

Original Research Article

Evaluating benefits of patient-specific 3D-printed phantom designs in visceral surgery

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Abstract: Scope of the presented study was to evaluate the suitability and usefulness of ten different 3D-printed patient-specific organ phantoms designs, created with SLS and Polyjet® additive manufacturing methods. 17 physicians of the Pius-Hospital; Oldenburg and the Gesundheit Nord (GeNo); Bremen were interrogated for their assessment of different organ phantoms designs within the framework of a formative evaluation. The participants preferred dyed phantoms with a scale of 50% of the original.

I. Introduction

Avoiding operative failure in clinical practice represents one of the main goals of pre-operative planning. To the current juncture generally, CT and MRT images represent the state-of-art, even though partially further advanced visualization techniques are set into place. Those technologies were able to improve operative planning in many cases [1].

With regard to particularly complex interventions or anatomical anomalies, further planning aids would be desirable enabling to convey a better understanding of spatial relations, the exact anatomical conditions and render haptical feedback. Such models might in the future also impart a better understanding of complex anatomies in training and education.

I.1. Design considerations

With the rapid progress in 3D-printing technologies, planning- and educational models, with the purpose to improve anatomical understanding and convey the correct haptic feedback, have become realizable and are already deployed in many hospitals worldwide [2].

For their creation, a huge variety of 3D-printing technologies, featuring a differentiated profile of advantages and disadvantages, is at hand. Various possibilities of hybrid manufacturing, combining different

methods to balance pros and cons, open up further potential. Therefore, a broad field of different design possibilities for patient-specific organ models arises.

As the design of patient-specific organ models is still in the early stages, a fixed standard for phantom design is not yet in sight. Developing the most reasonable, appropriate, effective, and realistic phantom designs for the corresponding problems will be the task and objective of the upcoming years.

Experimenting with different designs was a major topic of the VIVATOP project. Two additive manufacturing technologies respectively the combination of the two were subject to different design exercises: the Polyjet® technology, which enables both colorful and transparent models, and the SLS process, constituting a powder-based process. As material within SLS, hard PA12 (Polyamide), as well as softer TPU (thermoplastic polyurethane), were used. Both powder-based materials can be dyed after printing. Examples of different types of models are given in Figure 1.

The scope of the designs was to investigate different pathologies in the realm of visceral surgery, focusing on complex liver, pancreas, and hernia anatomy.

Depending on the pathology the main focus of interest differed. To highlight the crucial areas and enable detailed

examination, an adequate phantom design has to be chosen. Communicating the crucial objective of the phantom between the physicians and the 3D-printing designers was a central issue within the process.

This information is essential for designing and choosing an appropriate AM-process and phantom design. Based on that, certain organ areas can be emphasized or omitted, and critical details can be treated with higher diligence. Short sketchy descriptions within the segmented CAD pictures proved to be effective in this context. Standardizing and optimizing this communication process is a key challenge.



Figure 1: Different additively manufactured organ models: transparent liver, Polyjet® scale 50% (above left); liver and pancreas phantom, SLS, PA12 dyed in scale 100% (above right); Hernia phantom, Polyjet®, scale 30% (mid left); liver phantom, SLS, soft TPU dyed, scale 100% (mid right); Buehler Anastomosis, Hybrid SLS and Polyjet®, scale 100% (Below)

The ten featured phantom designs used for the study described below reflect this process: Whereas Polyjet® enables to display a vast amount of complex details within a transparent body, the latter are kind of trapped within,

since e.g. 3d-printed arteries outside this transparent “shelter” tend to be very fragile (e.g. Fig. 1 upper right panel). This led in the case of the “Buehler Anastomosis” (Fig. 1 bottom panel) to a hybrid design, combining SLS and Polyjet® in a single phantom. Another factor can be scale limitations or lens effects within Polyjet®. If a 100% scaled phantom is advantageous SLS is the process of choice.

For depicting liver segments at glance SLS can be also an elegant tool. Last but not least using TPU within SLS enables to give soft haptical feedback. Aim of the underlying study was to assess the different aspects of those patient-specific phantom designs with potential later users on a broader perspective. Therefore a questionnaire study was conducted with 17 physicians using 10 different designs.

II. Study framework and design

The target was to retrieve insights on the phantom’s comprehensibility, whether crucial aspects are visible to the observer e.g. the main pathology focus, and to deduct future design decisions. The questionnaire was developed based on a literature review and in a collaboration of surgeons and 3D-printing experts. Besides demographic questions, the participants on one side should consider for which application fields they would employ 3D-printed models.

On the other side, they should evaluate on a 5-point Likert-Scale ranging from “I fully agree” to “I totally disagree”, whether 3D-printed phantoms generally speaking provide a benefit: to gain a better comprehension of the anatomy, affect surgery results e.g. better understanding of resectability, effect surgery duration, avoid complications or provide other benefits in the different phases of the treatment (pre- or intraoperatively). Furthermore, they were asked to rank the ten exemplary organ phantoms regarding their information value, their clarity, and practicability respectively their manageability. Additionally, the preferred size category of the phantoms ranging from a scale of 30%, 50%, 75% to 100% of the original as well as the potential risks were interrogated. To check the intelligibility of the questionnaire, the questions were presented to two ingenious surgeons upfront.

The participants were recruited during team meetings and by direct approach. Inclusion criteria were good knowledge of the upper abdominal anatomy, verified by their expertise. Participation was voluntary.

The participants were given up to 10 minutes to examine the numbered models displayed on a table, left alone. Meanwhile, they should comment on their impressions (Thinking-aloud method). The comments were shortly summarized by the study staff. Following that, the participants had to fill out an online questionnaire (LimeSurvey), which took about 20 minutes.

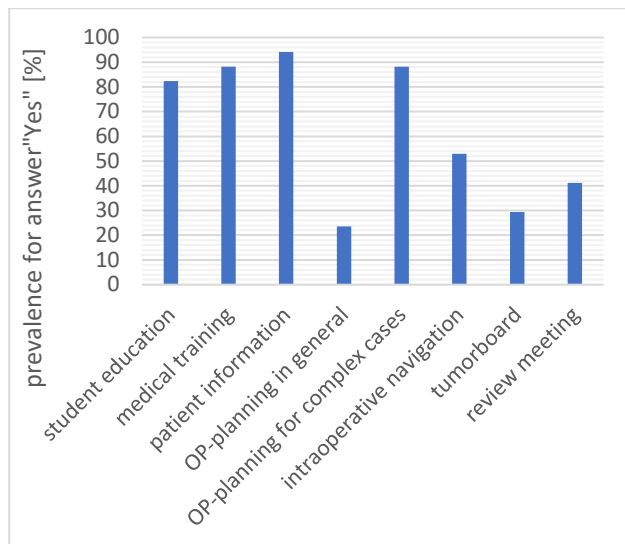


Figure 1: Distribution of responses, on adequate application fields of patient specific 3D-printed organ phantoms.

The evaluation of the questionnaires was executed computerized by means of SPSS 27 descriptive statistics.

III. Results and discussion

Overall, the participants consisted of overall 7 female and 10 male surgeons (8 chief- and senior physicians, 3 specialists, 4 assistant physicians and 2 practical year students). All participants had little to no experience at all with patient-specific organ phantoms.

As the main application areas for the 3D-printed patient-specific organ phantoms, most participants viewed the area of education and training, patient information, and planning of complex cases (Tab. 1). All participants agreed that the comprehension of anatomical relationships improves through 3D-prints whereas improvement with regard to the reduction of complications or surgery time was called into question.

Questioning information value, clarity and practicability respectively manageability resulted in relatively heterogeneous responses. The hiatus hernia (Fig.1, lower left panel) a similar liver block model, and the undyed segmented liver phantom ranked worst, (mean value between 5.1 and 7.5 in the ranking, where 1 was the best and 10 the worst model).

With regards to information value and clarity the dyed segment phantom scored best (Fig.1: mid right panel; mean values between 1.9 respectively 2.6). With respect to manageability the transparent liver phantom was favoured (mean value 2.6; Fig. 1 upper left panel). Nearly half of the participants (n=8) preferred phantoms on a scale of 50%, 5 preferred phantoms on 75% and 4 in 100% of the original size of the organ.

As the main risk the additional planning effort and thus a possible delay was identified (10 out of 17 respondents). Another consideration was the possible deviation between phantom and reality (7 from 17 respondents). One

participant had concerns about the sustainability of the process. Whether 3D-printed models take root in preoperative planning remains to be seen, not least as they have to compete here with other visualizations technologies [3], [5]. Having said that, a comprehensive and effective design of the 3D-printed phantom gets even more important. True added value can be carried in applications where haptical feedback is crucial or offers great advantages [4], [6]. This is without a doubt the case in education and training models designed to practice manual skills on a realistic level.

III. Conclusions

Patient-specific 3D-printed phantoms are mainly regarded to be conducive to education and training, patient information, and planning of complex interventions, as they have the potential to improve the comprehension of anatomical relations. Their impact on the postoperative outcome is considered to be minor. Dyeing the phantoms seems to be an important factor as colorful phantoms consistently are referred to as being significantly more useful than colorless variants. A scale of 50% to 75% of the original size of the organ seems to be sufficient, which can be advantageous to achieving significant cost savings,

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AUTHOR'S STATEMENT

Conflict of interest: H. Nopper, U. S. Freitas, T. Lueck, and F. Karayagiz are employees of cirp GmbH, Department Research and Development, Heimsheim, Germany. D. Salzmann is employee of apoQlar GmbH, Hamburg, Germany. Informed consent: Informed consent has been obtained from all individuals included in this study. Ethical approval: The research related to human use complies with all the relevant national regulations, institutional policies and was performed in accordance with the tenets of the Helsinki Declaration, and has been approved by the authors' institutional review board or equivalent committees are to be mentioned. Otherwise: Authors state no conflict of interest.

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