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Validity of a three-dimensional printed dry lab pancreaticojejunostomy model in surgical assesment

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29

Abstract

Objectives. Until now, there have been few tools to evaluate whether a surgeon was technically ready to perform a safe pancreaticojejunostomy (PJ). In the current study, we aimed to evaluate whether a three-dimensional model could mimic a real surgical situation and distinguish between surgeons of different levels of experiences.

Methods. A three-dimensional PJ dry laboratory model was printed. And eight experienced pancreatic surgeons were enrolled to evaluate the appearance and tactile sensation of the model. Fifteen surgeons with various levels of pancreatic experience performed a PJ on the three-dimensional model. And the proficiency was scored. Additionally, the time of manipulation and the NASA Task Load Index (NASA-TLX) scores were recorded for each operation.

Results. Compared with real surgical situations, this model had similar appearance (3.96 ± 0.55 out of five points) and tactile sensation (3.85 ± 0.46 out of five points) according to the expert evaluation. Additionally, the chief surgeon group scored the best in proficiency (based on NASA-TLX scores and operative time) and there were statistical differences for performances among surgeons of various levels ($p < 0.05$).

Conclusion. The three-dimensional PJ model could mimic a real surgical situation and can distinguish between surgeons of different levels of experiences.

Key words: Three-dimensional PJ model, validity, surgical assesment, appearance, tactile sensation

Strengths and limitations of this study

1. The three-dimensional PJ model has good tactile sensation and appearance.

2. The three-dimensional PJ model could mimic a real surgical situation and can distinguish between surgeons of different levels of experiences. And it can be used as a portable teaching and learning tool, which is easier to store, and can be used by students in the office or even at home.

3. This study selected softer silicone material to simulate the pancreatic parenchyma and its hardness was still slightly higher than that of the pancreatic tissue.

4. This study chose fifteen surgeons performed a PJ on the three-dimensional model. The sample size could be further expanded in future studies.

Introduction

A pancreaticojejunostomy (PJ) is one of the most challenging procedures in general surgery and a lack of proficiency and experience in doing this procedure may lead to postoperative pancreatic leakage, hemorrhage, or even death [1, 2]. Advanced techniques, such as 3D printing, have been widely used in the field of surgery for the purpose of education and preoperative designing, however, there are few reports indicating that they could be used as a tool to evaluate surgical competency.

According to Szasz and colleagues [3], due to work hour restrictions, limitations of operating room accessibility, and increased litigation against physicians, the educational opportunities of surgeons have dramatically decreased. Based on this status quo, the Accreditation Council for Graduate Medical Education [4], the Royal College of Physicians and Surgeons of Canada [5], and many others worldwide have developed training programs to improve surgical skills.

Compared with traditional pancreaticoduodenal surgery training methods, there remains a lack of an effective physical model to help distinguish between pancreatic surgeons of different levels and to roughly assess whether pancreatic surgeons are prepared. As an emerging technology, 3D printing technology has been widely used in the medical field [6] and has been broadly studied and reported on in a book on the training and application of simulation models in robotic gynecological surgery [7]. Additionally, 3D printed models are expected to be used in the future as one of the methods of pancreatic surgery training, reducing learning costs and helping young doctors improve surgical techniques. In the current study, experts in the field of pancreatic surgery were invited to evaluate the appearance of the model. We aimed to evaluate whether a three-dimensional model could mimic a real surgical situation and distinguish between surgeons of various levels of experience.

Materials & Methods

1 3D-Printed Dry Lab PJ Model Production

The 3D printed dry lab PJ model primarily contained the pancreas and small intestine and was printed using a dual-head silicone printer. The Sir Run Run Shaw hospital granted Ethical approval to carry out the study within its facilities (See appendix *S1*). First, the Computed

Tomography (CT) data was collected in the Digital Imaging and Communications in Medicine (DICOM) format, with 1mm thick slices. The E3D digital medical modeling software V17.06 (Central South E3D Digital Medical and Virtual Reality Research Center, China) was used for boundary segmentation and 3D reconstruction and the model structure was streamlined according to the specific application requirements (*Figure 1*). The open source slicing software Cura 4.4.1 (Ulitmaker, USA) was used for slicing the 3D printing. The material was made of silicone specialized for 3D printing. The silicone material used for the pancreatic parenchyma was pink, with a tear strength of 4.8N/mm and a tensile strength of 2 MPa. The silicone material used for the pancreatic duct was white, with a tear strength of 5.2N/mm and a tensile strength of 1.8 MPa. The silicone material used for the small intestine was red, with a tear strength of 5.2N/mm and a tensile strength of 1.8 MPa.

2 Patient and public involvement

Patients and public were not directly involved in the design of this study.

3 Evaluation scale design

The expert evaluation scale of the model was comprehensively designed with reference to the relevant literature [8-10], using a 5-point Likert scale (See Appendix *S2*). The main coverage areas include: the amount of pancreatic surgery the expert had conducted, the evaluation of the overall settings of the 3D printed model, the evaluation of the appearance, size, and tactile similarity of the 3D printed model, and a comprehensive evaluation of the 3D printed pancreas model for clinical and teaching work.

The model's operation rating scale was designed with reference to the relevant model training literature [11], which primarily evaluates the depth perception, force/tissue handling, dexterity, coordination of the arms, and the efficiency of the chief surgeon (attending), first assistant (fellow), and observer (resident) physicians in pancreatic surgery.

The functional psychology scale of the model refers to the NASA Task Load Index (NASA-TLX), which primarily evaluates the mental load of pancreatic surgeons. The significance of the related indices is reported in several articles as it relates to surgical model training [12, 13].

4 Assessment scale issuance

The current study selected eight pancreatic surgery experts and sent the 3D printed pancreas models and distributed the 3D printed pancreas model evaluation scales to each of the experts.

Experts in pancreatic surgery were invited to participate in the evaluation from all aspects according to the scale and to make professional recommendations.

Fifteen chief surgeon (attending), first assistant (fellow) and observer (resident) physicians from the general surgery department were selected and issued basic information collection forms. And all surgeons in this section were obtained written informed human participant consent. Model training operations were performed after teaching the procedures. The entirety of the operation was recorded on video and the proficiency was scored by two pancreatic experts who were blinded to the identities of surgeons. After the operation, all personnel were issued a NASA-TLX scale to assess the mental load of the operation.

5 Operation procedures

The operation procedures used in the current study refer to the classic Cattell-Warren anastomosis method. The operation steps are detailed in *Figure 2*.

6 Data analyses

The current study collected statistics on the overall settings and appearance, size, and tactile similarity of the 3D printed pancreas model and the functional evaluation indicators of the model (primarily including the surgical operation score, operation time, and NASA-TLX score). Microsoft Excel (2016) was used to establish the scoring and evaluation table of each item in the evaluation scale by experts. SPSS (Version 20.0, SPSS Inc, Chicago, IL, USA) software was then used for the subsequent data analyses and processing. All tests were 2-tailed and $p < 0.05$ was considered statistically significant. The results from the statistical analyses were entered into Graphpad Prism 7.0 and related charts were drawn. Each score was calculated by the mean ± standard deviation.

Results

1 Pancreatic surgery experts' anatomical evaluation of the model

The research invited eight pancreatic surgery experts to conduct a comprehensive evaluation. All experts had performed more than 20 cases of pancreaticoduodenectomy within the prior year and four had performed more than 100 cases of pancreaticoduodenectomy in the prior year. The model obtained an overall evaluation of 4.38 ± 0.74 (*Figure 3*) and all experts gave greater than "more similar" (3 points) as their evaluation. The evaluation of the model is divided into two parts: appearance and tactile sensation and this study also evaluated its comparison with a Whipple surgery and animal models. The current study also invited experts to make assessments on their recommendation of using this model for teaching. The results are presented below.

1.1 Appearance

The overall appearance of the 3D printed PJ dry laboratory model was evaluated at 3.96 ± 0.55. The appearance of the pancreatic parenchyma was evaluated at 4.13 ± 0.64, the appearance of the pancreatic duct was evaluated at 4.00 ± 0.53, and the appearance of the intestinal canal was evaluated at 3.75 ± 0.46.

1.2 Tactile sensation

The overall tactile evaluation of the 3D printed PJ dry laboratory model was evaluated at 3.85 ± 0.46. The elasticity of the model was evaluated at 3.88 ± 0.45 and the elasticity of the pancreas parenchyma, pancreatic duct, and intestinal duct of the model were equivalent. The ease of tearing of the model was evaluated at 3.83 ± 0.48 and the ease of tearing of the intestinal duct of the model was slightly higher than the other two parts, at 4.00 ± 0.53. The suture breakthrough of the model was evaluated at 3.83 ± 0.48 and the pancreatic parenchyma of the model was slightly lower than the other two, at 3.88 ± 0.35.

1.3 Education

All eight experts (100%) agreed that the 3D printed laboratory model of the PJ could/should be used for teaching.

2 General information of pancreatic surgeons

Five attendings, five fellows, and five residents were invited to participate in the current study. Their general information is shown in Table 1. There were significant differences in the working years of the three groups of surgeons (13.40 ± 3.21 vs. 6.00 ± 1.22 vs. 2.60 ± 1.82, respectively, $p < 0.001$), in which all attendings had worked for more than eight years and all residents had worked five or less years. The three groups of surgeons had a statistically significant difference in the number of cases of pancreatoenterostomy as the lead surgeon ($p = 0.008$) and the number of cases of pancreaticoduodenectomy as the first assistant ($p = 0.014$). All pancreatic surgeons

176 who participated in the study were right-handed and there was no significant statistical difference
177 between the three groups of surgeons in simulation training ($p = 0.287$), nor was there any
178 significant statistical difference between the three groups of participants in Virtual Reality(VR)
179 surgical training ($p = 0.562$).

180 **Table 1. General information of attendings, fellows, and residents.**

	Attendings (n=5)	**Fellows (n=5)**	**Residents (n=5)**	**P-value**
Years of working	13.40±3.21	6.00±1.22	2.60±1.82	<0.001***
Cases of Pancreatoenterostomy as lead surgeon				0.008**
0	0/5 (0%)	4/5 (80%)	5/5 (100%)	
< 10	1/5 (20%)	1/5 (20%)	0/5 (0%)	
≥ 10	4/5 (80%)	0/5 (0%)	0/5 (0%)	
Cases of Pancreatoenterostomy as first assistant				0.014*
0	0/5 (0%)	0/5 (0%)	2/5 (40%)	
< 10	0/5 (0%)	3/5 (60%)	3/5 (60%)	
10-50	0/5 (0%)	1/5 (20%)	0/5 (0%)	
> 50	5/5 (100%)	1/5 (20%)	0/5 (0%)	
Number of right handers	5/5 (100%)	5/5 (100%)	5/5 (100%)	1.000
Number who have participated in simulation training	1/5 (20%)	0/5 (0%)	2/5 (40%)	0.287
Number who have participated in VR operation training	1/5 (20%)	0/5 (0%)	1/5 (20%)	0.562

181 VR: Virtual Reality (*$p < 0.05$, **$p < 0.01$, ***$p < 0.001$

182 **3 Model functional evaluation**

183 The functional evaluation of the 3D printed PJ dry laboratory model included three outcome
184 indicators selected for evaluation, including operation time, operation score, and the NASA Task
185 Load Index (NASA-TLX score). Details are shown in Tables 2 and 3.

186 **Table 2. The operation time, operation score, and the NASA-TLX score of three groups.**

	Attendings (n=5)	Fellows (n=5)	Residents (n=5)	P-value
Operation time	569.20±170.01	797.80±186.40	1254.80±341.50	0.003**
Operation score	18.80±0.84	17.20±0.84	14.40±1.34	<0.001***
NASA-TLX score	265.40±99.02	261.60±86.41	412.80±79.74	0.031*

187 *$p < 0.05$, **$p < 0.01$, ***$p < 0.001$

3.1 Operation time

There were significant statistical differences in the operation time of the three groups of researchers (*p* = 0.003), as shown in *Figure 4A*, where the operation time of the resident group was significantly longer than fellow group (1254.80 ± 341.50 vs. 797.80 ± 186.40, *p* = 0.028) and the attending group (1254.80 ± 341.50 vs. 569.20 ± 170.01, *p* = 0.009), but there was no significant statistical difference between the attending group and the fellow group (569.20 ± 170.01 vs. 797.80 ± 186.40, *p* = 0.175).

3.2 Operation score

The operation time for the three groups of researchers was statistically significant (*p* < 0.001), as shown in *Figure 4B*, where the operation score of the attending group is significantly higher than fellow group (18.80 ± 0.84 vs. 17.20 ± 0.84, *p* = 0.023) and the resident group (18.80 ± 0.84 vs. 14.40 ± 1.34, *p* = 0.008).

3.3 NASA-TLX score

The NASA-TLX mental load scores of the three groups of researchers were statistically significantly different (*p* = 0.031), as shown in *Figure 4C*. The NASA-TLX score of the attending group was not significantly different from that of the fellow group (265.40 ± 99.02 vs. 261.60 ± 86.41, *p* = 0.754), while the NASA-TLX score of the resident group was significantly higher than fellow group (412.80 ± 79.74 vs. 261.60 ± 86.41, *p* = 0.028) and the attending group (412.80 ± 79.74 vs. 265.40 ± 99.02, *p* = 0.047).

Table 3. P-value of the pairwise group comparison.

	A vs. F	A vs. R	F vs. R
Operation time	0.175	0.009**	0.028*
Operation score	0.023*	0.008**	0.09
NASA-TLX score	0.754	0.047*	0.028*

A:Attending group; F:Fellow group; R:Resident group. (**p* < 0.05, ***p* < 0.01, ****p* < 0.001)

Discussion

Traditional surgical teaching and training methods are experiencing increasing learning costs under the modern background and pancreatic surgery is known for its relatively higher surgical difficulty. Within the digestive tract anastomosis, the PJ is the most complicated, which can lead to various postoperative complications. The PJ model based on biotissue [8] is considered to improve technical performance in surgical oncology fellows. However, to our knowledge, although they have been successfully applied to training in many fields of surgery, including head and neck surgery [14], colorectal surgery [15], vascular surgery [16], and neurosurgery [17], among others, there are few reports on PJ models using 3D printed models.

In the current study, eight pancreatic surgery experts were selected, all of whom exceeded the experience expectations for a pancreaticoduodenectomy, and a model evaluation scale was issued to these experts. The evaluation scale adopts the 5-point Likert scale [8-10], which comprehensively evaluates the appearance and touch of each component of the model, its similarity with real surgery, and its application in teaching. Experts rated the model highly on both appearance and touch, suggesting that the model has good simulation performance. All experts recommend it for teaching, suggesting a potential role of such models in surgical training.

The current study also selected three groups of surgeons to perform functional tests of the model. The selected research indicators primarily include operation time, operation score, and the NASA-TLX. There is a plethora of research on operation time and operation score, which can effectively reflect the operation level on the model [18, 19]. Additionally, Beard et al. [20] developed an objective structured assessment of technical skills (OSATS) scale based on the surgeon's technical competency evaluation. The research published by Wei et al. [11] was optimized on the basis of OSATS and was demonstrated to be a good assessment of the technical competency of surgeons. The operation scoring standard of the current research also refers to this modified version of the scoring design. In addition, the current study utilized the NASA-TLX as a subjective index to assess mental workload, which can reflect the surgeon's operating pressure, which has attracted increasing attention in recent years [12, 21]. Given the results of the above three indicators, the model is suggested to be able to effectively distinguish between the three groups of physicians in terms of operating time, operating scores, and mental stress, further indicating the effectiveness of the model. Among the groups, the attending group had a shorter operating time than the fellow group (569.20 ± 170.01 vs. 797.80 ± 186.40), however, this difference was not statistically significant. This may be due to an insufficient number of enrolled physicians. Additionally, there was no significant difference between the attending group and the fellow group doctors in terms of stress scores, plausibly due to a better psychological tolerance in the fellow group as the amount of surgery gradually increased. Furthermore, the mental stress of attendings and fellows in the model training was significantly lower than that of the residents, suggesting that the model can effectively simulate mental stress. The results of the current study demonstrate that the 3D printed PJ model has good simulation and effectiveness. It can help distinguish pancreatic surgeons at various levels can roughly assess whether pancreatic surgeons are prepared for surgery.

Organ models cut from cadaver tissue have certain advantages in training young doctors in the fields of trauma, plastic surgery, gynecology, general surgery, and vascular surgery. For example, SIM Life, which is an emerging model that uses corpses as a template to have an artificial heartbeat, circulation, and breathing, has been given high ratings by users. However, the application of living tissues has many problems such as storage, production, and cost. The cost of 3D printed organizational models is greatly reduced and due to advances in technology and materials, it has improved organizational similarity and training effects and it is easier to promote and train economically. Simultaneously, it is easier to produce with a short production cycle and it has a better prospect in clinical application.

However, the current study has some disadvantages. For one, we selected softer silicone material to simulate the pancreatic parenchyma and its hardness was still slightly higher than that of the pancreatic tissue. And we chose fifteen surgeons performed a PJ on the three-dimensional model. The sample size could be larger. In future studies, different materials should be tried to achieve better material simulation and compare their different training effects and expert evaluation. We also selected the open pancreaticoduodenal model for training and will use the laparoscopic model for additional future research.

Conclusions

The three-dimensional PJ model could mimic real surgical situations and can be used to distinguish surgeons of various levels of experience. Therefore, prior to doing a pancreaticoduodenectomy, this model may be a convenient tool to let surgeons to evaluate whether they are technically proficient to perform a high-quality and safe PJ on their patients.

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Conflicts of interest

All authors declares no conflicts of interest.

Ethics Approval

The Sir Run Run Shaw hospital granted Ethical approval to carry out the study within its facilities (Ethical Application Ref: jm420-c5a3d).(See appendix S2).All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2000 (5).

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Figures

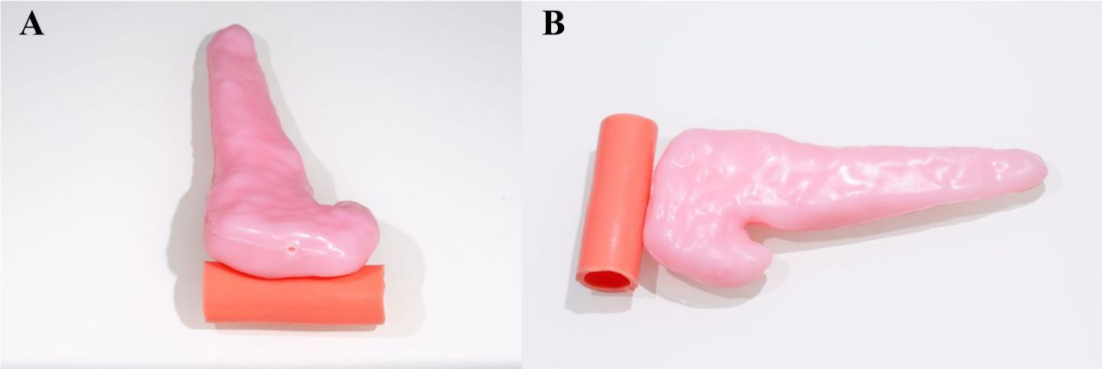


Figure 1. The appearance of the 3D-printed PJ model. **(A)** The 3D printed PJ model is primarily composed of three parts: the pancreatic parenchyma, pancreatic duct, and intestinal duct. **(B)** Side view of the 3D printed PJ model.

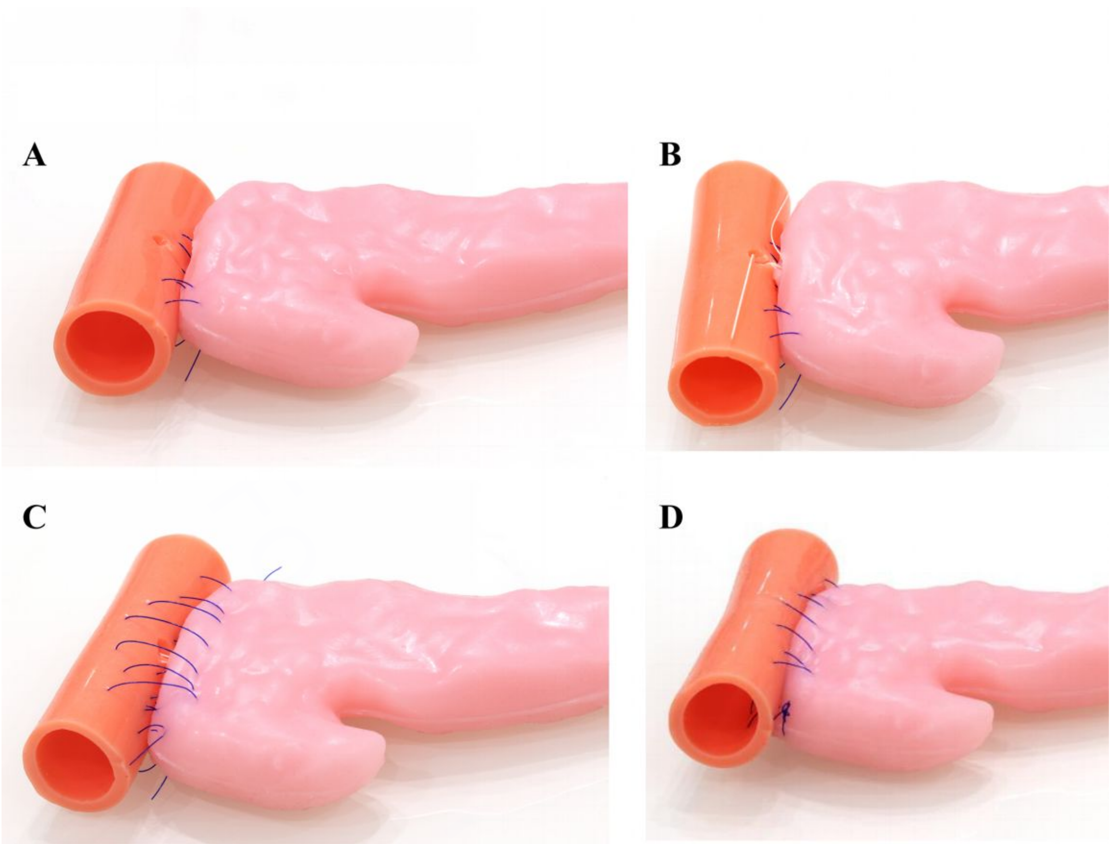


Figure 2. Cattell-Warren anastomosis **(A)** Continuously suture the posterior margin of the pancreas and the seromuscular layer of the jejunum; 2/3 of the pancreatic tissue on the dorsal side of the pancreas should be sutured. The sutures should not be tightened temporarily to facilitate exposure of the posterior pancreatic duct wall. **(B)** Cut the full thickness of the jejunum wall corresponding to the position of the pancreatic duct. When suturing the posterior wall of the pancreatic duct, it should include 1/3 of the pancreatic tissue around it and knot it together. The knot should be on the outside of the anastomosis. **(C)** The anterior wall of the pancreatic duct and its surrounding 1/3 of the pancreatic tissue and the entire anterior wall of the jejunum should be sutured continuously with the suture that was used when the posterior wall was sutured. **(D)** Tighten the sutures to complete the anastomosis.

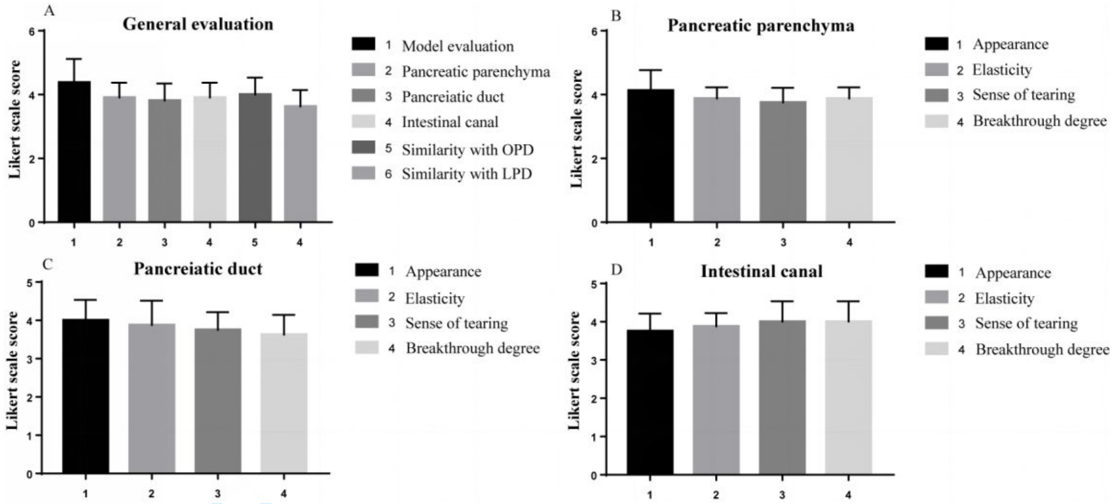


Figure 3. Panel A: General evaluation of the model. Panels B, C, D: The appearance, elasticity, sense of tearing, and breakthrough degree evaluation of the different parts of the model, including the pancreatic parenchyma, pancreatic duct, and the intestinal canal. *OPD: Open pancreaticoduodenectomy; LPD: Laparoscopic pancreaticoduodenectom

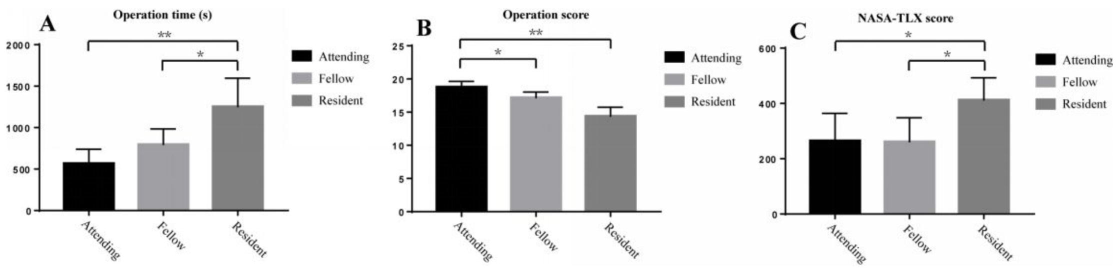


Figure 4. Panel A: The operation time of the resident group was significantly longer than the fellow group (1254.80 ± 341.50 vs. 797.80 ± 186.40, $p = 0.028$) and the attending group (1254.80 ± 341.50 vs. 569.20 ± 170.01, $p = 0.009$); Panel B: The operation score of the attending group was significantly higher than the fellow group (18.80 ± 0.84 vs. 17.20 ± 0.84, $p = 0.023$) and the resident group (18.80 ± 0.84 vs. 14.40 ± 1.34, $p = 0.008$); Panel C: The NASA-TLX score of the resident group was significantly higher than the fellow group (412.80 ± 79.74 vs. 261.60 ± 86.41, $p = 0.028$) and the attending group (412.80 ± 79.74 vs. 265.40 ± 99.02, $p = 0.047$).($*p < 0.05$, $**p < 0.01$,$***p < 0.001$).

References

[1] Ecker, B.L., McMillan, M.T., Asbun, H.J., Ball, C.G., Bassi, C., Beane, J.D., Behrman, S.W., Berger, A.C., Dickson, E.J., Bloomston, M., et al. 2018 Characterization and Optimal Management of High-risk Pancreatic Anastomoses During Pancreatoduodenectomy. *Annals of surgery* **267**, 608-616. (doi:10.1097/sla.0000000000002327).

[2] Besselink, M.G., van Rijssen, L.B., Bassi, C., Dervenis, C., Montorsi, M., Adham, M., Asbun, H.J., Bockhorn, M., Strobel, O., Büchler, M.W., et al. 2017 Definition and classification of chyle leak after pancreatic operation: A consensus statement by the International Study Group on Pancreatic Surgery. *Surgery* **161**, 365-372. (doi:10.1016/j.surg.2016.06.058).

[3] Szasz, P., Louridas, M., Harris, K.A., Aggarwal, R. & Grantcharov, T.P. 2015 Assessing Technical Competence in Surgical Trainees: A Systematic Review. *Annals of surgery* **261**, 1046-1055. (doi:10.1097/sla.0000000000000866).

[4] Ziv, A., Wolpe, P.R., Small, S.D. & Glick, S. 2003 Simulation-based medical education: an ethical imperative. *Academic medicine : journal of the Association of American Medical Colleges* **78**, 783-788. (doi:10.1097/00001888-200308000-00006).

[5] Frank, J.R., Snell, L.S., Cate, O.T., Holmboe, E.S., Carraccio, C., Swing, S.R., Harris, P., Glasgow, N.J., Campbell, C., Dath, D., et al. 2010 Competency-based medical education: theory to practice. *Medical teacher* **32**, 638-645. (doi:10.3109/0142159x.2010.501190).

[6] Tack, P., Victor, J., Gemmel, P. & Annemans, L. 2016 3D-printing techniques in a medical setting: a systematic literature review. *Biomedical engineering online* **15**, 115.

[7] Kiely, D.J. 2014 Advancing Surgical Simulation in Robotic Gynecologic Oncology, McGill University Libraries.

[8] Tam, V., Zenati, M., Novak, S., Chen, Y., Zureikat, A.H., Zeh, H.J., 3rd & Hogg, M.E. 2017 Robotic Pancreatoduodenectomy Biotissue Curriculum has Validity and Improves Technical Performance for Surgical Oncology Fellows. *Journal of surgical education* **74**, 1057-1065. (doi:10.1016/j.jsurg.2017.05.016).

[9] Maricic, M.A., Bailez, M.M. & Rodriguez, S.P. 2016 Validation of an inanimate low cost model for training minimal invasive surgery (MIS) of esophageal atresia with tracheoesophageal fistula (AE/TEF) repair. *Journal of pediatric surgery* **51**, 1429-1435. (doi:10.1016/j.jpedsurg.2016.04.018).

[10] Kiely, D.J., Gotlieb, W.H., Jardon, K., Lau, S. & Press, J.Z. 2015 Advancing surgical simulation in gynecologic oncology: robotic dissection of a novel pelvic lymphadenectomy model. *Simulation in healthcare : journal of the Society for Simulation in Healthcare* **10**, 38-42. (doi:10.1097/sih.0000000000000054).

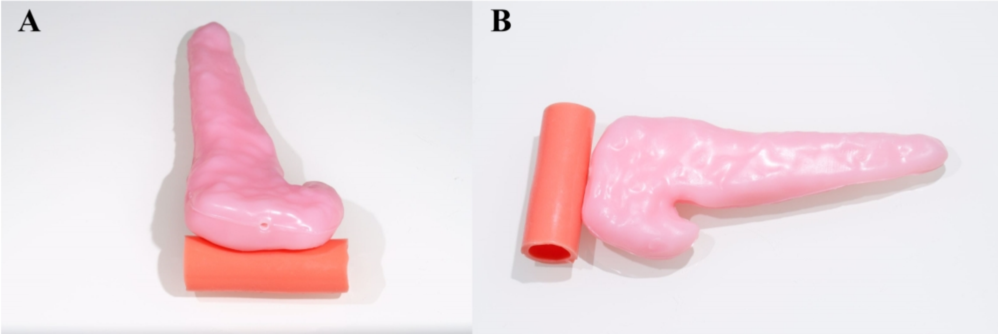
[11] Wei, F., Xu, M., Lai, X., Zhang, J., Yiengpruksawan, A., Lu, Y., Liu, J. & Wang, Z. 2019 Three-dimensional printed dry lab training models to simulate robotic-assisted pancreaticojejunostomy. *ANZ journal of surgery* **89**, 1631-1635. (doi:10.1111/ans.15544).

[12] Lowndes, B.R., Forsyth, K.L., Blocker, R.C., Dean, P.G., Truty, M.J., Heller, S.F., Blackmon, S., Hallbeck, M.S. & Nelson, H. 2020 NASA-TLX Assessment of Surgeon Workload Variation Across Specialties. *Annals of surgery* **271**, 686-692. (doi:10.1097/sla.0000000000003058).

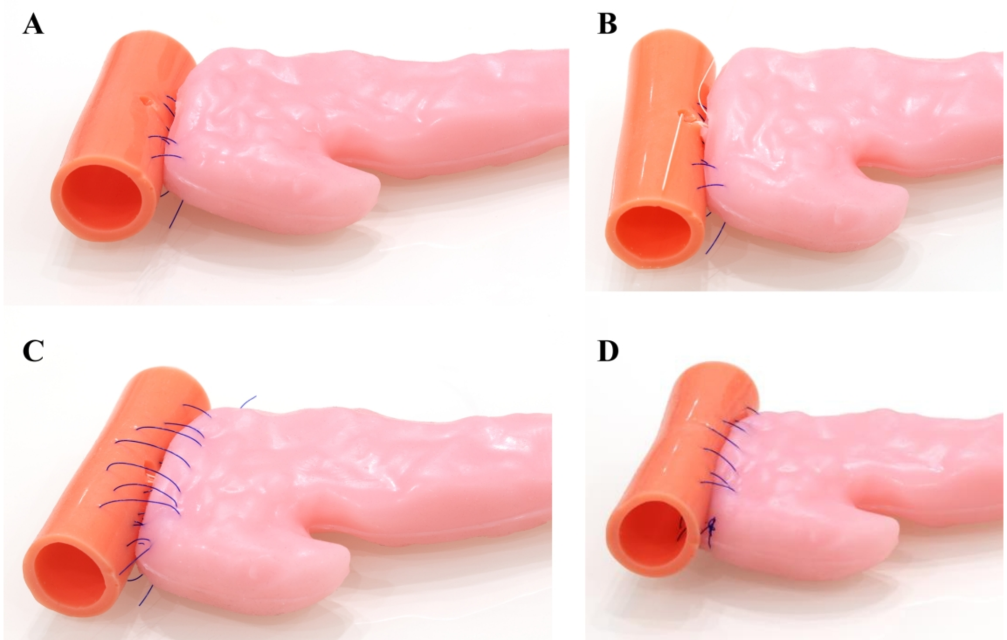
[13] Law, K.E., Lowndes, B.R., Kelley, S.R., Blocker, R.C., Larson, D.W., Hallbeck, M.S. & Nelson, H. 2020 NASA-Task Load Index Differentiates Surgical Approach: Opportunities for Improvement in Colon and Rectal Surgery. *Annals of surgery* **271**, 906-912. (doi:10.1097/sla.0000000000003173).

[14] Werz, S.M., Zeichner, S.J., Berg, B.I., Zeilhofer, H.F. & Thieringer, F. 2018 3D Printed Surgical Simulation Models as educational tool by maxillofacial surgeons. *European journal of dental education : official journal of the Association for Dental Education in Europe* **22**, e500-e505. (doi:10.1111/eje.12332).

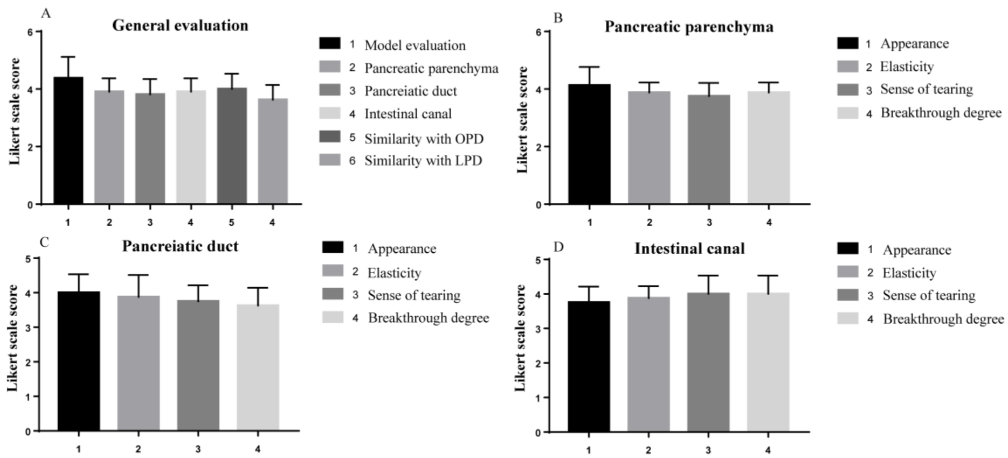
[15] Bangeas, P., Drevelegas, K., Agorastou, C., Tzounis, L., Chorti, A., Paramythiotis, D., Michalopoulos, A., Tsoulfas, G., Papadopoulos, V.N., Exadaktylos, A., et al. 2019 Three-dimensional printing as an educational tool in colorectal surgery. *Frontiers in bioscience (Elite edition)* **11**, 29-37.
[16] Wang, C., Zhang, L., Qin, T., Xi, Z., Sun, L., Wu, H. & Li, D. 2020 3D printing in adult cardiovascular surgery and interventions: a systematic review. *Journal of thoracic disease* **12**, 3227-3237. (doi:10.21037/jtd-20-455).
[17] Weinstock, P., Rehder, R., Prabhu, S.P., Forbes, P.W., Roussin, C.J. & Cohen, A.R. 2017 Creation of a novel simulator for minimally invasive neurosurgery: fusion of 3D printing and special effects. *Journal of neurosurgery. Pediatrics* **20**, 1-9. (doi:10.3171/2017.1.Peds16568).
[18] Pucci, J.U., Christophe, B.R., Sisti, J.A. & Connolly, E.S., Jr. 2017 Three-dimensional printing: technologies, applications, and limitations in neurosurgery. *Biotechnology advances* **35**, 521-529. (doi:10.1016/j.biotechadv.2017.05.007).
[19] Bartel, T., Rivard, A., Jimenez, A., Mestres, C.A. & Müller, S. 2018 Medical three-dimensional printing opens up new opportunities in cardiology and cardiac surgery. *European heart journal* **39**, 1246-1254. (doi:10.1093/eurheartj/ehx016).
[20] Beard, J.D. 2005 Setting standards for the assessment of operative competence. *European journal of vascular and endovascular surgery : the official journal of the European Society for Vascular Surgery* **30**, 215-218. (doi:10.1016/j.ejvs.2005.01.032).
[21] Abbott, E.F., Thompson, W., Pandian, T.K., Zendejas, B., Farley, D.R. & Cook, D.A. 2017 Personalized Video Feedback and Repeated Task Practice Improve Laparoscopic Knot-Tying Skills: Two Controlled Trials. *Academic medicine : journal of the Association of American Medical Colleges* **92**, S26-s32. (doi:10.1097/acm.0000000000001924).



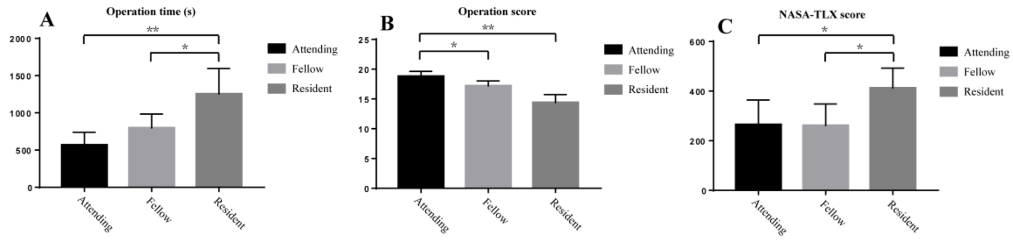
The appearance of the 3D-printed PJ model. (A) The 3D-printed PJ model is primarily composed of three parts: the pancreatic parenchyma, the pancreatic duct, and the intestinal duct. (B) Side view of the 3D-printed PJ model.



Cattell-Warren anastomosis (A) Continuously suture the posterior margin of the pancreas and the seromuscular layer of the jejunum; 2/3 of the pancreatic tissue on the dorsal side of the pancreas should be sutured. The sutures should not be tightened temporarily to facilitate exposure of the posterior pancreatic duct wall. (B) Cut the full thickness of the jejunum wall corresponding to the position of the pancreatic duct. When suturing the posterior wall of the pancreatic duct, it should include 1/3 of the pancreatic tissue around it and knot it together. The knot should be on the outside of the anastomosis. (C) The anterior wall of the pancreatic duct and its surrounding 1/3 of the pancreatic tissue and the entire anterior wall of the jejunum should be sutured continuously with the suture that was used when the posterior wall was sutured. (D) Tighten the sutures to complete the anastomosis.



Panel A: General evaluation of the model. Panels B, C, D: The appearance, elasticity, sense of tearing, and breakthrough degree evaluation of the different parts of the model, including the pancreatic parenchyma, pancreatic duct, and the intestinal canal.
*OPD: Open pancreaticoduodenectomy; LPD: Laparoscopic pancreaticoduodenectom



Panel A: The operation time of the resident group was significantly longer than either that of the fellow group (1254.80 ± 341.50 vs. 797.80 ± 186.40, p = 0.028) or the attending group (1254.80 ± 341.50 vs. 569.20 ± 170.01, p = 0.009); Panel B: The operation score of the attending group was significantly higher than either that of the fellow group (18.80 ± 0.84 vs. 17.20 ± 0.84, p = 0.023) or the resident group (18.80 ± 0.84 vs. 14.40 ± 1.34, p = 0.008); Panel C: The NASA-TLX score of the resident group was significantly higher than either that of the fellow group (412.80 ± 79.74 vs. 261.60 ± 86.41, p = 0.028) or the attending group (412.80 ± 79.74 vs. 265.40 ± 99.02, p = 0.047).
*p < 0.05, **p < 0.01, ***p < 0.001

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批件号：科研 20201217-41

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主要研究者：杨瑾	申请单位：浙江大学医学院附属邵逸夫医院普外科
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第 1 页 共 1 页

Appendix S2:Evaluation and Scoring.

The assessment of the proficiency of each individual trainee's anastomotic procedures is based on the time required to complete the task and the security of the anastomosis. Firstly assess the anterior and posterior anastomosis, and then perform the duct-to-mucosal anastomosis, which is checked by incising the jejunum model and checking the anastomosis from within. Any tearing of the model is noted. For all anastomosis, the duct is connected to a pump that can pump water in.

Distortions are carefully checked as well as strictures, which are identified by checking the water coming through the anastomosis, after turning on the pump. The distribution of the stitches, and whether the ties are loosened, are observed. General guidelines for assessing procedural skill include depth perception, applied force and tissue handling, dexterity and coordination of the arms, and efficiency(Table_ Appendix S1). Performance scores range from A to D, with A being the best.

Table Appendix S1: Criteria for evaluation of individual trainee anastomosis procedure proficiency.

Rank	Depth perception	Force/Tissue handling	Dexterity	Coordination of the arms	Efficiency
A	Good and can adjust well	Good at handling the tissue and suture, the tissue are not torn	Very good	Very good, can switch whenever necessary	All the sutures are perfect
B	Can adjust, but not always able to get to the best angle	Can handle the tissue and suture, with tissue occasionally torn or suture broken	Good	Good, able to switch but less than necessary	One torn of the tissue
C	Not good at finding the right angle	The tissue is too much distorted during the suturing	Fair	Fair, seldom switch among arms even the space or angle for suturing is not satisfied	One broken of the suture or two torn of the tissue
D	Poor at finding the right angle	Poor at handling the tissue and suture, the tissue, often torn the model	Poor	Poor, not at all good at coordination	more than above or distort of the anastomosis or strictures stopping the water going through the anastomosis

Reporting checklist for quality improvement in health care.

Based on the SQUIRE guidelines.

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		Reporting Item	Page Number
Title			
	#1	Indicate that the manuscript concerns an initiative to improve healthcare (broadly defined to include the quality, safety, effectiveness, patientcenteredness, timeliness, cost, efficiency, and equity of healthcare)	1
Abstract			
	#02a	Provide adequate information to aid in searching and indexing	2
	#02b	Summarize all key information from various sections of the text using the abstract format of the intended publication or a structured summary such as: background, local problem, methods, interventions, results, conclusions	2
Introduction			
Problem	#3	Nature and significance of the local problem	3

description			
Available knowledge	#4	Summary of what is currently known about the problem, including relevant previous studies	3
Rationale	#5	Informal or formal frameworks, models, concepts, and / or theories used to explain the problem, any reasons or assumptions that were used to develop the intervention(s), and reasons why the intervention(s) was expected to work	3
Specific aims	#6	Purpose of the project and of this report	3
Methods			
Context	#7	Contextual elements considered important at the outset of introducing the intervention(s)	3
Intervention(s)	#08a	Description of the intervention(s) in sufficient detail that others could reproduce it	3-5
Intervention(s)	#08b	Specifics of the team involved in the work	3-5
Study of the Intervention(s)	#09a	Approach chosen for assessing the impact of the intervention(s)	3-5
Study of the Intervention(s)	#09b	Approach used to establish whether the observed outcomes were due to the intervention(s)	3-5
Measures	#10a	Measures chosen for studying processes and outcomes of the intervention(s), including rationale for choosing them, their operational definitions, and their validity and reliability	3-5
Measures	#10b	Description of the approach to the ongoing assessment of contextual elements that contributed to the success, failure, efficiency, and cost	3-5
Measures	#10c	Methods employed for assessing completeness and accuracy of data	3-5
Analysis	#11a	Qualitative and quantitative methods used to draw inferences from the data	3-5
Analysis	#11b	Methods for understanding variation within the data, including the effects of time as a variable	3-5
Ethical considerations	#12	Ethical aspects of implementing and studying the intervention(s) and how they were addressed, including, but not limited to, formal ethics review and potential conflict(s) of interest	3-5

Results

	#13a	Initial steps of the intervention(s) and their evolution over time (e.g., time-line diagram, flow chart, or table), including modifications made to the intervention during the project	5-8
	#13b	Details of the process measures and outcome	5-8
	#13c	Contextual elements that interacted with the intervention(s)	5-8
	#13d	Observed associations between outcomes, interventions, and relevant contextual elements	5-8
	#13e	Unintended consequences such as unexpected benefits, problems, failures, or costs associated with the intervention(s).	5-8
	#13f	Details about missing data	5-8

Discussion

Summary	#14a	Key findings, including relevance to the rationale and specific aims	8-10
Summary	#14b	Particular strengths of the project	8-10
Interpretation	#15a	Nature of the association between the intervention(s) and the outcomes	8-10
Interpretation	#15b	Comparison of results with findings from other publications	8-10
Interpretation	#15c	Impact of the project on people and systems	8-10
Interpretation	#15d	Reasons for any differences between observed and anticipated outcomes, including the influence of context	8-10
Interpretation	#15e	Costs and strategic trade-offs, including opportunity costs	8-10
Limitations	#16a	Limits to the generalizability of the work	10
Limitations	#16b	Factors that might have limited internal validity such as confounding, bias, or imprecision in the design, methods, measurement, or analysis	10
Limitations	#16c	Efforts made to minimize and adjust for limitations	10
Conclusion	#17a	Usefulness of the work	10
Conclusion	#17b	Sustainability	10
Conclusion	#17c	Potential for spread to other contexts	10

Conclusion	#17d	Implications for practice and for further study in the field	10
Conclusion	#17e	Suggested next steps	10
Other information			
Funding	#18	Sources of funding that supported this work. Role, if any, of the funding organization in the design, implementation, interpretation, and reporting	11

 This checklist was completed on 11. April 2021 using https://www.goodreports.org/, a tool made by the EQUATOR Network in collaboration with Penelope.ai

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Validation of a three-dimensional printed dry lab pancreaticojejunostomy model in surgical assessment, a pioneering study

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Validation of a three-dimensional printed dry lab pancreaticojejunostomy model in surgical assessment, a pioneering study

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31

Abstract

Objectives. Until now, there have been few tools to evaluate whether a surgeon was technically ready to perform a safe pancreaticojejunostomy (PJ). In the current study, we aimed to evaluate whether a three-dimensional model could mimic a real surgical situation and distinguish between surgeons of different levels of experiences.

Methods. A three-dimensional PJ dry laboratory model was printed. And eight experienced pancreatic surgeons were enrolled to evaluate the appearance and tactile sensation of the model. Fifteen surgeons with various levels of pancreatic experience performed a PJ on the three-dimensional model. And the proficiency was scored. Additionally, the time of manipulation and the NASA Task Load Index (NASA-TLX) scores were recorded for each operation.

Results. Compared with real surgical situations, this model had similar appearance (3.96 ± 0.55 out of five points) and tactile sensation (3.85 ± 0.46 out of five points) according to the expert evaluation. Additionally, the chief surgeon group scored the best in proficiency (based on NASA-TLX scores and operative time) and there were statistical differences for performances among surgeons of various levels ($p < 0.05$).

Conclusion. The three-dimensional PJ model could mimic a real surgical situation and can distinguish between surgeons of different levels of experiences.

Key words: Three-dimensional PJ model, validity, surgical assesment, appearance, tactile sensation

Strengths and limitations of this study

1. Strengths of this pioneering study include that the three-dimensional PJ model could mimic a real surgical situation and it could be used as a portable teaching and learning tool, which is easier to store, and can be used by students in the office or even at home.

2. This study selected softer silicone material to simulate the pancreatic parenchyma and its hardness was still slightly higher than that of the pancreatic tissue.

3. This study chose fifteen surgeons performed a PJ on the three-dimensional model and the sample size could be further expanded in future studies.

4. This PJ model doesn't contain vessels such as splenic artery, etc which will allow for simulation of more realistic situation.

5. Characteristics of pancreatic tissue (consistency, elasticity, etc) are highly different from one patient to another which may influence both the technique and the results of pancreato-enteric anastomosis, but in the present study only one type of silicon model is used.

Introduction

A pancreaticojejunostomy (PJ) is one of the most challenging procedures in general surgery and a lack of proficiency and experience in doing this procedure may lead to postoperative pancreatic leakage, hemorrhage, or even death [1-3]. Advanced techniques, such as 3D printing, have been widely used in the field of surgery for the purpose of education and preoperative designing, however, there are few reports indicating that they could be used as a tool to evaluate surgical competency.

According to Szasz and colleagues [4], due to work hour restrictions, limitations of operating room accessibility, and increased litigation against physicians, the educational opportunities of surgeons have dramatically decreased. Based on this status quo, the Accreditation Council for Graduate Medical Education [5], the Royal College of Physicians and Surgeons of Canada [6], and many others worldwide have developed training programs to improve surgical skills.

Compared with traditional pancreaticoduodenal surgery training methods, there remains a lack of an effective physical model to help distinguish between pancreatic surgeons of different levels and to roughly assess whether pancreatic surgeons are prepared. As an emerging technology, 3D printing technology has been widely used in the medical field [7-9] and has been broadly studied and reported on in a book on the training and application of simulation models in robotic gynecological surgery [10]. Additionally, 3D printed models are expected to be used in the future as one of the methods of pancreatic surgery training, reducing learning costs and helping young doctors improve surgical techniques. In the current study, experts in the field of pancreatic surgery were invited to evaluate the appearance of the model. We aimed to evaluate whether a three-dimensional model could mimic a real surgical situation and distinguish between surgeons of various levels of experience.

Materials & Methods

1 Study design and setting

This pioneering study invited eight surgical experts from multiple pancreatic surgery centers in China to conduct an anatomical evaluation of the model. All eight experts had performed more than 20 cases of pancreaticoduodenectomy within the prior year and four had performed more than 100 cases of pancreaticoduodenectomy in the prior year. And fifteen doctors from our pancreatic surgery center were invited to participate in Model functional evaluation.

2 3D-Printed Dry Lab PJ Model Production

The 3D printed dry lab PJ model primarily contained the pancreas and small intestine and was printed using a dual-head silicone printer. The Sir Run Run Shaw hospital granted Ethical approval to carry out the study within its facilities (See appendix S1). First, the Computed Tomography (CT) data was collected in the Digital Imaging and Communications in Medicine (DICOM) format, with 1mm thick slices. The E3D digital medical modeling software V17.06 (Central South E3D Digital Medical and Virtual Reality Research Center, China) was used for boundary segmentation and 3D reconstruction and the model structure was streamlined according to manual editing (Figure 1). The open source slicing software Cura 4.4.1 (Ulitmaker, USA) was used for slicing the 3D printing. The material was made of silicone specialized for 3D printing. The silicone material used for the pancreatic parenchyma was pink, with a tear strength of 4.8N/mm and a tensile strength of 2 MPa. The silicone material used for the pancreatic duct was white, with a tear strength of 5.2N/mm and a tensile strength of 1.8 MPa. The silicone material used for the small intestine was red, with a tear strength of 5.2N/mm and a tensile strength of 1.8 MPa. The pancreas is the main component of the PJ model, and its stiffness is measured by ultrasound with a two-dimensional shear-wave elastography (2D-SWE) value for 9 times.

3 Patient and public involvement

Patients and public were not directly involved in the design of this study.

4 Evaluation scale design

The expert evaluation scale of the model was comprehensively designed with reference to the relevant literature[11-13], using a 5-point Likert scale (See Appendix *S2*). The main coverage areas include: the amount of pancreatic surgery the expert had conducted, the evaluation of the overall settings of the 3D printed model, the evaluation of the appearance, size, and tactile similarity of the 3D printed model, and a comprehensive evaluation of the 3D printed pancreas model for clinical and teaching work.

The model's operation rating scale was designed with reference to the relevant model training literature [14], which primarily evaluates the depth perception, force/tissue handling, dexterity, coordination of the arms, and the efficiency of the chief surgeon (attending), first assistant (fellow), and observer (resident) physicians in pancreatic surgery.

The functional psychology scale of the model refers to the NASA Task Load Index (NASA-TLX), which primarily evaluates the mental load of pancreatic surgeons. The significance of the related indices is reported in several articles as it relates to surgical model training [15, 16].

5 Assessment scale issuance

The current study selected eight pancreatic surgery experts and sent the 3D printed pancreas models and distributed the 3D printed pancreas model evaluation scales to each of the experts. Experts in pancreatic surgery were invited to participate in the evaluation from all aspects according to the scale and to make professional recommendations.

Fifteen chief surgeon (attending), first assistant (fellow) and observer (resident) physicians from the general surgery department were selected and issued basic information collection forms. And all surgeons in this section were obtained written informed human participant consent. Model training operations were performed after teaching the procedures. The entirety of the operation was recorded on video and the proficiency was scored by two pancreatic experts who were blinded to the identities of surgeons. After the operation, all personnel were issued a NASA-TLX scale to assess the mental load of the operation.

6 General information of pancreatic surgeons

Five attendings include 2 experts from the PJ anatomical evaluation part, five fellows, and five residents were invited to participate in the current study. Their general information is shown in Table 1. There were significant differences in the working years of the three groups of surgeons (13.40 ± 3.21 vs. 6.00 ± 1.22 vs. 2.60 ± 1.82, respectively, $p < 0.001$), in which all attendings had worked for more than eight years and all residents had worked five or less years. The three groups of surgeons had a statistically significant difference in the number of cases of pancreatoenterostomy as the lead surgeon (p = 0.008) and the number of cases of pancreaticoduodenectomy as the first assistant (p = 0.014). All pancreatic surgeons who participated in the study were right-handed and there was no significant statistical difference between the three groups of surgeons in simulation training (p = 0.287), nor was there any significant statistical difference between the three groups of participants in Virtual Reality(VR) surgical training (p = 0.562).

Table 1. General information of attendings, fellows, and residents.

	Attendings (n=5)	Fellows (n=5)	Residents (n=5)	P-value
Years of working	13.40±3.21	6.00±1.22	2.60±1.82	$<0.001^{***}$
Cases of Pancreatoenterostomy as lead surgeon				0.008^{**}
0	0/5 (0%)	4/5 (80%)	5/5 (100%)	
< 10	1/5 (20%)	1/5 (20%)	0/5 (0%)	
≥ 10	4/5 (80%)	0/5 (0%)	0/5 (0%)	
Cases of Pancreatoenterostomy as first assistant				0.014^{*}
0	0/5 (0%)	0/5 (0%)	2/5 (40%)	
< 10	0/5 (0%)	3/5 (60%)	3/5 (60%)	
10-50	0/5 (0%)	1/5 (20%)	0/5 (0%)	
> 50	5/5 (100%)	1/5 (20%)	0/5 (0%)	
Number of right handers	5/5 (100%)	5/5 (100%)	5/5 (100%)	1.000
Number who have participated in simulation training	1/5 (20%)	0/5 (0%)	2/5 (40%)	0.287
Number who have participated in VR operation training	1/5 (20%)	0/5 (0%)	1/5 (20%)	0.562

VR: Virtual Reality ($*p < 0.05$, $**p < 0.01$, $***p < 0.001$)

7 Operation procedures

The operation procedures used in the current study refer to the classic Cattell-Warren anastomosis method. The operation steps are detailed in *Figure 2*.

8 Data analyses

The current study collected statistics on the overall settings and appearance, size, and tactile similarity of the 3D printed pancreas model and the functional evaluation indicators of the model (primarily including the surgical operation score, operation time, and NASA-TLX score). Microsoft Excel (2016) was used to establish the scoring and evaluation table of each item in the evaluation scale by experts. SPSS (Version 20.0, SPSS Inc, Chicago, IL, USA) software was then used for the subsequent data analyses and processing. All tests were 2-tailed and $p < 0.05$ was considered statistically significant. The results from the statistical analyses were entered into Graphpad Prism 7.0 and related charts were drawn. Each score was calculated by the mean ± standard deviation.

Results

1 Pancreatic surgery experts' anatomical evaluation of the model

The research invited eight pancreatic surgery experts to conduct a comprehensive evaluation. All experts had performed more than 20 cases of pancreaticoduodenectomy within the prior year and four had performed more than 100 cases of pancreaticoduodenectomy in the prior year. The model obtained an overall evaluation of 4.38 ± 0.74 (*Figure 3B-E*) and all experts gave greater than "more similar" (3 points) as their evaluation. The current study also invited experts to make assessments on their recommendation of using this model for teaching. The results are presented below.

1.1 Appearance

The overall appearance of the 3D printed PJ dry laboratory model was evaluated at 3.96 ± 0.55. The appearance of the pancreatic parenchyma was evaluated at 4.13 ± 0.64, the appearance of the pancreatic duct was evaluated at 4.00 ± 0.53, and the appearance of the intestinal canal was evaluated at 3.75 ± 0.46.

1.2 Tactile sensation

The pancreas is the main component of the PJ model, and its stiffness is measured by ultrasound with a two-dimensional shear-wave elastography (2D-SWE) value of 10.08±6.50 kPa

(*Figure 3A*). The stiffness of PJ model is slightly higher ($p = 0.003$) than human tissue which is reported as 7.72±2.50 kPa[17]. The overall tactile evaluation of the 3D printed PJ dry laboratory model by experts was evaluated at 3.85 ± 0.46. The elasticity of the model was evaluated at 3.88 ± 0.45 and the elasticity of the pancreas parenchyma, pancreatic duct, and intestinal duct of the model were equivalent. The ease of tearing of the model was evaluated at 3.83 ± 0.48 and the ease of tearing of the intestinal duct of the model was slightly higher than the other two parts, at 4.00 ± 0.53. The suture breakthrough of the model was evaluated at 3.83 ± 0.48 and the pancreatic parenchyma of the model was slightly lower than the other two, at 3.88 ± 0.35.

1.3 Education

All eight experts (100%) agreed that the 3D printed laboratory model of the PJ could/should be used for teaching.

2 Model functional evaluation

The functional evaluation of the 3D printed PJ dry laboratory model included three outcome indicators selected for evaluation, including operation time, operation score, and the NASA Task Load Index (NASA-TLX score). Details are shown in Tables 2 and 3.

Table 2. The operation time, operation score, and the NASA-TLX score of three groups.

	Attendings (n=5)	Fellows (n=5)	Residents (n=5)	P-value
Operation time	569.20±170.01	797.80±186.40	1254.80±341.50	0.003^{**}
Operation score	18.80±0.84	17.20±0.84	14.40±1.34	$<0.001^{***}$
NASA-TLX score	265.40±99.02	261.60±86.41	412.80±79.74	0.031^{*}

$^*p < 0.05$, $^{**}p < 0.01$, $^{***}p < 0.001$

2.1 Operation time

There were significant statistical differences in the operation time of the three groups of researchers ($p = 0.003$), as shown in *Figure 4A*, where the operation time of the resident group was significantly longer than fellow group (1254.80 ± 341.50 vs. 797.80 ± 186.40, $p = 0.028$) and the attending group (1254.80 ± 341.50 vs. 569.20 ± 170.01, $p = 0.009$), but there was no significant statistical difference between the attending group and the fellow group (569.20 ± 170.01 vs. 797.80 ± 186.40, $p = 0.175$).

2.2 Operation score

The operation time for the three groups of researchers was statistically significant ($p < 0.001$), as shown in *Figure 4B*, where the operation score of the attending group is significantly higher than fellow group (18.80 ± 0.84 vs. 17.20 ± 0.84, $p = 0.023$) and the resident group (18.80 ± 0.84 vs. 14.40 ± 1.34, $p = 0.008$).

2.3 NASA-TLX score

The NASA-TLX mental load scores of the three groups of researchers were statistically significantly different ($p = 0.031$), as shown in *Figure 4C*. The NASA-TLX score of the attending group was not significantly different from that of the fellow group (265.40 ± 99.02 vs. 261.60 ± 86.41, $p = 0.754$), while the NASA-TLX score of the resident group was significantly higher than fellow group (412.80 ± 79.74 vs. 261.60 ± 86.41, $p = 0.028$) and the attending group (412.80 ± 79.74 vs. 265.40 ± 99.02, $p = 0.047$).

Table 3. P-value of the pairwise group comparison.

	A vs. F	A vs. R	F vs. R
Operation time	0.175	0.009**	0.028*
Operation score	0.023*	0.008**	0.09
NASA-TLX score	0.754	0.047*	0.028*

A:Attending group; F:Fellow group; R:Resident group. ($*p < 0.05$, $**p < 0.01$, $***p < 0.001$)

Discussion

Traditional surgical teaching and training methods are experiencing increasing learning costs under the modern background and pancreatic surgery is known for its relatively higher surgical difficulty. Within the digestive tract anastomosis, the PJ is the most complicated, which can lead to various postoperative complications. The PJ model based on biotissue[11] is considered to improve technical performance in surgical oncology fellows. However, to our knowledge, although they have been successfully applied to training in many fields of surgery, including head and neck surgery [18], colorectal surgery [19], vascular surgery [20], and neurosurgery [21], among others, there are few reports on PJ models using 3D printed models.

Elastography is an ultrasound imaging method. The concept of elastography was first proposed in 1991[22]. It has been used to assess the stiffness of tissues. During elastography evaluation, the stiffness of model can be estimated from the response of model to compression. This process can be performed in two ways: shear wave elastography (SWE) and strain elastography[23]. This study use soft silicone material to simulate the pancreatic parenchyma and its hardness was still slightly higher than that of the pancreatic tissue. At the same time, our team has also studied hydrogel as a 3D printing material to print PJ models. Its hardness is very close to that of the pancreas, but it's difficult to store which limits its application. Our team will also conduct in-depth research and conduct on this softer material in the future. In the current study, eight pancreatic surgery experts were selected, all of whom exceeded the experience expectations for a pancreaticoduodenectomy, and a model evaluation scale was issued to these experts. The evaluation scale adopts the 5-point Likert scale [11-13], which comprehensively evaluates the appearance and touch of each component of the model, its similarity with real surgery, and its application in teaching. Experts rated the model highly on both appearance and touch, suggesting that the model has good simulation performance. All experts recommend it for teaching, suggesting a potential role of such models in surgical training.

The current study also selected three groups of surgeons to perform functional tests of the model. The selected research indicators primarily include operation time, operation score, and the NASA-TLX. There is a plethora of research on operation time and operation score, which can effectively reflect the operation level on the model [24, 25]. Additionally, Beard et al. [26] developed an objective structured assessment of technical skills (OSATS) scale based on the surgeon's technical competency evaluation. The research published by Wei et al. [14] was optimized on the basis of OSATS and was demonstrated to be a good assessment of the technical competency of surgeons. The operation scoring standard of the current research also refers to this modified version of the scoring design. In addition, the current study utilized the NASA-TLX as a subjective index to assess mental workload, which can reflect the surgeon's operating pressure, which has attracted increasing attention in recent years [15, 27]. Given the results of the above three indicators, the model is suggested to be able to effectively distinguish between the three groups of physicians in terms of operating time, operating scores, and mental stress, further indicating the effectiveness of the model. Among the groups, the attending group had a shorter operating time than the fellow group (569.20 ± 170.01 vs. 797.80 ± 186.40), however, this difference was not statistically significant. This may be due to an insufficient number of enrolled physicians. Additionally, there was no significant difference between the attending group and the fellow group doctors in terms of stress scores, plausibly due to a better psychological tolerance in the fellow group as the amount of surgery gradually increased. Furthermore, the mental stress of attendings and fellows in the model training was significantly lower than that of the residents, suggesting that the model can effectively simulate mental stress. The results of the current study demonstrate that the 3D printed PJ model has good simulation and effectiveness. It can help distinguish pancreatic surgeons at various levels can roughly assess whether pancreatic surgeons are prepared for surgery.

Organ models cut from cadaver tissue have certain advantages in training young doctors in the fields of trauma, plastic surgery, gynecology, general surgery, and vascular surgery. For example, SIM Life, which is an emerging model that uses corpses as a template to have an artificial heartbeat, circulation, and breathing, has been given high ratings by users. However, the application of living tissues has many problems such as storage, production, and cost. The cost of 3D printed organizational models is greatly reduced and due to advances in technology and materials, it has improved organizational similarity and training effects and it is easier to promote and train economically. Simultaneously, it is easier to produce with a short production cycle and it has a better prospect in clinical application.

However, the current study has some disadvantages. I think one of the limitations or future research could consider printing the pancreas model with inclusion of vessels such as splenic artery, etc as this will allow for simulation of more realistic situation. And characteristics of pancreatic tissue (consistency, elasticity, etc) are highly different from one patient to another, and they influence both the technique and the results of pancreato-enteric anastomosis. In the present study only one type of silicon model is used. And we selected soft silicone material to simulate the pancreatic parenchyma and its hardness was still slightly higher than that of the pancreatic tissue. we chose fifteen surgeons performed a PJ on the three-dimensional model. The sample size could be larger. And In future studies, different materials should be tried to achieve better material simulation and compare their different training effects and expert evaluation. We also selected the open pancreaticoduodenal model for training and will use the laparoscopic model for additional future research.

Conclusions

The three-dimensional PJ model could mimic real surgical situations and can be used to distinguish surgeons of various levels of experience. Therefore, prior to doing a pancreaticoduodenectomy, this model may be a convenient tool to let surgeons to evaluate whether they are technically proficient to perform a high-quality and safe PJ on their patients.

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Conflicts of interest

All authors declares no conflicts of interest.

Ethics Approval

The Sir Run Run Shaw hospital granted Ethical approval to carry out the study within its facilities (Ethical Application Ref: jm420-c5a3d).(See appendix S2).All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2000 (5).

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Figure 1. The appearance of the 3D-printed PJ model. (A) The 3D printed PJ model is primarily composed of three parts: the pancreatic parenchyma, pancreatic duct, and intestinal duct. (B) Side view of the 3D printed PJ model.

Figure 2. Cattell-Warren anastomosis **(A)** Continuously suture the posterior margin of the pancreas and the seromuscular layer of the jejunum; 2/3 of the pancreatic tissue on the dorsal side of the pancreas should be sutured. The sutures should not be tightened temporarily to facilitate exposure of the posterior pancreatic duct wall. **(B)** Cut the full thickness of the jejunum wall corresponding to the position of the pancreatic duct. When suturing the posterior wall of the pancreatic duct, it should include 1/3 of the pancreatic tissue around it and knot it together. The knot should be on the outside of the anastomosis. **(C)** Suture the pancreatic duct and intestinal duct intermittently at 3, 6, 9, and 12 o'clock respectively to complete the anastomosis of the pancreatic duct and the jejunum wall. **(D)** The anterior wall of the pancreatic duct and its surrounding 1/3 of the pancreatic tissue and the entire anterior wall of the jejunum should be

355 sutured continuously with the suture that was used when the posterior wall was sutured. **(E)**
356 Tighten the sutures to complete the anastomosis.
357
358 **Figure 3.** Panel A: The pancreas stiffness of the PJ model is measured by ultrasound with a 2D-
359 SWE value of 10.08±6.50 kPa. Panel B: General evaluation of the model. Panels C, D, E: The
360 appearance, elasticity, sense of tearing, and breakthrough degree evaluation of the different parts
361 of the model, including the pancreatic parenchyma, pancreatic duct, and the intestinal canal.
362 *2D-SWE: Two-dimensional shear-wave elastography; OPD: Open pancreaticoduodenectomy;
363 LPD: Laparoscopic pancreaticoduodenectom
364
365 **Figure 4.** Panel A: The operation time of the resident group was significantly longer than the fellow
366 group (1254.80 ± 341.50 vs. 797.80 ± 186.40, $p = 0.028$) and the attending group (1254.80 ± 341.50 vs.
367 569.20 ± 170.01, $p = 0.009$); Panel B: The operation score of the attending group was significantly higher
368 than the fellow group (18.80 ± 0.84 vs. 17.20 ± 0.84, $p = 0.023$) and the resident group (18.80 ± 0.84 vs.
369 14.40 ± 1.34, $p = 0.008$); Panel C: The NASA-TLX score of the resident group was significantly higher
370 than the fellow group (412.80 ± 79.74 vs. 261.60 ± 86.41, $p = 0.028$) and the attending group (412.80 ±
371 79.74 vs. 265.40 ± 99.02, $p = 0.047$).($*p < 0.05$, $**p < 0.01$, $***p < 0.001$).

References

[1] Ecker, B.L., McMillan, M.T., Asbun, H.J., Ball, C.G., Bassi, C., Beane, J.D., Behrman, S.W., Berger, A.C., Dickson, E.J., Bloomston, M., et al. 2018 Characterization and Optimal Management of High-risk Pancreatic Anastomoses During Pancreatoduodenectomy. *Annals of surgery* **267**, 608-616. (doi:10.1097/sla.0000000000002327).

[2] Besselink, M.G., van Rijssen, L.B., Bassi, C., Dervenis, C., Montorsi, M., Adham, M., Asbun, H.J., Bockhorn, M., Strobel, O., Büchler, M.W., et al. 2017 Definition and classification of chyle leak after pancreatic operation: A consensus statement by the International Study Group on Pancreatic Surgery. *Surgery* **161**, 365-372. (doi:10.1016/j.surg.2016.06.058).

[3] Suzuki, S., Kajiyama, H., Takemura, A., Shimazaki, J., Nishida, K. & Shimoda, M. 2017 The Clinical Outcomes after Total Pancreatectomy. *Digestive surgery* **34**, 142-150. (doi:10.1159/000449234).

[4] Szasz, P., Louridas, M., Harris, K.A., Aggarwal, R. & Grantcharov, T.P. 2015 Assessing Technical Competence in Surgical Trainees: A Systematic Review. *Annals of surgery* **261**, 1046-1055. (doi:10.1097/sla.0000000000000866).

[5] Ziv, A., Wolpe, P.R., Small, S.D. & Glick, S. 2003 Simulation-based medical education: an ethical imperative. *Academic medicine : journal of the Association of American Medical Colleges* **78**, 783-788. (doi:10.1097/00001888-200308000-00006).

[6] Frank, J.R., Snell, L.S., Cate, O.T., Holmboe, E.S., Carraccio, C., Swing, S.R., Harris, P., Glasgow, N.J., Campbell, C., Dath, D., et al. 2010 Competency-based medical education: theory to practice. *Medical teacher* **32**, 638-645. (doi:10.3109/0142159x.2010.501190).

[7] Tack, P., Victor, J., Gemmel, P. & Annemans, L. 2016 3D-printing techniques in a medical setting: a systematic literature review. *Biomedical engineering online* **15**, 115. (doi:10.1186/s12938-016-0236-4).

[8] Perica, E.R. & Sun, Z. 2018 A Systematic Review of Three-Dimensional Printing in Liver Disease. *Journal of digital imaging* **31**, 692-701. (doi:10.1007/s10278-018-0067-x).

[9] Sun, Z. & Lee, S.Y. 2017 A systematic review of 3-D printing in cardiovascular and cerebrovascular diseases. *Anatolian journal of cardiology* **17**, 423-435. (doi:10.14744/AnatolJCardiol.2017.7464).

[10] Kiely, D.J. 2014 Advancing surgical simulation in robotic gynecologic oncology.

[11] Tam, V., Zenati, M., Novak, S., Chen, Y., Zureikat, A.H., Zeh, H.J., 3rd & Hogg, M.E. 2017 Robotic Pancreatoduodenectomy Biotissue Curriculum has Validity and Improves Technical Performance for Surgical Oncology Fellows. *Journal of surgical education* **74**, 1057-1065. (doi:10.1016/j.jsurg.2017.05.016).

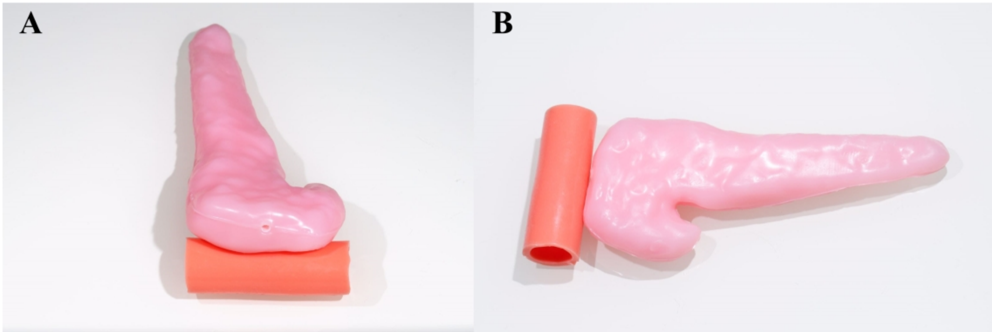
[12] Maricic, M.A., Bailez, M.M. & Rodriguez, S.P. 2016 Validation of an inanimate low cost model for training minimal invasive surgery (MIS) of esophageal atresia with tracheoesophageal fistula (AE/TEF) repair. *Journal of pediatric surgery* **51**, 1429-1435. (doi:10.1016/j.jpedsurg.2016.04.018).

[13] Kiely, D.J., Gotlieb, W.H., Jardon, K., Lau, S. & Press, J.Z. 2015 Advancing surgical simulation in gynecologic oncology: robotic dissection of a novel pelvic lymphadenectomy model. *Simulation in healthcare : journal of the Society for Simulation in Healthcare* **10**, 38-42. (doi:10.1097/sih.0000000000000054).

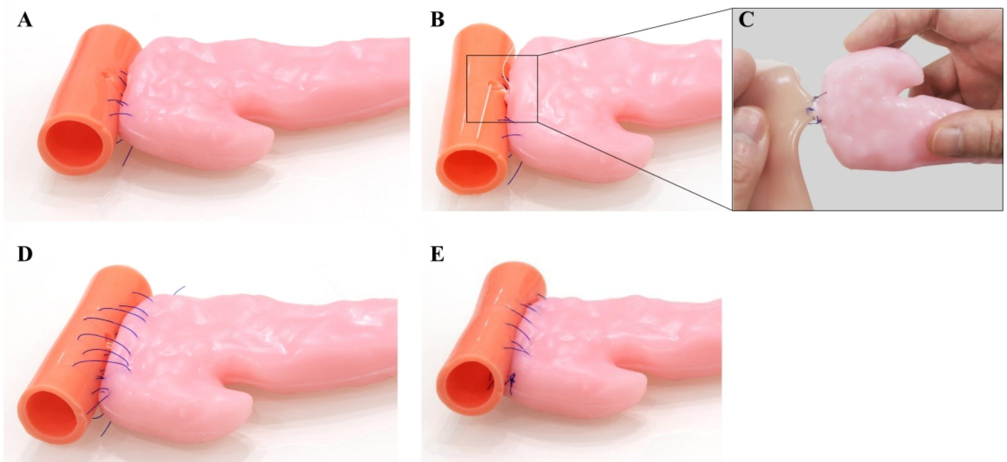
[14] Wei, F., Xu, M., Lai, X., Zhang, J., Yiengpruksawan, A., Lu, Y., Liu, J. & Wang, Z. 2019 Three-dimensional printed dry lab training models to simulate robotic-assisted pancreaticojejunostomy. *ANZ journal of surgery* **89**, 1631-1635. (doi:10.1111/ans.15544).

[15] Lowndes, B.R., Forsyth, K.L., Blocker, R.C., Dean, P.G., Truty, M.J., Heller, S.F., Blackmon, S., Hallbeck, M.S. & Nelson, H. 2020 NASA-TLX Assessment of Surgeon Workload Variation Across Specialties. *Annals of surgery* **271**, 686-692. (doi:10.1097/sla.0000000000003058).

[16] Law, K.E., Lowndes, B.R., Kelley, S.R., Blocker, R.C., Larson, D.W., Hallbeck, M.S. & Nelson, H. 2020 NASA-Task Load Index Differentiates Surgical Approach: Opportunities for Improvement in Colon and Rectal Surgery. *Annals of surgery* **271**, 906-912. (doi:10.1097/sla.0000000000003173).
[dataset] [17] Sezgin, O., Yaraş, S. & Özdoğan, O. 2021 The course and prognostic value of increased pancreas stiffness detected by ultrasound elastography during acute pancreatitis. *Pancreatology : official journal of the International Association of Pancreatology (IAP) ... [et al.]*. (doi:10.1016/j.pan.2021.07.006).
[18] Werz, S.M., Zeichner, S.J., Berg, B.I., Zeilhofer, H.F. & Thieringer, F. 2018 3D Printed Surgical Simulation Models as educational tool by maxillofacial surgeons. *European journal of dental education : official journal of the Association for Dental Education in Europe* **22**, e500-e505. (doi:10.1111/eje.12332).
[19] Bangeas, P., Drevelegas, K., Agorastou, C., Tzounis, L., Chorti, A., Paramythiotis, D., Michalopoulos, A., Tsoulfas, G., Papadopoulos, V.N., Exadaktylos, A., et al. 2019 Three-dimensional printing as an educational tool in colorectal surgery. *Frontiers in bioscience (Elite edition)* **11**, 29-37. (doi:10.2741/e844).
[20] Wang, C., Zhang, L., Qin, T., Xi, Z., Sun, L., Wu, H. & Li, D. 2020 3D printing in adult cardiovascular surgery and interventions: a systematic review. *Journal of thoracic disease* **12**, 3227-3237. (doi:10.21037/jtd-20-455).
[21] Weinstock, P., Rehder, R., Prabhu, S.P., Forbes, P.W., Roussin, C.J. & Cohen, A.R. 2017 Creation of a novel simulator for minimally invasive neurosurgery: fusion of 3D printing and special effects. *Journal of neurosurgery. Pediatrics* **20**, 1-9. (doi:10.3171/2017.1.Peds16568).
[22] Ophir, J., Céspedes, I., Ponnekanti, H., Yazdi, Y. & Li, X. 1991 Elastography: a quantitative method for imaging the elasticity of biological tissues. *Ultrasonic imaging* **13**, 111-134. (doi:10.1177/016173469101300201).
[23] Kuwahara, T., Hirooka, Y., Kawashima, H., Ohno, E., Sugimoto, H., Hayashi, D., Morishima, T., Kawai, M., Suhara, H., Takeyama, T., et al. 2016 Quantitative evaluation of pancreatic tumor fibrosis using shear wave elastography. *Pancreatology : official journal of the International Association of Pancreatology (IAP) ... [et al.]* **16**, 1063-1068. (doi:10.1016/j.pan.2016.09.012).
[24] Pucci, J.U., Christophe, B.R., Sisti, J.A. & Connolly, E.S., Jr. 2017 Three-dimensional printing: technologies, applications, and limitations in neurosurgery. *Biotechnology advances* **35**, 521-529. (doi:10.1016/j.biotechadv.2017.05.007).
[25] Bartel, T., Rivard, A., Jimenez, A., Mestres, C.A. & Müller, S. 2018 Medical three-dimensional printing opens up new opportunities in cardiology and cardiac surgery. *European heart journal* **39**, 1246-1254. (doi:10.1093/eurheartj/ehx016).
[26] Beard, J.D. 2005 Setting standards for the assessment of operative competence. *European journal of vascular and endovascular surgery : the official journal of the European Society for Vascular Surgery* **30**, 215-218. (doi:10.1016/j.ejvs.2005.01.032).
[27] Abbott, E.F., Thompson, W., Pandian, T.K., Zendejas, B., Farley, D.R. & Cook, D.A. 2017 Personalized Video Feedback and Repeated Task Practice Improve Laparoscopic Knot-Tying Skills: Two Controlled Trials. *Academic medicine : journal of the Association of American Medical Colleges* **92**, S26-s32. (doi:10.1097/acm.0000000000001924).



The appearance of the 3D-printed PJ model. (A) The 3D-printed PJ model is primarily composed of three parts: the pancreatic parenchyma, the pancreatic duct, and the intestinal duct. (B) Side view of the 3D-printed PJ model.



Cattell-Warren anastomosis instructions (A) Continuously suture the posterior margin of the pancreas and the seromuscular layer of the jejunum; 2/3 of the pancreatic tissue on the dorsal side of the pancreas should be sutured. The sutures should not be temporarily tightened to facilitate exposure of the posterior pancreatic duct wall. (B) Cut the full thickness of the jejunum wall corresponding to the position of the pancreatic duct. When suturing the posterior wall of the pancreatic duct, 1/3 of the surrounding pancreatic tissue should be included, then knot it together. The knot should be on the outside of the anastomosis. (C) Suture the pancreatic duct and the intestinal duct intermittently at 3, 6, 9, and 12 o'clock, respectively, to complete the anastomosis of the pancreatic duct and the jejunum wall. (D) The anterior wall of the pancreatic duct and its surrounding 1/3 of the pancreatic tissue and the entire anterior wall of the jejunum should be continuously sutured with the suture that was used when the posterior wall was sutured. (E) Tighten the sutures to complete the anastomosis.

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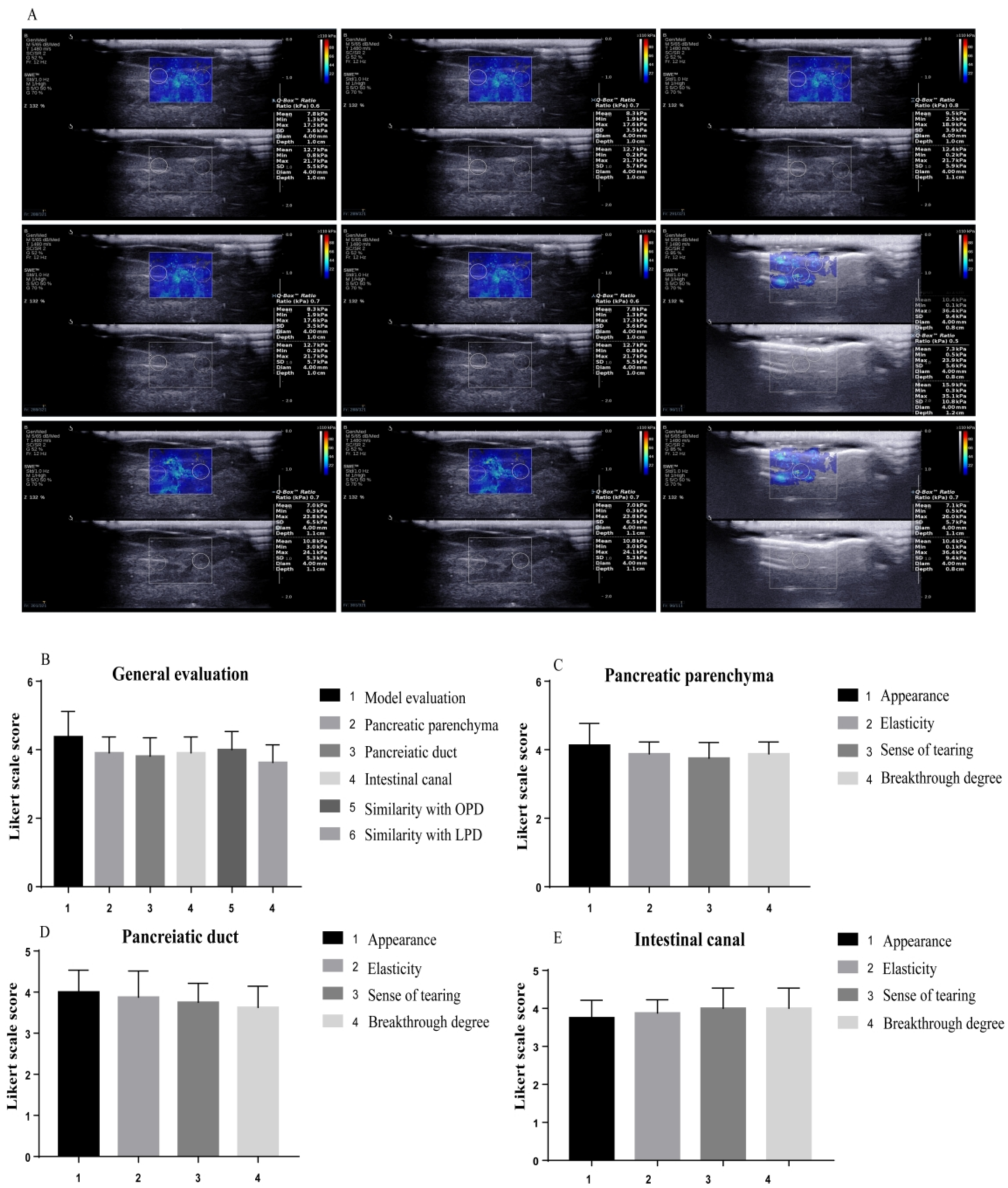

Panel A: The pancreas stiffness of the PJ model was measured by ultrasound with a 2D-SWE value of 10.08±6.50 kPa. Panel B: General evaluation of the model. Panels C, D, and E: The appearance, elasticity, sense of tearing, and breakthrough degree of evaluation of the various parts of the model, including the pancreatic parenchyma, pancreatic duct, and the intestinal canal.
*2D-SWE: Two-dimensional shear-wave elastography; OPD: Open pancreaticoduodenectomy; LPD: Laparoscopic pancreaticoduodenectom

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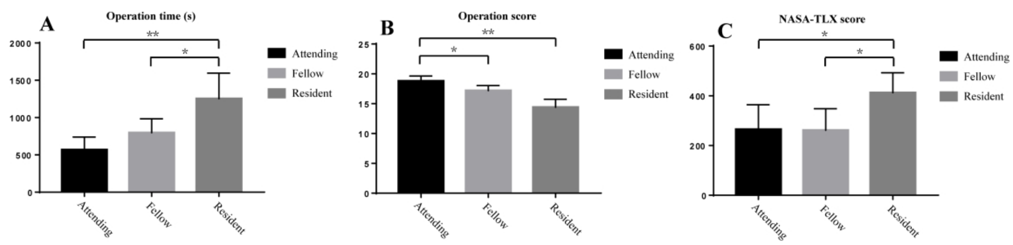

Panel A: The operation time of the resident group was significantly longer than either that of the fellow group (1254.80 ± 341.50 vs. 797.80 ± 186.40, p = 0.028) or the attending group (1254.80 ± 341.50 vs. 569.20 ± 170.01, p = 0.009); Panel B: The operation score of the attending group was significantly higher than either that of the fellow group (18.80 ± 0.84 vs. 17.20 ± 0.84, p = 0.023) or the resident group (18.80 ± 0.84 vs. 14.40 ± 1.34, p = 0.008); Panel C: The NASA-TLX score of the resident group was significantly higher than either that of the fellow group (412.80 ± 79.74 vs. 261.60 ± 86.41, p = 0.028) or the attending group (412.80 ± 79.74 vs. 265.40 ± 99.02, p = 0.047).
*p < 0.05, **p < 0.01, ***p < 0.001

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项目名称：3D 打印模型在胰肠吻合手术评估中的应用	
主要研究者：杨瑾	申请单位：浙江大学医学院附属邵逸夫医院普外科
有效期：1 年	跟踪审查频率：12 个月
审查类别：■初始审查 □复审 □修正案审查 □年度跟踪审查	
审查文件： 1、初始审查申请表 2、临床研究项目负责人承诺书 3、研究方案（版本号：V1.0，版本日期：2020-10-13） 4、知情同意书（版本号：V1.0，版本日期：2020-10-13） 5、免除知情同意书申请表 6、研究者简历	
主审委员：王青青、方滢芝	
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第 1 页 共 1 页

Appendix S2:Evaluation and Scoring.

The assessment of the proficiency of each individual trainee's anastomotic procedures is based on the time required to complete the task and the security of the anastomosis. Firstly assess the anterior and posterior anastomosis, and then perform the duct-to-mucosal anastomosis, which is checked by incising the jejunum model and checking the anastomosis from within. Any tearing of the model is noted. For all anastomosis, the duct is connected to a pump that can pump water in.

Distortions are carefully checked as well as strictures, which are identified by checking the water coming through the anastomosis, after turning on the pump. The distribution of the stitches, and whether the ties are loosened, are observed. General guidelines for assessing procedural skill include depth perception, applied force and tissue handling, dexterity and coordination of the arms, and efficiency(Table_ Appendix S1). Performance scores range from A to D, with A being the best.

Table Appendix S1: Criteria for evaluation of individual trainee anastomosis procedure proficiency.

Rank	Depth perception	Force/Tissue handling	Dexterity	Coordination of the arms	Efficiency
A	Good and can adjust well	Good at handling the tissue and suture, the tissue are not torn	Very good	Very good, can switch whenever necessary	All the sutures are perfect
B	Can adjust, but not always able to get to the best angle	Can handle the tissue and suture, with tissue occasionally torn or suture broken	Good	Good, able to switch but less than necessary	One torn of the tissue
C	Not good at finding the right angle	The tissue is too much distorted during the suturing	Fair	Fair, seldom switch among arms even the space or angle for suturing is not satisfied	One broken of the suture or two torn of the tissue
D	Poor at finding the right angle	Poor at handling the tissue and suture, the tissue, often torn the model	Poor	Poor, not at all good at coordination	more than above or distort of the anastomosis or strictures stopping the water going through the anastomosis

Reporting checklist for quality improvement in health care.

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		Reporting Item	Page Number
Title			
	#1	Indicate that the manuscript concerns an initiative to improve healthcare (broadly defined to include the quality, safety, effectiveness, patientcenteredness, timeliness, cost, efficiency, and equity of healthcare)	1
Abstract			
	#02a	Provide adequate information to aid in searching and indexing	2
	#02b	Summarize all key information from various sections of the text using the abstract format of the intended publication or a structured summary such as: background, local problem,	2

		methods, interventions, results, conclusions	
Introduction			
Problem description	#3	Nature and significance of the local problem	3
Available knowledge	#4	Summary of what is currently known about the problem, including relevant previous studies	3
Rationale	#5	Informal or formal frameworks, models, concepts, and / or theories used to explain the problem, any reasons or assumptions that were used to develop the intervention(s), and reasons why the intervention(s) was expected to work	3
Specific aims	#6	Purpose of the project and of this report	3
Methods			
Context	#7	Contextual elements considered important at the outset of introducing the intervention(s)	3
Intervention(s)	#08a	Description of the intervention(s) in sufficient detail that others could reproduce it	4-7
Intervention(s)	#08b	Specifics of the team involved in the work	4-7
Study of the Intervention(s)	#09a	Approach chosen for assessing the impact of the intervention(s)	4-7
Study of the Intervention(s)	#09b	Approach used to establish whether the observed outcomes were due to the intervention(s)	4-7
Measures	#10a	Measures chosen for studying processes and outcomes of the intervention(s), including rationale for choosing them, their operational definitions, and their validity and reliability	4-7
Measures	#10b	Description of the approach to the ongoing assessment of	4-7

		contextual elements that contributed to the success, failure, efficiency, and cost	
Measures	#10c	Methods employed for assessing completeness and accuracy of data	4-7
Analysis	#11a	Qualitative and quantitative methods used to draw inferences from the data	4-7
Analysis	#11b	Methods for understanding variation within the data, including the effects of time as a variable	4-7
Ethical considerations	#12	Ethical aspects of implementing and studying the intervention(s) and how they were addressed, including, but not limited to, formal ethics review and potential conflict(s) of interest	4-7
Results			
	#13a	Initial steps of the intervention(s) and their evolution over time (e.g., time-line diagram, flow chart, or table), including modifications made to the intervention during the project	7-9
	#13b	Details of the process measures and outcome	7-9
	#13c	Contextual elements that interacted with the intervention(s)	7-9
	#13d	Observed associations between outcomes, interventions, and relevant contextual elements	7-9
	#13e	Unintended consequences such as unexpected benefits, problems, failures, or costs associated with the intervention(s).	7-9
	#13f	Details about missing data	7-9
Discussion			
Summary	#14a	Key findings, including relevance to the rationale and specific aims	9-11

Summary	#14b	Particular strengths of the project	9-11
Interpretation	#15a	Nature of the association between the intervention(s) and the outcomes	9-11
Interpretation	#15b	Comparison of results with findings from other publications	9-11
Interpretation	#15c	Impact of the project on people and systems	9-11
Interpretation	#15d	Reasons for any differences between observed and anticipated outcomes, including the influence of context	9-11
Interpretation	#15e	Costs and strategic trade-offs, including opportunity costs	9-11
Limitations	#16a	Limits to the generalizability of the work	11
Limitations	#16b	Factors that might have limited internal validity such as confounding, bias, or imprecision in the design, methods, measurement, or analysis	11
Limitations	#16c	Efforts made to minimize and adjust for limitations	11
Conclusion	#17a	Usefulness of the work	11
Conclusion	#17b	Sustainability	11
Conclusion	#17c	Potential for spread to other contexts	11
Conclusion	#17d	Implications for practice and for further study in the field	11
Conclusion	#17e	Suggested next steps	11
Other information			
Funding	#18	Sources of funding that supported this work. Role, if any, of the funding organization in the design, implementation,	12

interpretation, and reporting

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Validation of a three-dimensional printed dry lab pancreaticojejunostomy model in surgical assessment: a cross-sectional study

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Validation of a three-dimensional printed dry lab pancreaticojejunostomy model in surgical assessment: a cross-sectional study

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Abstract

Objectives. Until now, there have been few tools to evaluate whether a surgeon was technically ready to perform a safe pancreaticojejunostomy (PJ). In the current study, we aimed to evaluate whether a three-dimensional model could mimic a real surgical situation and distinguish between surgeons of different levels of experiences.

Design. A three-dimensional pancreaticojejunostomy (PJ) dry laboratory model was printed. Eight experienced pancreatic surgeons were tasked to evaluate the appearance and tactile sensation of the model. Proficiency was scored based on fifteen surgeons with various levels of pancreatic experience performing a PJ on the three-dimensional model. Additionally, the time of manipulation and NASA Task Load Index (NASA-TLX) scores were recorded for each operation.

Setting. Our study was conducted in multi medical centre in China.

Results. Compared with real surgical situations, this model had similar appearance (3.96 ± 0.55 out of five points) and tactile sensation (3.85 ± 0.46 out of five points) according to the expert evaluation. Additionally, the chief surgeon group scored the best in proficiency (based on NASA-TLX scores and operative time) and there were statistical differences for performances among surgeons of various levels ($p < 0.05$).

Conclusion. The three-dimensional PJ model could mimic a real surgical situation and can distinguish between surgeons of different levels of experiences.

Key words: Three-dimensional PJ model, validity, surgical assessment, appearance, tactile sensation

Strengths and limitations of this study

Strengths of this cross-sectional study include that:

1. The three-dimensional PJ model could mimic a real surgical situation, allowing it to be used as a portable teaching and learning tool, and;

2. The model is easier to store, therefore it can be used by students in the office or even at home.

Limitations of the study include that:

1. Although the current study used softer silicone material to simulate the pancreatic parenchyma, its structure was still slightly higher than that of the pancreatic tissue;

2. The PJ model in the current study didn't contain vessels such as the splenic artery, which would have allowed for the simulation of a more realistic situation, and;

3. The characteristics of the pancreatic tissue (consistency, elasticity, etc) are highly different from one patient to another, which may influence both the technique and the results of pancreato-enteric anastomosis, but in the current study only one type of silicon model was used.

Introduction

A pancreaticojejunostomy (PJ) is one of the most challenging procedures in general surgery and a lack of proficiency and experience in doing this procedure may lead to postoperative pancreatic leakage, hemorrhage, or even death [1-3]. Advanced techniques, such as 3D printing, have been widely used in the field of surgery for the purpose of education and preoperative designing, however, there are few reports indicating that they could be used as a tool to evaluate surgical competency.

According to Szasz and colleagues [4], due to work hour restrictions, limitations of operating room accessibility, and increased litigation against physicians, the educational opportunities of surgeons have dramatically decreased. Based on this status quo, the Accreditation Council for Graduate Medical Education [5], the Royal College of Physicians and Surgeons of Canada [6], and many others worldwide have developed training programs to improve surgical skills.

Compared with traditional pancreaticoduodenal surgery training methods, there remains a lack of an effective physical model to help distinguish between pancreatic surgeons of different levels and to roughly assess whether pancreatic surgeons are prepared. As an emerging technology, 3D printing technology has been widely used in the medical field [7-9] and has been broadly studied and reported on in a book on the training and application of simulation models in robotic gynecological surgery [10]. Additionally, 3D printed models are expected to be used in the future as one of the methods of pancreatic surgery training, reducing learning costs and helping young doctors improve surgical techniques. In the current study, experts in the field of pancreatic surgery were invited to evaluate the appearance of the model. We aimed to evaluate whether a three-dimensional model could mimic a real surgical situation and distinguish between surgeons of various levels of experience.

Materials & Methods

1 Study Design and Setting

The current revolutionary study invited eight surgical experts from multiple pancreatic surgery centers in China to conduct an anatomical evaluation of a 3D-printed model. All eight experts had performed more than 20 instances of pancreaticoduodenectomy within the prior year and four had performed more than 100 instances of pancreaticoduodenectomy in the prior year. Fifteen doctors from our pancreatic surgery center were invited to participate in the model function evaluation.

2 3D-Printed Dry Lab PJ Model Production

The 3D-printed dry lab PJ model primarily contained the pancreas and small intestine and was printed using a dual-head silicone printer. The Sir Run Run Shaw Hospital granted Ethical approval to conduct the study within its facilities (see appendix S1). First, the Computed Tomography (CT) data was collected in a Digital Imaging and Communications in Medicine (DICOM) format, with 1 mm thick slices. The E3D digital medical modeling software V17.06 (Central South E3D Digital Medical and Virtual Reality Research Center, China) was used for boundary segmentation and 3D reconstruction and the model structure was streamlined according to manual editing (Figure 1). The open source slicing software Cura 4.4.1 (Ulitmaker, USA) was used for slicing the 3D printing. The material was made of silicone specialized for 3D printing. The silicone material used for the pancreatic parenchyma was pink, with a tear strength of 4.8 N/mm and a tensile strength of 2 MPa. The silicone material used for the pancreatic duct was white, with a tear strength of 5.2 N/mm and a tensile strength of 1.8 MPa. The silicone material used for the small intestine was red, with a tear strength of 5.2 N/mm and a tensile strength of 1.8 MPa. The pancreas was the primary component of the PJ model and its stiffness was measured via ultrasound, with a two-dimensional shear-wave elastography (2D-SWE) value of nine times.

3 Patient and Public Involvement

Neither patients nor the public were directly involved in the design of the current study.

4 Evaluation scale design

The expert evaluation scale of the model was comprehensively designed with reference to the relevant literature[11-13], using a 5-point Likert scale (See Appendix *S2*). The main coverage areas include: the amount of pancreatic surgery the expert had conducted, the evaluation of the overall settings of the 3D printed model, the evaluation of the appearance, size, and tactile similarity of the 3D printed model, and a comprehensive evaluation of the 3D printed pancreas model for clinical and teaching work.

The model's operation rating scale was designed with reference to the relevant model training literature [14], which primarily evaluates the depth perception, force/tissue handling, dexterity, coordination of the arms, and the efficiency of the chief surgeon (attending), first assistant (fellow), and observer (resident) physicians in pancreatic surgery.

The functional psychology scale of the model refers to the NASA Task Load Index (NASA-TLX), which primarily evaluates the mental load of pancreatic surgeons. The significance of the related indices is reported in several articles as it relates to surgical model training [15, 16].

5 Assessment scale issuance

The current study selected eight pancreatic surgery experts and sent the 3D printed pancreas models and distributed the 3D printed pancreas model evaluation scales to each of the experts. Experts in pancreatic surgery were invited to participate in the evaluation from all aspects according to the scale and to make professional recommendations.

Fifteen chief surgeons (attendings), first assistants (fellows), and observers (residents) from the general surgery department were selected and issued basic information collection forms. All surgeons in the section provided written informed human participant consent. Model training operations were performed after teaching the procedures. The entirety of the operation was recorded on video and the proficiency was scored by two pancreatic experts who were blinded to the identities of surgeons. After the operation, all personnel were issued a NASA-TLX scale to assess the mental load of the operation.

6 General Information of Pancreatic Surgeons

Five attendings, including two experts from the PJ anatomical evaluation department, five fellows, and five residents were invited to participate in the current study (general information of the physicians is shown in Table 1). There were significant differences in the working years of the three groups of surgeons (13.40 ± 3.21 vs. 6.00 ± 1.22 vs. 2.60 ± 1.82, respectively; $p <$

0.001), in which all attendings had worked for more than eight years and all residents had worked for five or fewer years. The three groups of surgeons had a statistically significant difference both in the number of cases of pancreatoenterostomies as lead surgeons (p = 0.008) as well as in the number of cases of pancreaticoduodenectomy as the first assistant (p = 0.014). All pancreatic surgeons who participated in the study were right-handed, with no significant statistical difference between the three groups of surgeons in simulation training ($p = 0.287$), nor were there any significant statistical differences between the three groups of participants in Virtual Reality (VR) surgical training ($p = 0.562$).

Table 1. General information of attendings, fellows, and residents.

	Attendings (n=5)	Fellows (n=5)	Residents (n=5)	P-value
Years of working	13.40±3.21	6.00±1.22	2.60±1.82	<0.001***
Cases of Pancreatoenterostomy as lead surgeon				0.008**
0	0/5 (0%)	4/5 (80%)	5/5 (100%)	
< 10	1/5 (20%)	1/5 (20%)	0/5 (0%)	
≥ 10	4/5 (80%)	0/5 (0%)	0/5 (0%)	
Cases of Pancreatoenterostomy as first assistant				0.014*
0	0/5 (0%)	0/5 (0%)	2/5 (40%)	
< 10	0/5 (0%)	3/5 (60%)	3/5 (60%)	
10-50	0/5 (0%)	1/5 (20%)	0/5 (0%)	
> 50	5/5 (100%)	1/5 (20%)	0/5 (0%)	
Number of right handers	5/5 (100%)	5/5 (100%)	5/5 (100%)	1.000
Number who have participated in simulation training	1/5 (20%)	0/5 (0%)	2/5 (40%)	0.287
Number who have participated in VR operation training	1/5 (20%)	0/5 (0%)	1/5 (20%)	0.562

VR: Virtual Reality (*$p < 0.05$, **$p < 0.01$, ***$p < 0.001$)

7 Operation procedures

The operation procedures used in the current study refer to the classic Cattell-Warren anastomosis method. The operation steps are detailed in *Figure 2*.

8 Data analyses

The current study collected statistics on the overall settings and appearance, size, and tactile similarity of the 3D printed pancreas model and the functional evaluation indicators of the model (primarily including the surgical operation score, operation time, and NASA-TLX score). Microsoft Excel (2016) was used to establish the scoring and evaluation table of each item in the evaluation scale by experts. SPSS (Version 20.0, SPSS Inc, Chicago, IL, USA) software was then used for the subsequent data analyses and processing. All tests were 2-tailed and $p < 0.05$ was considered statistically significant. The results from the statistical analyses were entered into Graphpad Prism 7.0 and related charts were drawn. Each score was calculated by the mean ± standard deviation.

Results

1 Pancreatic surgery experts' anatomical evaluation of the model

The research invited eight pancreatic surgery experts to conduct a comprehensive evaluation. All experts had performed more than 20 cases of pancreaticoduodenectomy within the prior year and four had performed more than 100 cases of pancreaticoduodenectomy in the prior year. The model obtained an overall evaluation of 4.38 ± 0.74 (*Figure 3B-E*) and all experts gave greater than "more similar" (3 points) as their evaluation. The current study also invited experts to make assessments on their recommendation of using this model for teaching. The results are presented below.

1.1 Appearance

The overall appearance of the 3D printed PJ dry laboratory model was evaluated at 3.96 ± 0.55. The appearance of the pancreatic parenchyma was evaluated at 4.13 ± 0.64, the appearance of the pancreatic duct was evaluated at 4.00 ± 0.53, and the appearance of the intestinal canal was evaluated at 3.75 ± 0.46.

1.2 Tactile Sensations

The pancreas was the primary component of the PJ model and its stiffness was measured via ultrasound with a two-dimensional shear-wave elastography (2D-SWE) value of 10.08 ± 6.50 kPa (*Figure 3A*). The stiffness of the PJ model was slightly higher ($p = 0.003$) than that of

192 human tissue, which has been reported as 7.72 ± 2.50 kPa [17]. The overall tactile evaluation of the 3D printed PJ dry laboratory model by experts was evaluated at 3.85 ± 0.46. The elasticity of the model was evaluated at 3.88 ± 0.45 and the elasticity of the pancreas parenchyma, pancreatic duct, and intestinal duct of the model were equivalent. The ease of tearing of the model was evaluated at 3.83 ± 0.48 and the ease of tearing of the intestinal duct of the model was slightly higher than the other two parts, at 4.00 ± 0.53. The suture breakthrough of the model was evaluated at 3.83 ± 0.48 and the pancreatic parenchyma of the model was slightly lower than the other two, at 3.88 ± 0.35.

200 **1.3 Education**

201 All eight experts (100%) agreed that the 3D printed laboratory model of the PJ could/should be used for teaching.

203 **2 Model functional evaluation**

204 The functional evaluation of the 3D printed PJ dry laboratory model included three outcome indicators selected for evaluation, including operation time, operation score, and the NASA Task Load Index (NASA-TLX score). Details are shown in Tables 2 and 3.

207 **Table 2. The operation time, operation score, and the NASA-TLX score of the three groups.**

	Attendings (n=5)	Fellows (n=5)	Residents (n=5)	P-value
Operation time	569.20±170.01	797.80±186.40	1254.80±341.50	0.003**
Operation score	18.80±0.84	17.20±0.84	14.40±1.34	<0.001***
NASA-TLX score	265.40±99.02	261.60±86.41	412.80±79.74	0.031*

208 *$p < 0.05$, **$p < 0.01$, ***$p < 0.001$

209 **2.1 Operation Time**

210 There were significant statistical differences in the operation time of the three groups of researchers (p = 0.003) (shown in *Figure 4A*), where the operation time of the resident group was significantly longer than either that of the fellow group (1254.80 ± 341.50 vs. 797.80 ± 186.40, p = 0.028) or the attending group (1254.80 ± 341.50 vs. 569.20 ± 170.01; p = 0.009), but there was no significant statistical difference between the attending group and the fellow group (569.20 ± 170.01 vs. 797.80 ± 186.40, p = 0.175).

216 **2.2 Operation score**

217 The operation score for the three groups of researchers was statistically significant (p < 0.001), as shown in *Figure 4B*, where the operation score of the attending group is significantly

higher than fellow group (18.80 ± 0.84 vs. 17.20 ± 0.84, $p = 0.023$) and the resident group (18.80 ± 0.84 vs. 14.40 ± 1.34, $p = 0.008$).

2.3 NASA-TLX score

The NASA-TLX mental load scores of the three groups of researchers were statistically significantly different ($p = 0.031$), as shown in *Figure 4C*. The NASA-TLX score of the attending group was not significantly different from that of the fellow group (265.40 ± 99.02 vs. 261.60 ± 86.41, $p = 0.754$), while the NASA-TLX score of the resident group was significantly higher than fellow group (412.80 ± 79.74 vs. 261.60 ± 86.41, $p = 0.028$) and the attending group (412.80 ± 79.74 vs. 265.40 ± 99.02, $p = 0.047$).

Table 3. P-value of the pairwise group comparison.

	A vs. F	A vs. R	F vs. R
Operation time	0.175	0.009**	0.028*
Operation score	0.023*	0.008**	0.09
NASA-TLX score	0.754	0.047*	0.028*

A: Attending group; F: Fellow group; R: Resident group. (*$p < 0.05$, **$p < 0.01$, ***$p < 0.001$)

Discussion

Traditional surgical teaching and training methods are experiencing increasing learning costs under the modern background and pancreatic surgery is known for its relatively higher surgical difficulty. Within the digestive tract anastomosis, the PJ is the most complicated, which can lead to various postoperative complications. The PJ model based on biotissue[11] is considered to improve technical performance in surgical oncology fellows. However, to our knowledge, although they have been successfully applied to training in many fields of surgery, including head and neck surgery [18], colorectal surgery [19], vascular surgery [20], and neurosurgery [21], among others, there are few reports on PJ models using 3D printed models.

Elastography is an ultrasound imaging method that has been used to assess the stiffness of tissues. The concept of elastography was first proposed in 1991 [22]. During an elastography evaluation, the stiffness of the model can be estimated from the response of the model to compression. This process can be performed in two ways; shear wave elastography (SWE) or strain elastography [23]. The current study used soft silicone material to simulate the pancreatic parenchyma and its hardness, which was slightly higher than that of the pancreatic tissue. Our team has also studied hydrogel as a 3D printing material to print PJ models. Its hardness is very close to that of the pancreas. But the moisture in hydrogel tends to evaporate over time, which causes difficulties with storage, thereby limiting its use. Future studies are planned to conduct in-depth research on this softer material. In the current study, eight pancreatic surgery experts were selected, all of whom exceeded the experience expectations for a pancreaticoduodenectomy, and a model evaluation scale was issued to these experts. The evaluation scale adopts the 5-point Likert scale [11-13], which comprehensively evaluates the appearance and touch of each component of the model, its similarity with real surgery, and its application in teaching. Experts rated the model highly on both appearance and touch, suggesting that the model has good simulation performance. All experts recommend it for teaching, suggesting a potential role of such models in surgical training.

The current study also selected three groups of surgeons to perform functional tests of the model. The selected research indicators primarily include operation time, operation score, and the NASA-TLX. There is a plethora of research on operation time and operation score, which can effectively reflect the operation level on the model [24, 25]. Additionally, Beard et al. [26] developed an objective structured assessment of technical skills (OSATS) scale based on the surgeon's technical competency evaluation. The research published by Wei et al. [14] was optimized on the basis of OSATS and was demonstrated to be a good assessment of the technical competency of surgeons. The operation scoring standard of the current research also refers to this modified version of the scoring design. In addition, the current study utilized the NASA-TLX as a subjective index to assess mental workload, which can reflect the surgeon's operating pressure, which has attracted increasing attention in recent years [15, 27]. Given the results of the above three indicators, the model is suggested to be able to effectively distinguish between the three groups of physicians in terms of operating time, operating scores, and mental stress, further indicating the effectiveness of the model. Among the groups, the attending group had a shorter operating time than the fellow group (569.20 ± 170.01 vs. 797.80 ± 186.40), however, this difference was not statistically significant. This may be due to an insufficient number of enrolled physicians. Additionally, there was no significant difference between the attending group and the fellow group doctors in terms of stress scores, plausibly due to a better psychological tolerance in the fellow group as the amount of surgery gradually increased. Furthermore, the mental stress of attendings and fellows in the model training was significantly lower than that of the residents, suggesting that the model can effectively simulate mental stress. The results of the current study demonstrate that the 3D printed PJ model has good simulation and effectiveness. It can help distinguish pancreatic surgeons at various levels can roughly assess whether pancreatic surgeons are prepared for surgery.

Organ models cut from cadaver tissue have certain advantages in training young doctors in the fields of trauma, plastic surgery, gynecology, general surgery, and vascular surgery. For example, SIM Life, which is an emerging model that uses corpses as a template to have an artificial heartbeat, circulation, and breathing, has been given high ratings by users. However, the application of living tissues has many problems such as storage, production, and cost. The cost of 3D printed organizational models is greatly reduced and due to advances in technology and materials, it has improved organizational similarity and training effects and it is easier to promote and train economically. Simultaneously, it is easier to produce with a short production cycle and it has a better prospect in clinical application.

However, the current study has some disadvantages. One of the limitations that future research should consider is the printing of the pancreas model with the inclusion of vessels, such as the splenic artery, as this will allow for the simulation of a more realistic situation. Additionally, characteristics of the pancreatic tissue (consistency, elasticity, etc.) are highly different from one patient to another and influence both the technique and the results of the pancreato-enteric anastomosis. In the current study, only one type of silicon model was used. Furthermore, while a soft silicone material was selected to simulate the pancreatic parenchyma, its hardness was still slightly higher than that of the pancreatic tissue. Additionally, while we chose fifteen surgeons performed a PJ on the three-dimensional model, the sample size could be larger. In future studies, different materials should be tried to achieve better material simulation and compare their different training effects and expert evaluation. We also selected the open pancreaticoduodenal model for training and will use the laparoscopic model for additional future research.

Conclusions

The three-dimensional PJ model could mimic real surgical situations and can be used to distinguish surgeons of various levels of experience. Therefore, prior to doing a pancreaticoduodenectomy, this model may be a convenient tool to let surgeons to evaluate whether they are technically proficient to perform a high-quality and safe PJ on their patients.

Author Contribution

HY, JY, ZFW, TNY, JLW co-conceived the study design, planned and prepared study protocols. HY, FQW, HBG, JLW, XZH conducted the research including data collection, data analysis and data interpretation. HY, HYD, ZFW, JY, and TNY reported the work.

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Conflicts of interest

All authors declare no conflicts of interest.

Ethics Approval

The Sir Run Run Shaw Hospital granted ethical approval to conduct the current study within its facilities (Ethical Application Ref: jm420-c5a3d, see appendix S2). All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2000 (5).

Data availability statement

All data that used in the writing of our article in the text are publicly available and the reference list were cited. See

Doi: https://doi.org/10.5281/zenodo.5842799

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Figure 1. The appearance of the 3D-printed PJ model. **(A)** The 3D-printed PJ model is primarily composed of three parts: the pancreatic parenchyma, the pancreatic duct, and the intestinal duct. **(B)** Side view of the 3D-printed PJ model.

Figure 2. Cattell-Warren anastomosis instructions **(A)** Continuously suture the posterior margin of the pancreas and the seromuscular layer of the jejunum; 2/3 of the pancreatic tissue on the dorsal side of the pancreas should be sutured. The sutures should not be temporarily tightened to facilitate exposure of the posterior pancreatic duct wall. **(B)** Cut the full thickness of the jejunum wall corresponding to the position of the pancreatic duct. When suturing the posterior wall of the pancreatic duct, 1/3 of the surrounding pancreatic tissue should be included, then knot it together. The knot should be on the outside of the anastomosis. **(C)** Suture the pancreatic duct and the intestinal duct intermittently at 3, 6, 9, and 12 o'clock, respectively, to complete the anastomosis of the pancreatic duct and the jejunum wall. **(D)** The anterior wall of the pancreatic duct and its surrounding 1/3 of the pancreatic tissue and the entire anterior wall of the jejunum should be continuously sutured with the suture that was used when the posterior wall was sutured. **(E)** Tighten the sutures to complete the anastomosis.

Figure 3. Panel A: The pancreas stiffness of the PJ model was measured by ultrasound with a 2D-SWE value of 10.08±6.50 kPa. Panel B: General evaluation of the model. Panels C, D, and E: The appearance, elasticity, sense of tearing, and breakthrough degree of evaluation of the various parts of the model, including the pancreatic parenchyma, pancreatic duct, and the intestinal canal.

*2D-SWE: Two-dimensional shear-wave elastography; OPD: Open pancreaticoduodenectomy; LPD: Laparoscopic pancreaticoduodenectom

Figure 4. Panel A: The operation time of the resident group was significantly longer than either that of the fellow group (1254.80 ± 341.50 vs. 797.80 ± 186.40, $p = 0.028$) or the attending group (1254.80 ± 341.50 vs. 569.20 ± 170.01, $p = 0.009$); Panel B: The operation score of the attending group was significantly higher than either that of the fellow group (18.80 ± 0.84 vs. 17.20 ± 0.84, $p = 0.023$) or the resident group (18.80 ± 0.84 vs. 14.40 ± 1.34, $p = 0.008$); Panel C: The NASA-TLX score of the resident group was significantly higher than either that of the fellow group (412.80 ± 79.74 vs. 261.60 ± 86.41, $p = 0.028$) or the attending group (412.80 ± 79.74 vs. 265.40 ± 99.02, $p = 0.047$).

*$p < 0.05$, **$p < 0.01$, ***$p < 0.001$

References

[1] Ecker, B.L., McMillan, M.T., Asbun, H.J., Ball, C.G., Bassi, C., Beane, J.D., Behrman, S.W., Berger, A.C., Dickson, E.J., Bloomston, M., et al. 2018 Characterization and Optimal Management of High-risk Pancreatic Anastomoses During Pancreatoduodenectomy. *Annals of surgery* **267**, 608-616. (doi:10.1097/sla.0000000000002327).

[2] Besselink, M.G., van Rijssen, L.B., Bassi, C., Dervenis, C., Montorsi, M., Adham, M., Asbun, H.J., Bockhorn, M., Strobel, O., Büchler, M.W., et al. 2017 Definition and classification of chyle leak after pancreatic operation: A consensus statement by the International Study Group on Pancreatic Surgery. *Surgery* **161**, 365-372. (doi:10.1016/j.surg.2016.06.058).

[3] Suzuki, S., Kajiyama, H., Takemura, A., Shimazaki, J., Nishida, K. & Shimoda, M. 2017 The Clinical Outcomes after Total Pancreatectomy. *Digestive surgery* **34**, 142-150. (doi:10.1159/000449234).

[4] Szasz, P., Louridas, M., Harris, K.A., Aggarwal, R. & Grantcharov, T.P. 2015 Assessing Technical Competence in Surgical Trainees: A Systematic Review. *Annals of surgery* **261**, 1046-1055. (doi:10.1097/sla.0000000000000866).

[5] Ziv, A., Wolpe, P.R., Small, S.D. & Glick, S. 2003 Simulation-based medical education: an ethical imperative. *Academic medicine : journal of the Association of American Medical Colleges* **78**, 783-788. (doi:10.1097/00001888-200308000-00006).

[6] Frank, J.R., Snell, L.S., Cate, O.T., Holmboe, E.S., Carraccio, C., Swing, S.R., Harris, P., Glasgow, N.J., Campbell, C., Dath, D., et al. 2010 Competency-based medical education: theory to practice. *Medical teacher* **32**, 638-645. (doi:10.3109/0142159x.2010.501190).

[7] Tack, P., Victor, J., Gemmel, P. & Annemans, L. 2016 3D-printing techniques in a medical setting: a systematic literature review. *Biomedical engineering online* **15**, 115. (doi:10.1186/s12938-016-0236-4).

[8] Perica, E.R. & Sun, Z. 2018 A Systematic Review of Three-Dimensional Printing in Liver Disease. *Journal of digital imaging* **31**, 692-701. (doi:10.1007/s10278-018-0067-x).

[9] Sun, Z. & Lee, S.Y. 2017 A systematic review of 3-D printing in cardiovascular and cerebrovascular diseases. *Anatolian journal of cardiology* **17**, 423-435. (doi:10.14744/AnatolJCardiol.2017.7464).

[10] Kiely, D.J. 2014 Advancing surgical simulation in robotic gynecologic oncology.

[11] Tam, V., Zenati, M., Novak, S., Chen, Y., Zureikat, A.H., Zeh, H.J., 3rd & Hogg, M.E. 2017 Robotic Pancreatoduodenectomy Biotissue Curriculum has Validity and Improves Technical Performance for Surgical Oncology Fellows. *Journal of surgical education* **74**, 1057-1065. (doi:10.1016/j.jsurg.2017.05.016).

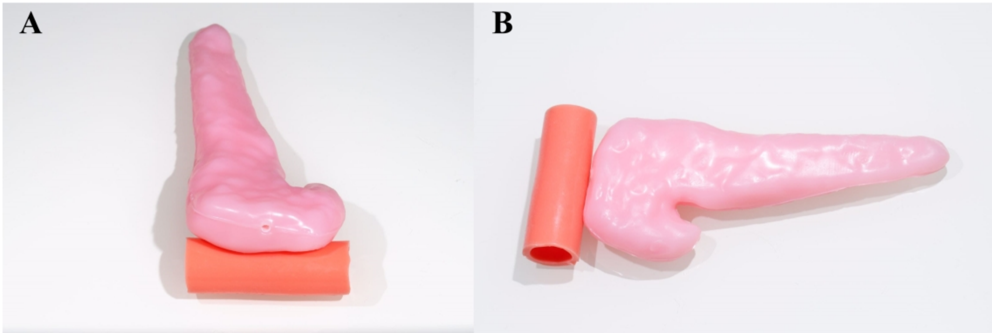
[12] Maricic, M.A., Bailez, M.M. & Rodriguez, S.P. 2016 Validation of an inanimate low cost model for training minimal invasive surgery (MIS) of esophageal atresia with tracheoesophageal fistula (AE/TEF) repair. *Journal of pediatric surgery* **51**, 1429-1435. (doi:10.1016/j.jpedsurg.2016.04.018).

[13] Kiely, D.J., Gotlieb, W.H., Jardon, K., Lau, S. & Press, J.Z. 2015 Advancing surgical simulation in gynecologic oncology: robotic dissection of a novel pelvic lymphadenectomy model. *Simulation in healthcare : journal of the Society for Simulation in Healthcare* **10**, 38-42. (doi:10.1097/sih.0000000000000054).

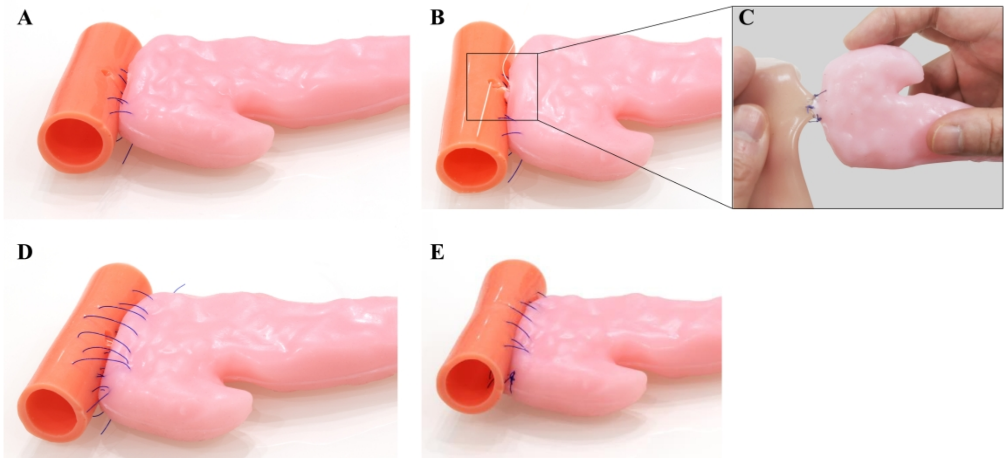
[14] Wei, F., Xu, M., Lai, X., Zhang, J., Yiengpruksawan, A., Lu, Y., Liu, J. & Wang, Z. 2019 Three-dimensional printed dry lab training models to simulate robotic-assisted pancreaticojejunostomy. *ANZ journal of surgery* **89**, 1631-1635. (doi:10.1111/ans.15544).

[15] Lowndes, B.R., Forsyth, K.L., Blocker, R.C., Dean, P.G., Truty, M.J., Heller, S.F., Blackmon, S., Hallbeck, M.S. & Nelson, H. 2020 NASA-TLX Assessment of Surgeon Workload Variation Across Specialties. *Annals of surgery* **271**, 686-692. (doi:10.1097/sla.0000000000003058).

[16] Law, K.E., Lowndes, B.R., Kelley, S.R., Blocker, R.C., Larson, D.W., Hallbeck, M.S. & Nelson, H. 2020 NASA-Task Load Index Differentiates Surgical Approach: Opportunities for Improvement in Colon and Rectal Surgery. *Annals of surgery* **271**, 906-912. (doi:10.1097/sla.0000000000003173).
[dataset] [17] Sezgin, O., Yaraş, S. & Özdoğan, O. 2021 The course and prognostic value of increased pancreas stiffness detected by ultrasound elastography during acute pancreatitis. *Pancreatology : official journal of the International Association of Pancreatology (IAP) ... [et al.]*. (doi:10.1016/j.pan.2021.07.006).
[18] Werz, S.M., Zeichner, S.J., Berg, B.I., Zeilhofer, H.F. & Thieringer, F. 2018 3D Printed Surgical Simulation Models as educational tool by maxillofacial surgeons. *European journal of dental education : official journal of the Association for Dental Education in Europe* **22**, e500-e505. (doi:10.1111/eje.12332).
[19] Bangeas, P., Drevelegas, K., Agorastou, C., Tzounis, L., Chorti, A., Paramythiotis, D., Michalopoulos, A., Tsoulfas, G., Papadopoulos, V.N., Exadaktylos, A., et al. 2019 Three-dimensional printing as an educational tool in colorectal surgery. *Frontiers in bioscience (Elite edition)* **11**, 29-37. (doi:10.2741/e844).
[20] Wang, C., Zhang, L., Qin, T., Xi, Z., Sun, L., Wu, H. & Li, D. 2020 3D printing in adult cardiovascular surgery and interventions: a systematic review. *Journal of thoracic disease* **12**, 3227-3237. (doi:10.21037/jtd-20-455).
[21] Weinstock, P., Rehder, R., Prabhu, S.P., Forbes, P.W., Roussin, C.J. & Cohen, A.R. 2017 Creation of a novel simulator for minimally invasive neurosurgery: fusion of 3D printing and special effects. *Journal of neurosurgery. Pediatrics* **20**, 1-9. (doi:10.3171/2017.1.Peds16568).
[22] Ophir, J., Céspedes, I., Ponnekanti, H., Yazdi, Y. & Li, X. 1991 Elastography: a quantitative method for imaging the elasticity of biological tissues. *Ultrasonic imaging* **13**, 111-134. (doi:10.1177/016173469101300201).
[23] Kuwahara, T., Hirooka, Y., Kawashima, H., Ohno, E., Sugimoto, H., Hayashi, D., Morishima, T., Kawai, M., Suhara, H., Takeyama, T., et al. 2016 Quantitative evaluation of pancreatic tumor fibrosis using shear wave elastography. *Pancreatology : official journal of the International Association of Pancreatology (IAP) ... [et al.]* **16**, 1063-1068. (doi:10.1016/j.pan.2016.09.012).
[24] Pucci, J.U., Christophe, B.R., Sisti, J.A. & Connolly, E.S., Jr. 2017 Three-dimensional printing: technologies, applications, and limitations in neurosurgery. *Biotechnology advances* **35**, 521-529. (doi:10.1016/j.biotechadv.2017.05.007).
[25] Bartel, T., Rivard, A., Jimenez, A., Mestres, C.A. & Müller, S. 2018 Medical three-dimensional printing opens up new opportunities in cardiology and cardiac surgery. *European heart journal* **39**, 1246-1254. (doi:10.1093/eurheartj/ehx016).
[26] Beard, J.D. 2005 Setting standards for the assessment of operative competence. *European journal of vascular and endovascular surgery : the official journal of the European Society for Vascular Surgery* **30**, 215-218. (doi:10.1016/j.ejvs.2005.01.032).
[27] Abbott, E.F., Thompson, W., Pandian, T.K., Zendejas, B., Farley, D.R. & Cook, D.A. 2017 Personalized Video Feedback and Repeated Task Practice Improve Laparoscopic Knot-Tying Skills: Two Controlled Trials. *Academic medicine : journal of the Association of American Medical Colleges* **92**, S26-s32. (doi:10.1097/acm.0000000000001924).



The appearance of the 3D-printed PJ model. (A) The 3D-printed PJ model is primarily composed of three parts: the pancreatic parenchyma, the pancreatic duct, and the intestinal duct. (B) Side view of the 3D-printed PJ model.



Cattell-Warren anastomosis instructions (A) Continuously suture the posterior margin of the pancreas and the seromuscular layer of the jejunum; 2/3 of the pancreatic tissue on the dorsal side of the pancreas should be sutured. The sutures should not be temporarily tightened to facilitate exposure of the posterior pancreatic duct wall. (B) Cut the full thickness of the jejunum wall corresponding to the position of the pancreatic duct. When suturing the posterior wall of the pancreatic duct, 1/3 of the surrounding pancreatic tissue should be included, then knot it together. The knot should be on the outside of the anastomosis. (C) Suture the pancreatic duct and the intestinal duct intermittently at 3, 6, 9, and 12 o'clock, respectively, to complete the anastomosis of the pancreatic duct and the jejunum wall. (D) The anterior wall of the pancreatic duct and its surrounding 1/3 of the pancreatic tissue and the entire anterior wall of the jejunum should be continuously sutured with the suture that was used when the posterior wall was sutured. (E) Tighten the sutures to complete the anastomosis.

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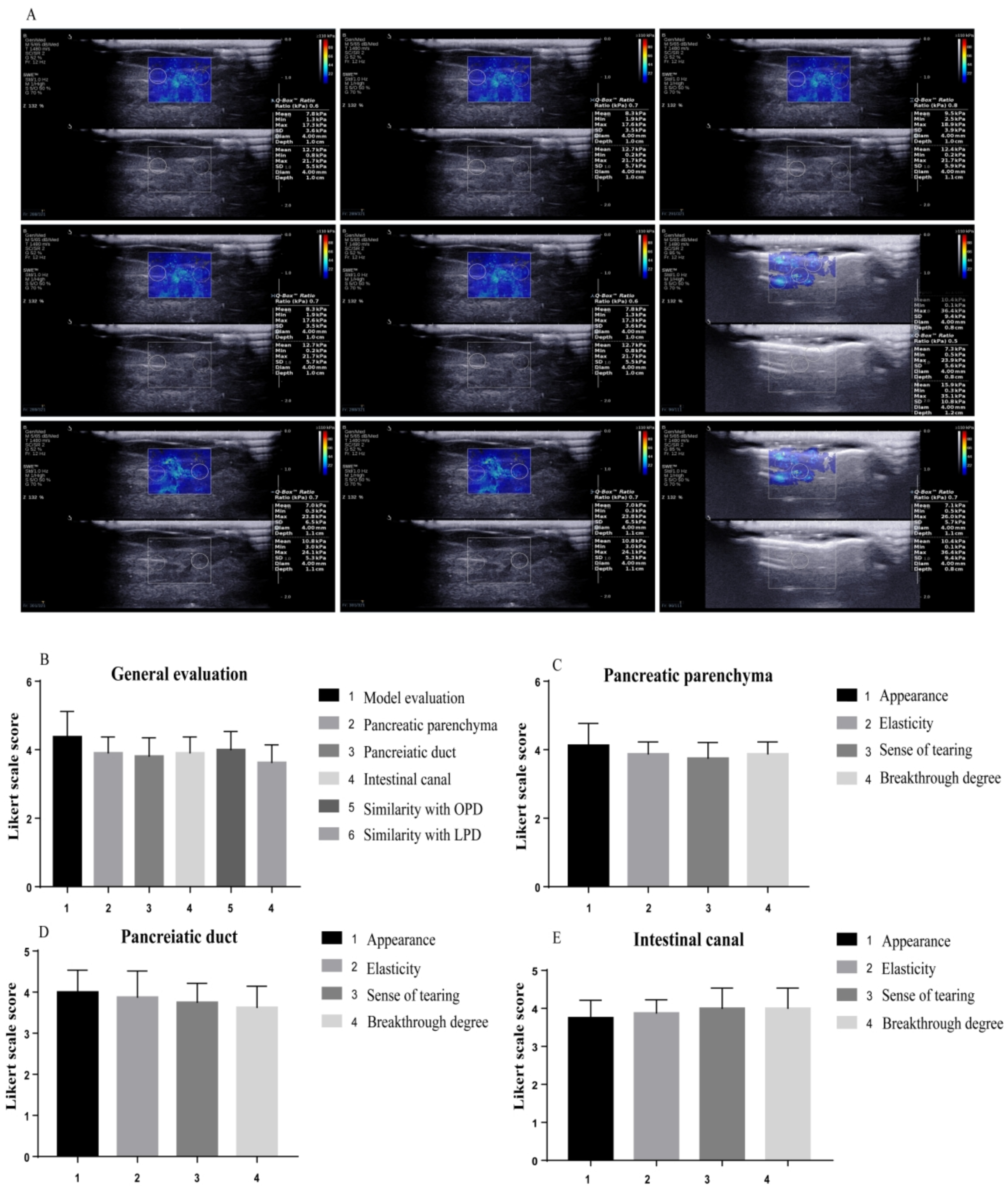

Panel A: The pancreas stiffness of the PJ model was measured by ultrasound with a 2D-SWE value of 10.08±6.50 kPa. Panel B: General evaluation of the model. Panels C, D, and E: The appearance, elasticity, sense of tearing, and breakthrough degree of evaluation of the various parts of the model, including the pancreatic parenchyma, pancreatic duct, and the intestinal canal.
*2D-SWE: Two-dimensional shear-wave elastography; OPD: Open pancreaticoduodenectomy; LPD: Laparoscopic pancreaticoduodenectom

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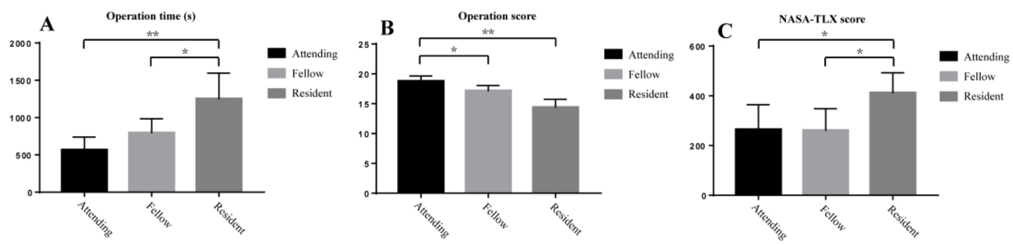

Panel A: The operation time of the resident group was significantly longer than either that of the fellow group (1254.80 ± 341.50 vs. 797.80 ± 186.40, p = 0.028) or the attending group (1254.80 ± 341.50 vs. 569.20 ± 170.01, p = 0.009); Panel B: The operation score of the attending group was significantly higher than either that of the fellow group (18.80 ± 0.84 vs. 17.20 ± 0.84, p = 0.023) or the resident group (18.80 ± 0.84 vs. 14.40 ± 1.34, p = 0.008); Panel C: The NASA-TLX score of the resident group was significantly higher than either that of the fellow group (412.80 ± 79.74 vs. 261.60 ± 86.41, p = 0.028) or the attending group (412.80 ± 79.74 vs. 265.40 ± 99.02, p = 0.047).
*p < 0.05, **p < 0.01, ***p < 0.001

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项目名称：3D 打印模型在胰肠吻合手术评估中的应用	
主要研究者：杨瑾	申请单位：浙江大学医学院附属邵逸夫医院普外科
有效期：1 年	跟踪审查频率：12 个月
审查类别：■初始审查 □复审 □修正案审查 □年度跟踪审查	
审查文件： 1、初始审查申请表 2、临床研究项目负责人承诺书 3、研究方案（版本号：V1.0，版本日期：2020-10-13） 4、知情同意书（版本号：V1.0，版本日期：2020-10-13） 5、免除知情同意书申请表 6、研究者简历	
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第 1 页 共 1 页

Appendix S2:Evaluation and Scoring.

The assessment of the proficiency of each individual trainee's anastomotic procedures is based on the time required to complete the task and the security of the anastomosis. Firstly assess the anterior and posterior anastomosis, and then perform the duct-to-mucosal anastomosis, which is checked by incising the jejunum model and checking the anastomosis from within. Any tearing of the model is noted. For all anastomosis, the duct is connected to a pump that can pump water in.

Distortions are carefully checked as well as strictures, which are identified by checking the water coming through the anastomosis, after turning on the pump. The distribution of the stitches, and whether the ties are loosened, are observed. General guidelines for assessing procedural skill include depth perception, applied force and tissue handling, dexterity and coordination of the arms, and efficiency(Table_ Appendix S1). Performance scores range from A to D, with A being the best.

Table Appendix S1: Criteria for evaluation of individual trainee anastomosis procedure proficiency.

Rank	Depth perception	Force/Tissue handling	Dexterity	Coordination of the arms	Efficiency
A	Good and can adjust well	Good at handling the tissue and suture, the tissue are not torn	Very good	Very good, can switch whenever necessary	All the sutures are perfect
B	Can adjust, but not always able to get to the best angle	Can handle the tissue and suture, with tissue occasionally torn or suture broken	Good	Good, able to switch but less than necessary	One torn of the tissue
C	Not good at finding the right angle	The tissue is too much distorted during the suturing	Fair	Fair, seldom switch among arms even the space or angle for suturing is not satisfied	One broken of the suture or two torn of the tissue
D	Poor at finding the right angle	Poor at handling the tissue and suture, the tissue, often torn the model	Poor	Poor, not at all good at coordination	more than above or distort of the anastomosis or strictures stopping the water going through the anastomosis

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		Reporting Item	Page Number
Title			
	#1	Indicate that the manuscript concerns an initiative to improve healthcare (broadly defined to include the quality, safety, effectiveness, patientcenteredness, timeliness, cost, efficiency, and equity of healthcare)	1
Abstract			
	#02a	Provide adequate information to aid in searching and indexing	2
	#02b	Summarize all key information from various sections of the text using the abstract format of the intended publication or a structured summary such as: background, local problem,	2

		methods, interventions, results, conclusions	
Introduction			
Problem description	#3	Nature and significance of the local problem	3
Available knowledge	#4	Summary of what is currently known about the problem, including relevant previous studies	3
Rationale	#5	Informal or formal frameworks, models, concepts, and / or theories used to explain the problem, any reasons or assumptions that were used to develop the intervention(s), and reasons why the intervention(s) was expected to work	3
Specific aims	#6	Purpose of the project and of this report	3
Methods			
Context	#7	Contextual elements considered important at the outset of introducing the intervention(s)	3
Intervention(s)	#08a	Description of the intervention(s) in sufficient detail that others could reproduce it	4-7
Intervention(s)	#08b	Specifics of the team involved in the work	4-7
Study of the Intervention(s)	#09a	Approach chosen for assessing the impact of the intervention(s)	4-7
Study of the Intervention(s)	#09b	Approach used to establish whether the observed outcomes were due to the intervention(s)	4-7
Measures	#10a	Measures chosen for studying processes and outcomes of the intervention(s), including rationale for choosing them, their operational definitions, and their validity and reliability	4-7
Measures	#10b	Description of the approach to the ongoing assessment of	4-7

		contextual elements that contributed to the success, failure, efficiency, and cost	
Measures	#10c	Methods employed for assessing completeness and accuracy of data	4-7
Analysis	#11a	Qualitative and quantitative methods used to draw inferences from the data	4-7
Analysis	#11b	Methods for understanding variation within the data, including the effects of time as a variable	4-7
Ethical considerations	#12	Ethical aspects of implementing and studying the intervention(s) and how they were addressed, including, but not limited to, formal ethics review and potential conflict(s) of interest	4-7
Results			
	#13a	Initial steps of the intervention(s) and their evolution over time (e.g., time-line diagram, flow chart, or table), including modifications made to the intervention during the project	7-9
	#13b	Details of the process measures and outcome	7-9
	#13c	Contextual elements that interacted with the intervention(s)	7-9
	#13d	Observed associations between outcomes, interventions, and relevant contextual elements	7-9
	#13e	Unintended consequences such as unexpected benefits, problems, failures, or costs associated with the intervention(s).	7-9
	#13f	Details about missing data	7-9
Discussion			
Summary	#14a	Key findings, including relevance to the rationale and specific aims	9-11

Summary	#14b	Particular strengths of the project	9-11
Interpretation	#15a	Nature of the association between the intervention(s) and the outcomes	9-11
Interpretation	#15b	Comparison of results with findings from other publications	9-11
Interpretation	#15c	Impact of the project on people and systems	9-11
Interpretation	#15d	Reasons for any differences between observed and anticipated outcomes, including the influence of context	9-11
Interpretation	#15e	Costs and strategic trade-offs, including opportunity costs	9-11
Limitations	#16a	Limits to the generalizability of the work	11
Limitations	#16b	Factors that might have limited internal validity such as confounding, bias, or imprecision in the design, methods, measurement, or analysis	11
Limitations	#16c	Efforts made to minimize and adjust for limitations	11
Conclusion	#17a	Usefulness of the work	11
Conclusion	#17b	Sustainability	11
Conclusion	#17c	Potential for spread to other contexts	11
Conclusion	#17d	Implications for practice and for further study in the field	11
Conclusion	#17e	Suggested next steps	11
Other information			
Funding	#18	Sources of funding that supported this work. Role, if any, of the funding organization in the design, implementation,	12

interpretation, and reporting