steps

Implementing in-house 3D-printing requires the availability of high-resolution medical imaging and professional software and hardware, managed by trained technicians. In order to minimize the risk of error during design, manufacture and post-processing, every step of the procedure has to be submitted to adapted risk management and quality control, including taking into account long-term maintenance.

Beyond technical considerations, the in-house implementation of a 3D-printing platform implies local organizational changes, notably in term of staff training, recruitment, and logistic circuits. The success of an in-house platform relies on the close collaboration between imaging experts, biomedical engineers, pharmacists, and hospital management, with the constant inclusion of users (surgeons and other medical professionals) into strategic discussions [4].

Fused Deposition Modeling techniques (FDM) can be recommended for the production of standard anatomical models (for instance lower jaw or midface) [5–8]. Stereolithography (SLA) or polyjet can be recommended when more precision is required, and for the production of medical devices (surgical guides, splints) [9–11]. Importantly, printing accuracy and the mechanical properties of the produced devices can be influenced by printing parameters, the quality of post-processing, time between production and use, and even storage conditions. These fields are currently being scientifically investigated and may lead to changes in 3D-printing strategies in the future.

2. Regulatory issues: the main limitation to initiating in-house 3D-printing implementation

In the European Union, the 3D-printing of medical devices (MD) falls under the EU Regulation 2017/745, effective in France since May 2021 (https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745&from=EN) [2]. Importantly, anatomical models used for patient care (for instance for discussing surgical approaches) are considered as medical devices. In brief, regulation 2017/745 implies that hospitals wishing to 3D-print medical devices need to design a risk management plan, provide proofs for pre-clinical evaluation of the devices and account for clinical follow-up. Every step of the process has to rely on CE-marked products, including software. In France, the in-house production of medical devices has to be declared to the National Security Agency of Medicines and Health Products (*Agence Nationale de Sécurité du Médicament et des Produits de Santé*, ANSM), an administrative body part of the Ministry of Health (*Ministère des Solidarités et de la Santé*), who evaluates the conformity of the production process and the quality of the safety devices' (*materiovigilance*) measures. Regulatory considerations are a crucial step when building a 3D-printing platform aiming at producing medical devices; the current 2017/745 regulation is intricate enough to require systematic collaboration with regulatory specialists. To date, no health center in France has managed to match the requirement of 2017/745. While the safety concerns motivating such regulations are legitimate, they also lead to absurd situations impairing patient care. For instance, splints for orthognathic surgery are usually manufactured within maxillofacial surgery department by dental technicians. Dental technicians are unfortunately progressively disappearing from French academic maxillofacial surgery units due to economical restrictions in state-owned hospitals. A natural evolution of this traditional but endangered in-house manufacture would be the use of 3D-printing, a safer, faster and

more precise technique for splint production. Nevertheless, due to the requirements of 2017/745, the in-house production of splints using 3D printers is currently very complex, and most departments rely on externalized manufacture, an expensive option poorly adapted to the practical requirements of orthognathic surgery.

3. Current recommended use of in-house 3D-printing

A large number of studies recommend the use of 3D-printed anatomical models for teaching surgery and training surgeons, as an alternative to traditional bedside methods or as an addition to them. 3D-models can also be used for communication with patients, and for scientific exchanges between health professionals [12–17].

In clinical practice, 3D-printed models can be used for osteosynthesis plate conformation during all types of surgery, in order to increase precision and decrease the duration of procedures.

More precisely, in trauma surgery, plate conformation on 3D-printed models can be recommended in order to decrease surgery time and improve results. In this case, the model is considered as a medical device. Furthermore, and particularly for mandibular reconstruction using free fibula transfers, cutting guides can be recommended in order to reduce surgical durations and most probably improve morphological results [18–23]. Specific studies evaluating similar questions but focusing on in-house 3D-printing rather than externalized 3D-printing have led to similar conclusions [24–29].

In orthognathic surgery, 3D-printed models for plate conformation, 3D-printed splints, cutting guides and 3D-printed plates all currently benefit from sufficient precision to be recommended in standard clinical use, according to local availabilities [29]. These

personalized surgery approaches all improve precision and lower surgical times [19]. As previously mentioned, the benefits of personalized approaches in orthognathic surgery have been confirmed in the specific case of in-house 3D-printing [30–32].

For dental implant placement, 3D-printed placement guides printed using SLA can be recommended as an alternative to traditional approaches, with a preference for dental-borne guides [33–35].

In brief, in-house 3D-printed custom-made medical devices for personalized surgery can be currently recommended in trauma surgery, lower jaw reconstruction using free fibula transfers and dental implant placement. Further studies are published on a daily basis assessing the use of 3D-printing medical devices in other sub-specialties of our field, such as for instance in craniosynostosis surgery, free bone transfers other than fibula and orbital surgery – all with promising results – paving the way for a generalized use of personalized approaches for the surgery of craniofacial bones and jaws [3].

4. In-house 3D-printing: financial concerns

Due to the recent changes in EU regulations, it is currently difficult to precisely assess the costs related to the settlement of an in-house 3D-printing platform allowed to produce medical devices. Nevertheless, printing anatomical models and surgical guides can already be recommended based on the international literature, and lead to potential savings, mostly by reducing surgery durations [3].

When building an in-house 3D-printing platform project, economic feasibility relies on potential logistic and organizational costs, on the initial investment in printers, software and supplies, on the need for hiring new staff (maintenance, engineers) but also on the regulatory process required for producing medical devices [36–38].

In brief, in-house printing has been proven to be a source of savings for the production of anatomical models, but the question is on hold for the production of medical devices. Current exploratory projects across the country (for instance at Assistance Publique – Hôpitaux de Paris and Besançon University Hospital) will provide evidence-based answers to these issues in the near future.

Conclusion

In-house 3D printing will be part of standard practice in the near future. Currently, most of surgeons using additive manufacturing for producing anatomical models, medical devices and simulators still rely on externalized services. Technical considerations related to printers and CAD software, which were the main challenges in the last ten years, are now nearly trivial questions. The central current issues when planning the implementation of an in-house 3D-printing platform are economic and regulatory. Successful in-house 3D platforms rely on close collaborations between health professionals and engineers, backed by regulatory and logistic specialists. Several large-scale academic projects across France such as in Paris and Besançon will soon provide definitive answers to governance and economical questions related to the use of in-house 3D printing.

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