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An ad hoc three dimensionally printed tool facilitates intraesophageal suturing in experimental surgery

Daniel C. Steinemann, MD,[a,b] Philip C. Müller, MD,[a] Martin Apitz, MD,[a] Felix Nickel, MD,[a] Hannes G. Kenngott, MD,[a] Beat P. Müller-Stich, MD,[a] and Georg R. Linke, MD[a,c,*]

[a] Department of General, Visceral and Transplant Surgery, University Hospital of Heidelberg, Heidelberg, Germany
[b] Department of Surgery, St. Claraspital, Basel, Switzerland
[c] Department of Surgery, Hospital STS Thun AG, Thun, Switzerland

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ABSTRACT

Background: Three-dimensional printing (3DP) has become popular for development of anatomic models, preoperative planning, and production of tailored implants. A novel laparoscopic, transgastric procedure for distal esophageal mucosectomy was developed. During this procedure, a space holder had to be introduced into the distal esophagus for exposure during suturing. The production process and evaluation of a 3DP space holder are described herein.

Materials and methods: Computer-aided design software was used to develop models printed from polylactic acid. The prototype was adapted after testing in a cadaveric model. Subsequently, the device was evaluated in a nonsurvival porcine model. A mucosal purse-string suture was placed as orally as possible in the esophagus, in the intervention group with and in the control group without use of the tool ($n = 8$ each). The distance of the stitches from the Z-line was measured. The variability of stitches indicated the suture quality.

Results: The median maximum distance from the Z-line to purse-string suture was larger in the intervention group (5.0 [3.3-6.4] *versus* 2.4 [2.0-4.1] cm; $P = 0.013$). The time taken to place the sutures was shorter in the control group ($P < 0.001$). Stitch variance tended to be greater in the intervention group (2.3 [0.9-2.5] *versus* 0.7 [0.2-0.4] cm; $P = 0.051$). The time required for design and production of a tailored tool was less than 24 h.

Conclusions: 3DP in experimental surgery enables rapid production, permits repeated adaptation until a tailored tool is obtained, and ensures independence from industrial partners. With the aid of the space holder more orally located esophageal lesions came within reach.

* *Corresponding author*. Department of Surgery, Hospital STS Thun AG, Krankenhausstrasse 12, Thun 3600, Switzerland. Tel.: +41 33 226 26 63; fax: +41 33 226 29 26.
E-mail address: georg.linke@spitalstsag.ch (G.R. Linke).
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Introduction

There is rising interest in the use of three-dimensional printing (3DP) in medicine and particularly in surgical disciplines.[1-4] When 3DP was introduced more than 30 years ago, the technique was expensive and exclusive. Recently, however, 3DP has become affordable, and printers are commercially available. It has become possible to produce an individual product in a short amount of time. As a consequence, 3DP has gained importance in different fields of surgery for preoperative planning and better intraoperative orientation.[5-8] The 3D models are based on high-quality radiological images of complex anatomical structures. Furthermore, 3DP is used to create prototypes of individual implants. In preclinical experiments, surgical instruments such as trocars for laparoscopy, retractors, and implants such as ureteral stents have been printed and tested in porcine models and humans.[9,10]

However, there is scant literature on the production of prototypes for experimental surgery using 3DP. A novel laparoscopic surgical procedure aimed at resecting the distal esophageal mucosa with the aid of a circular surgical stapler. The procedure, intended for use in patients with dysplastic Barrett's esophagus,[11] involved placement of two submucosal purse-string sutures in the distal esophagus. The instruments and the stapler were introduced transabdominally and transgastrically. As the distal esophagus is narrow and the exposure of the mucosal esophageal aspect is critical, there was a need for a customized space holder to be inserted in order to expose the esophageal mucosa. The goal was to ensure sufficient exposure of the esophageal mucosa and achieve an adequate height to reach Barrett mucosa extensions. We describe herein the production process of a 3DP tool and the evaluation of the printed space holder in a porcine model.

Material and methods

The idea of the esophageal space holder was derived from existing anal retractors that expose the anal canal and enable the surgeon to place a purse-string suture in the mucosa of the anal canal. Such tools are used for stapled hemorrhoidopexy.[12] The prototype of the esophageal space holder was developed and evaluated in a multi-step process. Instrument requirements were determined by anatomical measurements in an *ex vivo* porcine esophageal specimen (Fig. 1) and the size of laparoscopic suturing instruments. The space holder needed to advance along the distal esophagus without tension and ensure good exposure of the mucosa. The aperture of the space holder had to be large enough to permit placement of sutures with laparoscopic instruments. This includes a surgical needle holder and the needle of a polypropylene monofilament suture (Surgipro II, Covidien, Dublin, Ireland) with 19 mm diameter. After 3DP (Fig. 2), prototypes (Fig. 3) were tested in *ex vivo* porcine esophageal specimens in a box trainer, and adjustments were made according to the need of the surgeon (Table 1).

The final space holder was evaluated in whole-body freshly euthanized German Landrace pigs that had previously been used for experimental pancreatic resection. Ethical approval was obtained from the local animal care committee in Karlsruhe, Germany (reference number: 35-9185.81/G-63/15). The animals had been sacrificed by an intravenous injection of 30 mmol KCl under general anesthesia before testing the space holder. A single surgeon (D.C.S.) performed all procedures in this experiment. He has extensive experience in laparoscopic surgery and holds a certificate in advanced laparoscopic surgery from the Swiss Association for Laparoscopic and Thoracoscopic Surgery.

Fig. 1 – Gastroesophageal junction in porcine cadaver model used for definition of the dimensions of the space holder. (Color version of figure is available online.)

Development of the prototype

The prototype was created using the computer-aided design (CAD) software Autodesk Inventor (Version 2016, Autodesk, San Rafael, CA) and Autodesk Meshmixer (Version 10.10.170, Autodesk). The 3D model was printed with the Ultimaker 2 printer (Ultimaker B.V., Geldermalsen, Netherlands) using polylactic acid (Ultimaker). The 3D printer works by fused filament fabrication, distributing and adding melted polylactic

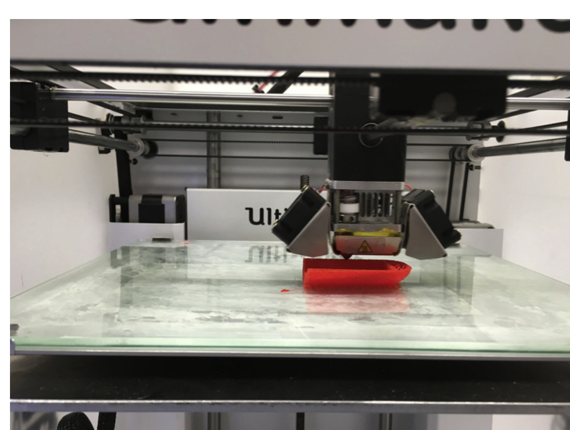

Fig. 2 – 3D printing of the designed retractor using Ultimaker 2 printer. (Color version of figure is available online.)