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Technical note

3D-printed suture guide for thoracic and cardiovascular surgery produced during the COVID19 pandemic

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ABSTRACT

Emergency 3D-printing of medical devices came out as a potential solution to tackle shortages during the COVID-19 pandemic. Manufacturing medical devices in small series within hospitals is an exciting perspective in crisis management. Health professionals and additive manufacturing technology are ready for this revolution but regulative adaptations are still required. Here we present the design and production of a suture guide for cardiac surgery as a case study for a 3D-printed medical device manufactured during the COVID-19 pandemic.

Introduction

Suture guides are used by cardiac and thoracic surgeons to fix sutures during critical procedures such as heart valve surgery. Existing models – Gabbay-Frater EGFS-10A (Teleflex, Morrisville, NC, USA) (Fig. 1a) – allow to fix 8 sutures on each rack. During the first COVID-19 wave in France, the supply chains for this device were interrupted and the Greater Paris University Hospitals (AP-HP), the largest hospital trust in Europe, had limited access to suture guides. Cardiovascular surgeons used to have suture guides available were experiencing difficulties to sort different sutures during their procedures and attach them to the borders of the operating field, leading to longer surgical times.

In order to manage shortages, AP-HP launched the 3D COVID project, which consisted in settling within a week (April 2020) a 3D facility inside a central university hospital [1,2]. 3D COVID was a private-funded (Kering, Paris, France) platform of 60 professional Fused Deposition Modeling (FDM) printers (J123 series, Stratasys, Eden Prairie, MN, USA) managed by 5 full-time engineers (BONE 3D, Paris), dispatching personal protection and medical devices for free to all Greater Paris public hospitals. All designs were open-source and available online on a dedicated website. Engineers were available 24/7 to interact with health professionals and design the devices required for facing the first pandemic wave. Over 30,000 devices were produced from April till June 2020, corresponding to over 100 different designs.

Regulative issues were central in this process, especially in the unprecedented context of an emergency production platform settled within a hospital. In response to the launch of 3D COVID, the French authority assessing medical devices (Agence Nationale de la Sécurité du Médicament, ANSM) released a framework allowing obtaining the status of medical device based on a reduced but demanding process,[1] following an earlier European Union recommendation also released in response to COVID-19.[2] In fact, while the rules for the 'in house' production of custom-made medical devices have been recently updated,[3] regulations guiding the

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[1] https://www.ansm.sante.fr/var/ansm_site/storage/original/application/5815bdac1a0df00eb1d08ba1a0e459fa.pdf
[2] Commission recommendation (EU) 2020/403 of 13 March 2020 on conformity assessment and market surveillance procedures within the context of the COVID-19 threat: https://eur-lex.europa.eu/legal-content/eng/TXT/PDF/?uri=CELEX:32020H0403&from=EN
[3] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Coun-

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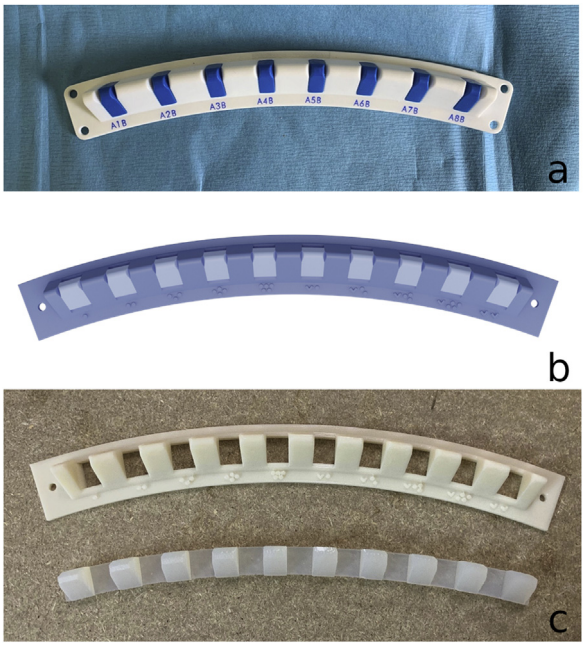

Fig. 1. (**a**) Gabbay-Frater EGFS-10A suture guide (Teleflex, Morrisville, NC, USA); (**b**) 3D design of a 10-plot in-house suture guide; (**c**) armature printed in ABS and silicon bar produced by injection in a 3D-printed ABS mould (not shown).

production of small series of 3D-printed medical devices in an emergency context were missing.

The accelerated design of the suture guide was a unique case study showing that medical devices can be practically produced in critical situations using dedicated crisis platforms. This report furthermore highlights the current limitations of this approach.

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Design (Fig. 1b) was performed on Fusion360 (Autodesk, San Rafael, CA, USA) and followed three requirements: (1) ability to retain and release sutures, (2) enough plots on the rack and (3) ability to fix the rack on surgical drapes.

The guide was composed of 2 elements (Fig. 1c): (1) 3D-printed armature in Acrylonitrile Butadiene Styrene (ABS) and (2) bar produced by silicon injection (Dropstil F556 10 shore A, Prevent Transformation, Châteauneuf-sur-Isère, France) into an ABS-printed mould. Layer thicknesses for the armature and the mould were 0.33 mm, with a filling density of 100 %. Printing time was 8 h for the mould and the armature. Cradiovascular surgeons required racks with 10 plots – two more than the Gabbay-Frater model. Both elements (ABS armature and silicon bar) were sterilized using Sterrad [3]. The design process, with numerous exchanges between engineers and cardiovascular surgeons, lasted less than 24 h.

The certification process required the assessment of the following items, that were submitted to ANSM: (1) **design and production report** – design process, software, printing process, traceability, sterilisation, conditioning, (2) **technical specifications**, (3) **assessment** – biomechanical testing and clinical evaluation and (4) **risk analysis**.

The suture guide was not accepted as a medical device by ANSM, who furthermore rejected all other submissions of 3D-printed medical devices designed during the first COVID-19 wave in France by other initiative from various academic centers. The rejection of the suture guide by ANSM was not based on its intrinsic characteristics, which were satisfactory, but on the production process: ANSM stated that an emergency platform set in a record time during the crisis had to be investigated further before being approved and could not be used for producing medical devices, even in a context of severe shortage. This statement implied that no certified medical device could be produced during the COVID-19 crisis by our platform based on the current regulations.

The guide was nevertheless produced in small quantities (100 copies) and used by several AP-HP surgery departments during the pandemic as a prototype, without any reported issue.

Discussion and conclusion

During the pandemic, an urgent need for protection and medical devices triggered the fast development of many 3D printing initiatives. Numerous medical devices were produced by independent makers and used in hospitals despite the lack of formal approval by regulative bodies [1]. The 3D COVID initiative was the first large-scale 'in-house' 3D-printing design and production platform ever settled in a hospital in response to a sanitary crisis. Our initial goal was to provide a safe interface for the production of both non-medical and medical devices, flexible enough to answer the needs of a large hospital trust on a daily basis.

Regarding the specific issue of medical devices, we unsuccessfully attempted to comply with the French regulations released by ANSM, even though these rules were designed to be adapted to the pandemic. As such, there is no current realistic regulatory framework allowing the production of medical devices in small series in emergency situations.

Similarly, all other French initiatives aiming at printing medical devices during the pandemic failed, due to staggered assessment procedures of production chains – a formal, unavoidable consequence of the crisis situation – and despite the reliability of the devices themselves.

Regulative work is still required before deploying approved emergency 3D-printing platforms in crisis zones for producing medical devices in small series. Solutions such as 3D COVID nevertheless already offer partial but reliable responses to supply chains issues: during the first pandemic wave, our platform produced a considerable number of protection devices and a wide range of medical material that were not formally considered as medical devices.

The future in this field is in the hands of regulative bodies, as both health professionals and 3D-printing technology are ready for a revolution in the production of medical devices.

Declaration of competing interest

No conflict of interest.

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