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# BMJ Open

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

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# 1 **Validity of a three-dimensional printed dry lab pancreaticojejunostomy model** 2 **in surgical assesment**

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For peer review only

## 30 Abstract

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

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

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

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

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

## 49 Strengths and limitations of this study

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

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3 56 3. This study selected softer silicone material to simulate the pancreatic parenchyma and its  
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5 57 hardness was still slightly higher than that of the pancreatic tissue.  
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7 58 4. This study chose fifteen surgeons performed a PJ on the three-dimensional model. The sample  
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9 59 size could be further expanded in future studies.  
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## 60 Introduction

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

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

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

83

## 84 Materials & Methods

### 85 1 3D-Printed Dry Lab PJ Model Production

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

89 Tomography (CT) data was collected in the Digital Imaging and Communications in Medicine  
90 (DICOM) format, with 1mm thick slices. The E3D digital medical modeling software V17.06  
91 (Central South E3D Digital Medical and Virtual Reality Research Center, China) was used for  
92 boundary segmentation and 3D reconstruction and the model structure was streamlined  
93 according to the specific application requirements (*Figure 1*). The open source slicing software  
94 Cura 4.4.1 (Ultimaker, USA) was used for slicing the 3D printing. The material was made of  
95 silicone specialized for 3D printing. The silicone material used for the pancreatic parenchyma  
96 was pink, with a tear strength of 4.8N/mm and a tensile strength of 2 MPa. The silicone material  
97 used for the pancreatic duct was white, with a tear strength of 5.2N/mm and a tensile strength of  
98 1.8 MPa. The silicone material used for the small intestine was red, with a tear strength of  
99 5.2N/mm and a tensile strength of 1.8 MPa.

## 100 **2 Patient and public involvement**

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

## 102 **3 Evaluation scale design**

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

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

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

## 116 **4 Assessment scale issuance**

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

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3 119 Experts in pancreatic surgery were invited to participate in the evaluation from all aspects  
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5 120 according to the scale and to make professional recommendations.

6 121 Fifteen chief surgeon (attending), first assistant (fellow) and observer (resident) physicians  
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8 122 from the general surgery department were selected and issued basic information collection  
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10 123 forms. And all surgeons in this section were obtained written informed human participant  
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12 124 consent. Model training operations were performed after teaching the procedures. The entirety of  
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14 125 the operation was recorded on video and the proficiency was scored by two pancreatic experts  
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16 126 who were blinded to the identities of surgeons. After the operation, all personnel were issued a  
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18 127 NASA-TLX scale to assess the mental load of the operation.

## 19 128 **5 Operation procedures**

20 129 The operation procedures used in the current study refer to the classic Cattell-Warren  
21  
22 130 anastomosis method. The operation steps are detailed in *Figure 2*.

## 24 131 **6 Data analyses**

25 132 The current study collected statistics on the overall settings and appearance, size, and tactile  
26  
27 133 similarity of the 3D printed pancreas model and the functional evaluation indicators of the model  
28  
29 134 (primarily including the surgical operation score, operation time, and NASA-TLX score).  
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31 135 Microsoft Excel (2016) was used to establish the scoring and evaluation table of each item in the  
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33 136 evaluation scale by experts. SPSS (Version 20.0, SPSS Inc, Chicago, IL, USA) software was  
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35 137 then used for the subsequent data analyses and processing. All tests were 2-tailed and  $p < 0.05$   
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37 138 was considered statistically significant. The results from the statistical analyses were entered into  
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39 139 Graphpad Prism 7.0 and related charts were drawn. Each score was calculated by the mean  $\pm$   
40  
41 140 standard deviation.

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## 45 142 **Results**

### 48 143 **1 Pancreatic surgery experts' anatomical evaluation of the model**

49 144 The research invited eight pancreatic surgery experts to conduct a comprehensive evaluation.  
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51 145 All experts had performed more than 20 cases of pancreaticoduodenectomy within the prior year  
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53 146 and four had performed more than 100 cases of pancreaticoduodenectomy in the prior year. The  
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55 147 model obtained an overall evaluation of  $4.38 \pm 0.74$  (*Figure 3*) and all experts gave greater than

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3 148 "more similar" (3 points) as their evaluation. The evaluation of the model is divided into two  
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5 149 parts: appearance and tactile sensation and this study also evaluated its comparison with a  
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7 150 Whipple surgery and animal models. The current study also invited experts to make assessments  
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9 151 on their recommendation of using this model for teaching. The results are presented below.

### 11 152 **1.1 Appearance**

13  
14 153 The overall appearance of the 3D printed PJ dry laboratory model was evaluated at  $3.96 \pm$   
15  
16 154  $0.55$ . The appearance of the pancreatic parenchyma was evaluated at  $4.13 \pm 0.64$ , the appearance  
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18 155 of the pancreatic duct was evaluated at  $4.00 \pm 0.53$ , and the appearance of the intestinal canal  
19  
20 156 was evaluated at  $3.75 \pm 0.46$ .

### 21 157 **1.2 Tactile sensation**

23  
24 158 The overall tactile evaluation of the 3D printed PJ dry laboratory model was evaluated at  $3.85$   
25  
26 159  $\pm 0.46$ . The elasticity of the model was evaluated at  $3.88 \pm 0.45$  and the elasticity of the pancreas  
27  
28 160 parenchyma, pancreatic duct, and intestinal duct of the model were equivalent. The ease of  
29  
30 161 tearing of the model was evaluated at  $3.83 \pm 0.48$  and the ease of tearing of the intestinal duct of  
31  
32 162 the model was slightly higher than the other two parts, at  $4.00 \pm 0.53$ . The suture breakthrough of  
33  
34 163 the model was evaluated at  $3.83 \pm 0.48$  and the pancreatic parenchyma of the model was slightly  
35  
36 164 lower than the other two, at  $3.88 \pm 0.35$ .

### 37 165 **1.3 Education**

38  
39 166 All eight experts (100%) agreed that the 3D printed laboratory model of the PJ could/should  
40  
41 167 be used for teaching.

## 42 168 **2 General information of pancreatic surgeons**

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44 169 Five attendings, five fellows, and five residents were invited to participate in the current study.  
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46 170 Their general information is shown in Table 1. There were significant differences in the working  
47  
48 171 years of the three groups of surgeons ( $13.40 \pm 3.21$  vs.  $6.00 \pm 1.22$  vs.  $2.60 \pm 1.82$ , respectively,  
49  
50 172  $p < 0.001$ ), in which all attendings had worked for more than eight years and all residents had  
51  
52 173 worked five or less years. The three groups of surgeons had a statistically significant difference  
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54 174 in the number of cases of pancreatoenterostomy as the lead surgeon ( $p = 0.008$ ) and the number  
55  
56 175 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 \* $p < 0.05$ , \*\* $p < 0.01$ , \*\*\* $p < 0.001$



### 188 3.1 Operation time

189 There were significant statistical differences in the operation time of the three groups of  
 190 researchers ( $p = 0.003$ ), as shown in *Figure 4A*, where the operation time of the resident group  
 191 was significantly longer than fellow group ( $1254.80 \pm 341.50$  vs.  $797.80 \pm 186.40$ ,  $p = 0.028$ )  
 192 and the attending group ( $1254.80 \pm 341.50$  vs.  $569.20 \pm 170.01$ ,  $p = 0.009$ ), but there was no  
 193 significant statistical difference between the attending group and the fellow group ( $569.20 \pm$   
 194  $170.01$  vs.  $797.80 \pm 186.40$ ,  $p = 0.175$ ).

### 195 3.2 Operation score

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

### 200 3.3 NASA-TLX score

201 The NASA-TLX mental load scores of the three groups of researchers were statistically  
 202 significantly different ( $p = 0.031$ ), as shown in *Figure 4C*. The NASA-TLX score of the  
 203 attending group was not significantly different from that of the fellow group ( $265.40 \pm 99.02$  vs.  
 204  $261.60 \pm 86.41$ ,  $p = 0.754$ ), while the NASA-TLX score of the resident group was significantly  
 205 higher than fellow group ( $412.80 \pm 79.74$  vs.  $261.60 \pm 86.41$ ,  $p = 0.028$ ) and the attending group  
 206 ( $412.80 \pm 79.74$  vs.  $265.40 \pm 99.02$ ,  $p = 0.047$ ).

207 **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*

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

## 210 Discussion

211 Traditional surgical teaching and training methods are experiencing increasing learning costs  
 212 under the modern background and pancreatic surgery is known for its relatively higher surgical  
 213 difficulty. Within the digestive tract anastomosis, the PJ is the most complicated, which can lead  
 214 to various postoperative complications. The PJ model based on biotissue [8] is considered to  
 215 improve technical performance in surgical oncology fellows. However, to our knowledge,

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3 216 although they have been successfully applied to training in many fields of surgery, including  
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5 217 head and neck surgery [14], colorectal surgery [15], vascular surgery [16], and neurosurgery  
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7 218 [17], among others, there are few reports on PJ models using 3D printed models.

8 219 In the current study, eight pancreatic surgery experts were selected, all of whom exceeded the  
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10 220 experience expectations for a pancreaticoduodenectomy, and a model evaluation scale was  
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12 221 issued to these experts. The evaluation scale adopts the 5-point Likert scale [8-10], which  
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14 222 comprehensively evaluates the appearance and touch of each component of the model, its  
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16 223 similarity with real surgery, and its application in teaching. Experts rated the model highly on  
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18 224 both appearance and touch, suggesting that the model has good simulation performance. All  
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20 225 experts recommend it for teaching, suggesting a potential role of such models in surgical  
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22 226 training.

22 227 The current study also selected three groups of surgeons to perform functional tests of the  
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24 228 model. The selected research indicators primarily include operation time, operation score, and  
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26 229 the NASA-TLX. There is a plethora of research on operation time and operation score, which  
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28 230 can effectively reflect the operation level on the model [18, 19]. Additionally, Beard et al. [20]  
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30 231 developed an objective structured assessment of technical skills (OSATS) scale based on the  
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32 232 surgeon's technical competency evaluation. The research published by Wei et al. [11] was  
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34 233 optimized on the basis of OSATS and was demonstrated to be a good assessment of the technical  
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36 234 competency of surgeons. The operation scoring standard of the current research also refers to this  
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38 235 modified version of the scoring design. In addition, the current study utilized the NASA-TLX as  
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40 236 a subjective index to assess mental workload, which can reflect the surgeon's operating pressure,  
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42 237 which has attracted increasing attention in recent years [12, 21]. Given the results of the above  
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44 238 three indicators, the model is suggested to be able to effectively distinguish between the three  
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46 239 groups of physicians in terms of operating time, operating scores, and mental stress, further  
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48 240 indicating the effectiveness of the model. Among the groups, the attending group had a shorter  
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50 241 operating time than the fellow group ( $569.20 \pm 170.01$  vs.  $797.80 \pm 186.40$ ), however, this  
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52 242 difference was not statistically significant. This may be due to an insufficient number of enrolled  
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54 243 physicians. Additionally, there was no significant difference between the attending group and the  
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56 244 fellow group doctors in terms of stress scores, plausibly due to a better psychological tolerance in  
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58 245 the fellow group as the amount of surgery gradually increased. Furthermore, the mental stress of  
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60 246 attendings and fellows in the model training was significantly lower than that of the residents,

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3 247 suggesting that the model can effectively simulate mental stress. The results of the current study  
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5 248 demonstrate that the 3D printed PJ model has good simulation and effectiveness. It can help  
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7 249 distinguish pancreatic surgeons at various levels can roughly assess whether pancreatic surgeons  
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9 250 are prepared for surgery.

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11 251 Organ models cut from cadaver tissue have certain advantages in training young doctors in the  
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13 252 fields of trauma, plastic surgery, gynecology, general surgery, and vascular surgery. For  
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15 253 example, SIM Life, which is an emerging model that uses corpses as a template to have an  
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17 254 artificial heartbeat, circulation, and breathing, has been given high ratings by users. However, the  
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19 255 application of living tissues has many problems such as storage, production, and cost. The cost of  
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21 256 3D printed organizational models is greatly reduced and due to advances in technology and  
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23 257 materials, it has improved organizational similarity and training effects and it is easier to  
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25 258 promote and train economically. Simultaneously, it is easier to produce with a short production  
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27 259 cycle and it has a better prospect in clinical application.

28  
29 260 However, the current study has some disadvantages. For one, we selected softer silicone  
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31 261 material to simulate the pancreatic parenchyma and its hardness was still slightly higher than that  
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33 262 of the pancreatic tissue. And we chose fifteen surgeons performed a PJ on the three-dimensional  
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35 263 model. The sample size could be larger. In future studies, different materials should be tried to  
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37 264 achieve better material simulation and compare their different training effects and expert  
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39 265 evaluation. We also selected the open pancreaticoduodenal model for training and will use the  
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41 266 laparoscopic model for additional future research.

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## 44 268 **Conclusions**

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46 269 The three-dimensional PJ model could mimic real surgical situations and can be used to  
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48 270 distinguish surgeons of various levels of experience. Therefore, prior to doing a  
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50 271 pancreaticoduodenectomy, this model may be a convenient tool to let surgeons to evaluate  
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52 272 whether they are technically proficient to perform a high-quality and safe PJ on their patients.

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280

## 281 **Conflicts of interest**

282 All authors declares no conflicts of interest.

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## 284 **Ethics Approval**

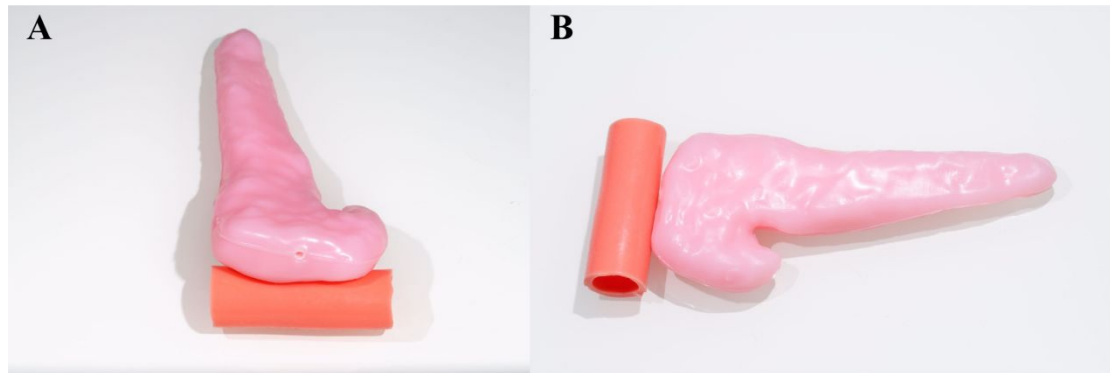
285 The Sir Run Run Shaw hospital granted Ethical approval to carry out the study within its  
286 facilities (Ethical Application Ref: jm420-c5a3d).(See appendix S2).All procedures followed  
287 were in accordance with the ethical standards of the responsible committee on human  
288 experimentation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

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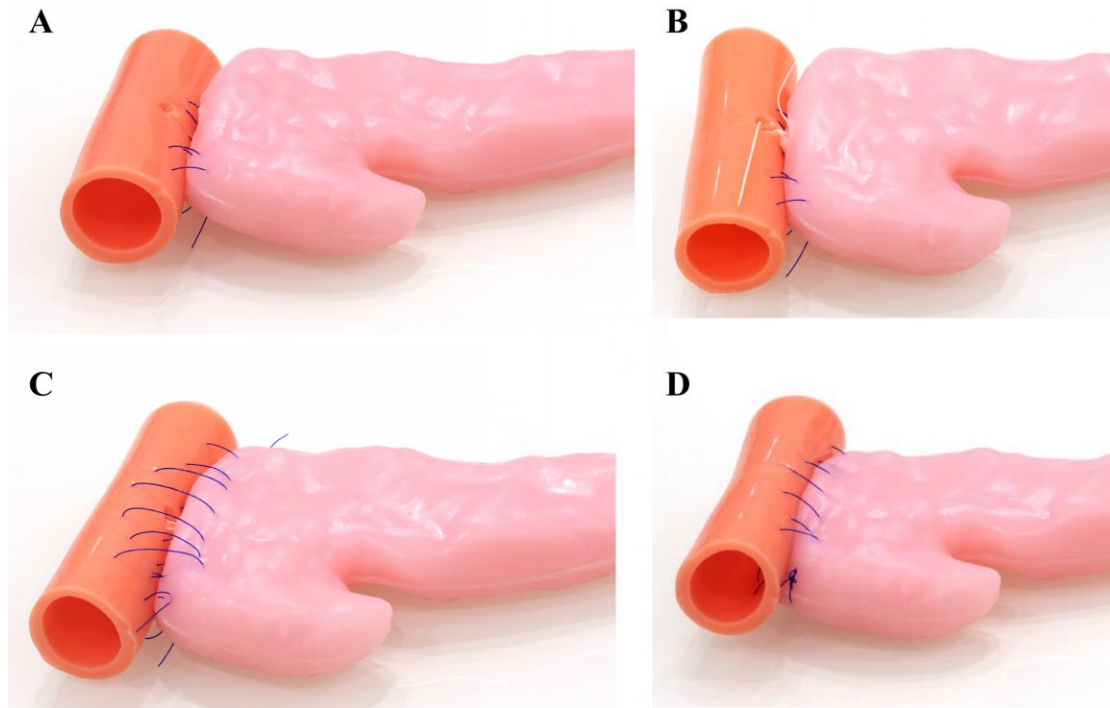
## 291 **Funding**

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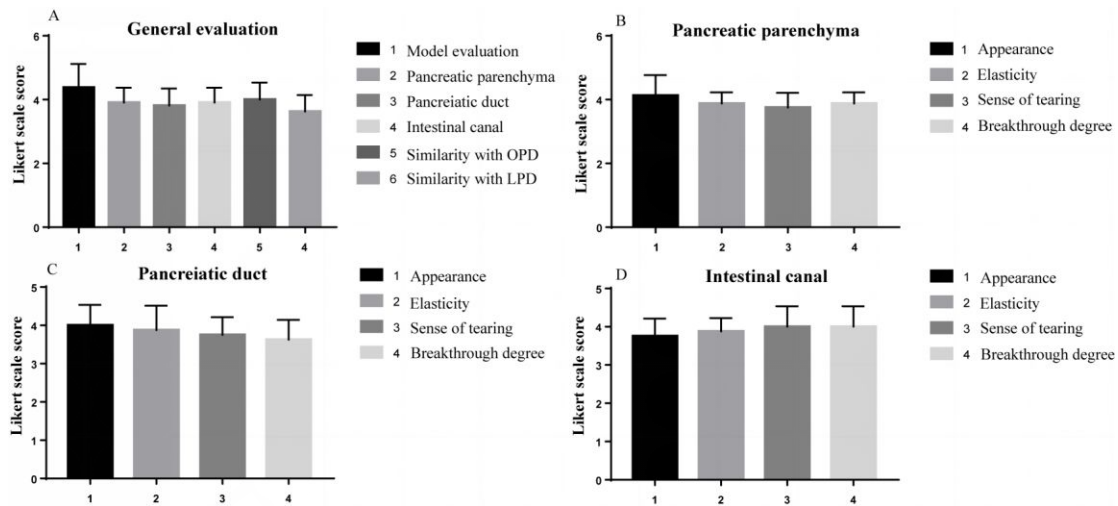
## Figures



**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.



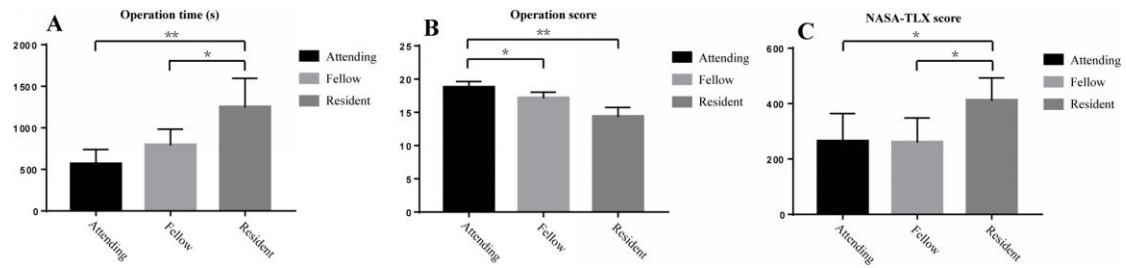
**Figure 2.** Cattell-Warren anastomosis **(A)** Continuously suture the posterior margin of the pancreas and the seromuscular layer of the jejunum;  $\frac{2}{3}$  of the pancreatic tissue on the dorsal side of the pancreas should be sutured. The sutures should not be tightened temporarily to facilitate 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  $\frac{1}{3}$  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  $\frac{1}{3}$  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 pancreaticoduodenectomy





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

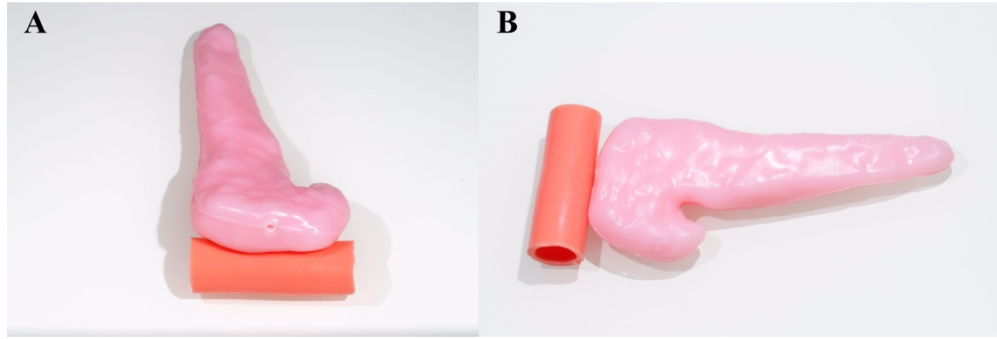


299 **References**

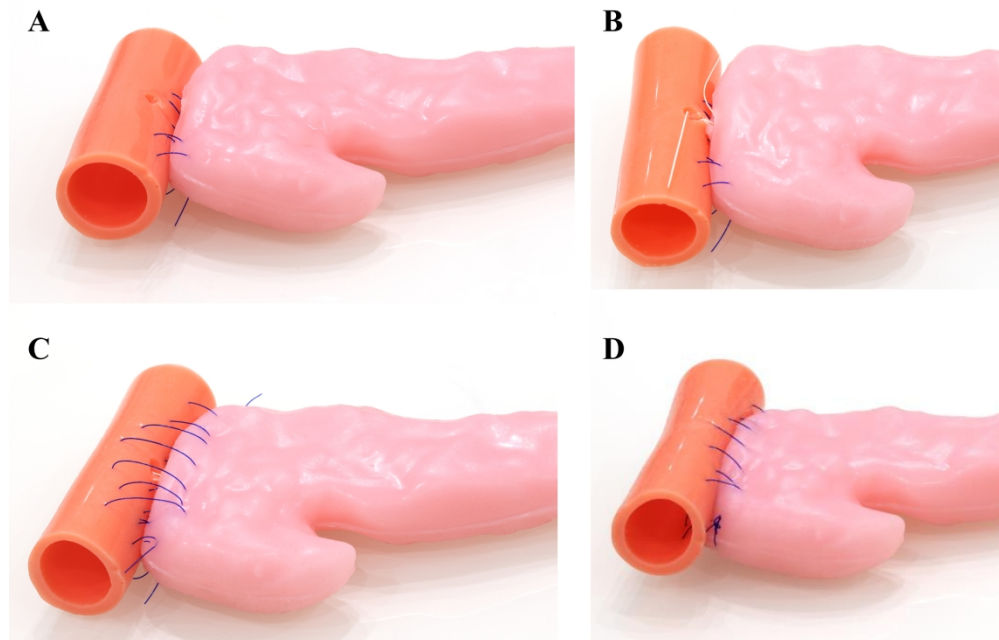
- [1] Ecker, B.L., McMillan, M.T., Asbun, H.J., Ball, C.G., Bassi, C., Beane, J.D., Behrman, S.W., Berger, A.C., Dickson, E.J., Bloomston, M., et al. 2018 Characterization and Optimal Management of High-risk Pancreatic Anastomoses During Pancreatoduodenectomy. *Annals of surgery* **267**, 608-616. (doi:10.1097/sla.0000000000002327).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

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2  
3 348 [15] Bangeas, P., Drevelegas, K., Agorastou, C., Tzounis, L., Chorti, A., Paramythiotis, D.,  
4 349 Michalopoulos, A., Tsoufas, G., Papadopoulos, V.N., Exadaktylos, A., et al. 2019 Three-  
5 350 dimensional printing as an educational tool in colorectal surgery. *Frontiers in bioscience (Elite*  
6 351 *edition)* **11**, 29-37.
- 7 352 [16] Wang, C., Zhang, L., Qin, T., Xi, Z., Sun, L., Wu, H. & Li, D. 2020 3D printing in adult  
8 353 cardiovascular surgery and interventions: a systematic review. *Journal of thoracic disease* **12**,  
9 354 3227-3237. (doi:10.21037/jtd-20-455).
- 10 355 [17] Weinstock, P., Rehder, R., Prabhu, S.P., Forbes, P.W., Roussin, C.J. & Cohen, A.R. 2017  
11 356 Creation of a novel simulator for minimally invasive neurosurgery: fusion of 3D printing and  
12 357 special effects. *Journal of neurosurgery. Pediatrics* **20**, 1-9. (doi:10.3171/2017.1.Peds16568).
- 13 358 [18] Pucci, J.U., Christophe, B.R., Sisti, J.A. & Connolly, E.S., Jr. 2017 Three-dimensional  
14 359 printing: technologies, applications, and limitations in neurosurgery. *Biotechnology advances* **35**,  
15 360 521-529. (doi:10.1016/j.biotechadv.2017.05.007).
- 16 361 [19] Bartel, T., Rivard, A., Jimenez, A., Mestres, C.A. & Müller, S. 2018 Medical three-  
17 362 dimensional printing opens up new opportunities in cardiology and cardiac surgery. *European*  
18 363 *heart journal* **39**, 1246-1254. (doi:10.1093/eurheartj/ehx016).
- 19 364 [20] Beard, J.D. 2005 Setting standards for the assessment of operative competence. *European*  
20 365 *journal of vascular and endovascular surgery : the official journal of the European Society for*  
21 366 *Vascular Surgery* **30**, 215-218. (doi:10.1016/j.ejvs.2005.01.032).
- 22 367 [21] Abbott, E.F., Thompson, W., Pandian, T.K., Zendejas, B., Farley, D.R. & Cook, D.A. 2017  
23 368 Personalized Video Feedback and Repeated Task Practice Improve Laparoscopic Knot-Tying  
24 369 Skills: Two Controlled Trials. *Academic medicine : journal of the Association of American*  
25 370 *Medical Colleges* **92**, S26-s32. (doi:10.1097/acm.0000000000001924).

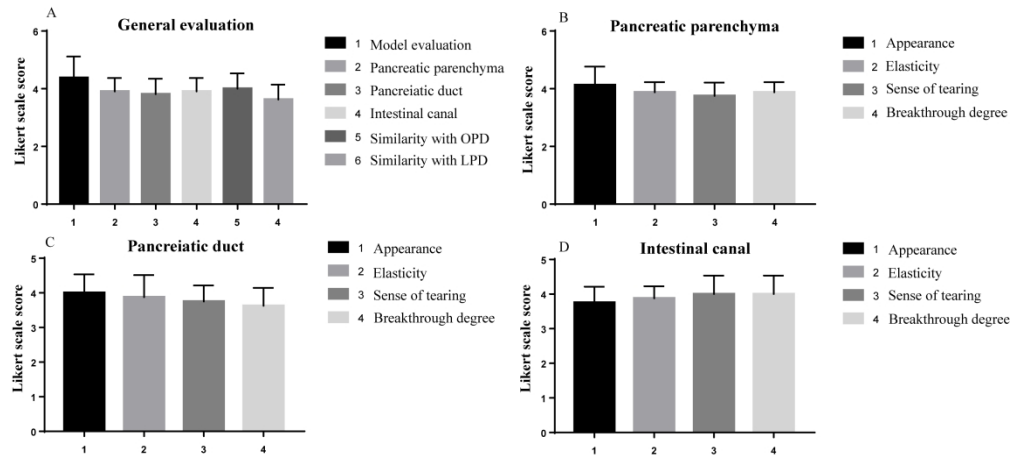
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The appearance of the 3D-printed PJ model. (A) The 3D-printed PJ model is primarily composed of three parts: the pancreatic parenchyma, the pancreatic duct, and the intestinal duct. (B) Side view of the 3D-printed PJ model.

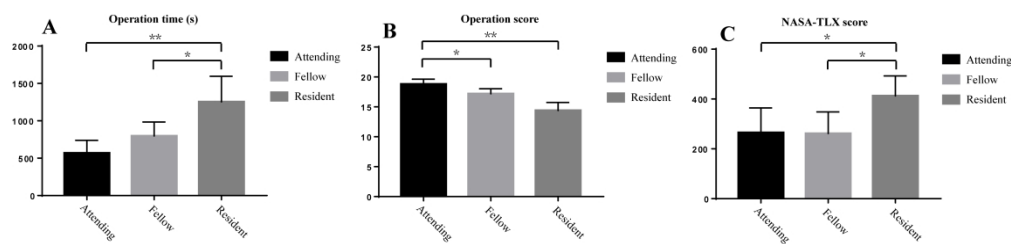


Cattell-Warren anastomosis (A) Continuously suture the posterior margin of the pancreas and the seromuscular layer of the jejunum; 2/3 of the pancreatic tissue on the dorsal side of the pancreas should be sutured. The sutures should not be tightened temporarily to facilitate exposure of the posterior 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 pancreaticoduodenectomy



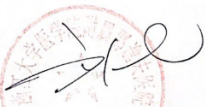
Panel A: The operation time of the resident group was significantly longer than either that of the fellow group ( $1254.80 \pm 341.50$  vs.  $797.80 \pm 186.40$ ,  $p = 0.028$ ) or the attending group ( $1254.80 \pm 341.50$  vs.  $569.20 \pm 170.01$ ,  $p = 0.009$ ); Panel B: The operation score of the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

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



## 浙江大学医学院附属邵逸夫医院医学伦理委员会 快速伦理批件

批件号：科研 20201217-41

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： <input checked="" type="checkbox"/> 初始审查 <input type="checkbox"/> 复审 <input type="checkbox"/> 修正案审查 <input type="checkbox"/> 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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## 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
<b>Title</b>		
	<a href="#">#1</a> 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
<b>Abstract</b>		
	<a href="#">#02a</a> Provide adequate information to aid in searching and indexing	2
	<a href="#">#02b</a> 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
<b>Introduction</b>		
Problem	<a href="#">#3</a> Nature and significance of the local problem	3

1	description			
2	Available	<a href="#">#4</a>	Summary of what is currently known about the problem, including	3
3	knowledge		relevant previous studies	
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6	Rationale	<a href="#">#5</a>	Informal or formal frameworks, models, concepts, and / or theories used	3
7			to explain the problem, any reasons or assumptions that were used to	
8			develop the intervention(s), and reasons why the intervention(s) was	
9			expected to work	
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13	Specific aims	<a href="#">#6</a>	Purpose of the project and of this report	3
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18	Context	<a href="#">#7</a>	Contextual elements considered important at the outset of introducing	3
19			the intervention(s)	
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21	Intervention(s)	<a href="#">#08a</a>	Description of the intervention(s) in sufficient detail that others could	3-5
22			reproduce it	
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25	Intervention(s)	<a href="#">#08b</a>	Specifics of the team involved in the work	3-5
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28	Study of the	<a href="#">#09a</a>	Approach chosen for assessing the impact of the intervention(s)	3-5
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31	Study of the	<a href="#">#09b</a>	Approach used to establish whether the observed outcomes were due to	3-5
32	Intervention(s)		the intervention(s)	
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35	Measures	<a href="#">#10a</a>	Measures chosen for studying processes and outcomes of the	3-5
36			intervention(s), including rationale for choosing them, their operational	
37			definitions, and their validity and reliability	
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40	Measures	<a href="#">#10b</a>	Description of the approach to the ongoing assessment of contextual	3-5
41			elements that contributed to the success, failure, efficiency, and cost	
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44	Measures	<a href="#">#10c</a>	Methods employed for assessing completeness and accuracy of data	3-5
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47	Analysis	<a href="#">#11a</a>	Qualitative and quantitative methods used to draw inferences from the	3-5
48			data	
49				
50	Analysis	<a href="#">#11b</a>	Methods for understanding variation within the data, including the	3-5
51			effects of time as a variable	
52				
53				
54	Ethical	<a href="#">#12</a>	Ethical aspects of implementing and studying the intervention(s) and	3-5
55	considerations		how they were addressed, including, but not limited to, formal ethics	
56			review and potential conflict(s) of interest	
57				
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59				

## 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

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- 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

1	Conclusion	<a href="#">#17d</a>	Implications for practice and for further study in the field	10
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3	Conclusion	<a href="#">#17e</a>	Suggested next steps	10
4				
5	<b>Other</b>			
6	<b>information</b>			
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8				
9	Funding	<a href="#">#18</a>	Sources of funding that supported this work. Role, if any, of the funding organization in the design, implementation, interpretation, and reporting	11
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# BMJ Open

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

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# 1 Validation of a three-dimensional printed dry lab pancreaticojejunostomy 2 model in surgical assessment, a pioneering study

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31



## 32 Abstract

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

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

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

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

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

## 52 Strengths and limitations of this study

- 53 1. Strengths of this pioneering study include that the three-dimensional PJ model could mimic a  
54 real surgical situation and it could be used as a portable teaching and learning tool, which is  
55 easier to store, and can be used by students in the office or even at home.
- 56 2. This study selected softer silicone material to simulate the pancreatic parenchyma and its  
57 hardness was still slightly higher than that of the pancreatic tissue.

3 58 3. This study chose fifteen surgeons performed a PJ on the three-dimensional model and the  
4 59 sample size could be further expanded in future studies.

6 60 4. This PJ model doesn't contain vessels such as splenic artery, etc which will allow for  
7 61 simulation of more realistic situation.

8 62 5. Characteristics of pancreatic tissue (consistency, elasticity, etc) are highly different from one  
9 63 patient to another which may influence both the technique and the results of pancreato-enteric  
10 64 anastomosis, but in the present study only one type of silicon model is used.

## 11 65 **Introduction**

12 66 A pancreaticojejunostomy (PJ) is one of the most challenging procedures in general surgery  
13 67 and a lack of proficiency and experience in doing this procedure may lead to postoperative  
14 68 pancreatic leakage, hemorrhage, or even death [1-3]. Advanced techniques, such as 3D printing,  
15 69 have been widely used in the field of surgery for the purpose of education and preoperative  
16 70 designing, however, there are few reports indicating that they could be used as a tool to evaluate  
17 71 surgical competency.

18 72 According to Szasz and colleagues [4], due to work hour restrictions, limitations of operating  
19 73 room accessibility, and increased litigation against physicians, the educational opportunities of  
20 74 surgeons have dramatically decreased. Based on this status quo, the Accreditation Council for  
21 75 Graduate Medical Education [5], the Royal College of Physicians and Surgeons of Canada [6],  
22 76 and many others worldwide have developed training programs to improve surgical skills.

23 77 Compared with traditional pancreaticoduodenal surgery training methods, there remains a lack  
24 78 of an effective physical model to help distinguish between pancreatic surgeons of different levels  
25 79 and to roughly assess whether pancreatic surgeons are prepared. As an emerging technology, 3D  
26 80 printing technology has been widely used in the medical field [7-9] and has been broadly studied  
27 81 and reported on in a book on the training and application of simulation models in robotic  
28 82 gynecological surgery [10]. Additionally, 3D printed models are expected to be used in the future  
29 83 as one of the methods of pancreatic surgery training, reducing learning costs and helping young  
30 84 doctors improve surgical techniques. In the current study, experts in the field of pancreatic  
31 85 surgery were invited to evaluate the appearance of the model. We aimed to evaluate whether a

86 three-dimensional model could mimic a real surgical situation and distinguish between surgeons  
87 of various levels of experience.

88

## 89 **Materials & Methods**

### 90 **1 Study design and setting**

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

### 96 **2 3D-Printed Dry Lab PJ Model Production**

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

### 113 **3 Patient and public involvement**

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

#### 115 **4 Evaluation scale design**

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

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

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

#### 129 **5 Assessment scale issuance**

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

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

#### 141 **6 General information of pancreatic surgeons**

142 Five attendings include 2 experts from the PJ anatomical evaluation part, five fellows, and five  
143 residents were invited to participate in the current study. Their general information is shown in  
144 Table 1. There were significant differences in the working years of the three groups of surgeons  
145 ( $13.40 \pm 3.21$  vs.  $6.00 \pm 1.22$  vs.  $2.60 \pm 1.82$ , respectively,  $p < 0.001$ ), in which all attendings

146 had worked for more than eight years and all residents had worked five or less years. The three  
 147 groups of surgeons had a statistically significant difference in the number of cases of  
 148 pancreatoenterostomy as the lead surgeon ( $p = 0.008$ ) and the number of cases of  
 149 pancreaticoduodenectomy as the first assistant ( $p = 0.014$ ). All pancreatic surgeons who  
 150 participated in the study were right-handed and there was no significant statistical difference  
 151 between the three groups of surgeons in simulation training ( $p = 0.287$ ), nor was there any  
 152 significant statistical difference between the three groups of participants in Virtual Reality(VR)  
 153 surgical training ( $p = 0.562$ ).

154 **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

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

## 156 7 Operation procedures

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

## 159 8 Data analyses

1  
2  
3 160 The current study collected statistics on the overall settings and appearance, size, and tactile  
4  
5 161 similarity of the 3D printed pancreas model and the functional evaluation indicators of the model  
6  
7 162 (primarily including the surgical operation score, operation time, and NASA-TLX score).  
8  
9 163 Microsoft Excel (2016) was used to establish the scoring and evaluation table of each item in the  
10  
11 164 evaluation scale by experts. SPSS (Version 20.0, SPSS Inc, Chicago, IL, USA) software was  
12  
13 165 then used for the subsequent data analyses and processing. All tests were 2-tailed and  $p < 0.05$   
14  
15 166 was considered statistically significant. The results from the statistical analyses were entered into  
16  
17 167 Graphpad Prism 7.0 and related charts were drawn. Each score was calculated by the mean  $\pm$   
18  
19 168 standard deviation.

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## 21 22 170 **Results**

### 23 24 25 171 **1 Pancreatic surgery experts' anatomical evaluation of the model**

26  
27 172 The research invited eight pancreatic surgery experts to conduct a comprehensive evaluation.  
28  
29 173 All experts had performed more than 20 cases of pancreaticoduodenectomy within the prior year  
30  
31 174 and four had performed more than 100 cases of pancreaticoduodenectomy in the prior year. The  
32  
33 175 model obtained an overall evaluation of  $4.38 \pm 0.74$  (*Figure 3B-E*) and all experts gave greater  
34  
35 176 than "more similar" (3 points) as their evaluation. The current study also invited experts to make  
36  
37 177 assessments on their recommendation of using this model for teaching. The results are presented  
38  
39 178 below.

#### 40 179 **1.1 Appearance**

41  
42 180 The overall appearance of the 3D printed PJ dry laboratory model was evaluated at  $3.96 \pm$   
43  
44 181  $0.55$ . The appearance of the pancreatic parenchyma was evaluated at  $4.13 \pm 0.64$ , the appearance  
45  
46 182 of the pancreatic duct was evaluated at  $4.00 \pm 0.53$ , and the appearance of the intestinal canal  
47  
48 183 was evaluated at  $3.75 \pm 0.46$ .

#### 49 50 184 **1.2 Tactile sensation**

51  
52  
53 185 The pancreas is the main component of the PJ model, and its stiffness is measured by  
54  
55 186 ultrasound with a two-dimensional shear-wave elastography (2D-SWE) value of  $10.08 \pm 6.50$  kPa



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

### 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 ( $1254.80 \pm 341.50$  vs.  $797.80 \pm 186.40$ ,  $p = 0.028$ ) and the attending group ( $1254.80 \pm 341.50$  vs.  $569.20 \pm 170.01$ ,  $p = 0.009$ ), but there was no significant statistical difference between the attending group and the fellow group ( $569.20 \pm 170.01$  vs.  $797.80 \pm 186.40$ ,  $p = 0.175$ ).

### 2.2 Operation score

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

### 217 2.3 NASA-TLX score

218 The NASA-TLX mental load scores of the three groups of researchers were statistically  
 219 significantly different ( $p = 0.031$ ), as shown in *Figure 4C*. The NASA-TLX score of the  
 220 attending group was not significantly different from that of the fellow group ( $265.40 \pm 99.02$  vs.  
 221  $261.60 \pm 86.41$ ,  $p = 0.754$ ), while the NASA-TLX score of the resident group was significantly  
 222 higher than fellow group ( $412.80 \pm 79.74$  vs.  $261.60 \pm 86.41$ ,  $p = 0.028$ ) and the attending group  
 223 ( $412.80 \pm 79.74$  vs.  $265.40 \pm 99.02$ ,  $p = 0.047$ ).

224 **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*

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

## 227 Discussion

228 Traditional surgical teaching and training methods are experiencing increasing learning costs  
 229 under the modern background and pancreatic surgery is known for its relatively higher surgical  
 230 difficulty. Within the digestive tract anastomosis, the PJ is the most complicated, which can lead  
 231 to various postoperative complications. The PJ model based on biotissue[11] is considered to  
 232 improve technical performance in surgical oncology fellows. However, to our knowledge,  
 233 although they have been successfully applied to training in many fields of surgery, including  
 234 head and neck surgery [18], colorectal surgery [19], vascular surgery [20], and neurosurgery  
 235 [21], among others, there are few reports on PJ models using 3D printed models.

236 Elastography is an ultrasound imaging method. The concept of elastography was first  
 237 proposed in 1991[22]. It has been used to assess the stiffness of tissues. During elastography  
 238 evaluation, the stiffness of model can be estimated from the response of model to compression.  
 239 This process can be performed in two ways: shear wave elastography (SWE) and strain  
 240 elastography[23]. This study use soft silicone material to simulate the pancreatic parenchyma



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3 241 and its hardness was still slightly higher than that of the pancreatic tissue. At the same time, our  
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5 242 team has also studied hydrogel as a 3D printing material to print PJ models. Its hardness is very  
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7 243 close to that of the pancreas, but it's difficult to store which limits its application. Our team will  
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9 244 also conduct in-depth research and conduct on this softer material in the future. In the current  
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11 245 study, eight pancreatic surgery experts were selected, all of whom exceeded the experience  
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13 246 expectations for a pancreaticoduodenectomy, and a model evaluation scale was issued to these  
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15 247 experts. The evaluation scale adopts the 5-point Likert scale [11-13], which comprehensively  
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17 248 evaluates the appearance and touch of each component of the model, its similarity with real  
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19 249 surgery, and its application in teaching. Experts rated the model highly on both appearance and  
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21 250 touch, suggesting that the model has good simulation performance. All experts recommend it for  
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23 251 teaching, suggesting a potential role of such models in surgical training.

24 252 The current study also selected three groups of surgeons to perform functional tests of the  
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26 253 model. The selected research indicators primarily include operation time, operation score, and  
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28 254 the NASA-TLX. There is a plethora of research on operation time and operation score, which  
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30 255 can effectively reflect the operation level on the model [24, 25]. Additionally, Beard et al. [26]  
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32 256 developed an objective structured assessment of technical skills (OSATS) scale based on the  
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34 257 surgeon's technical competency evaluation. The research published by Wei et al. [14] was  
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36 258 optimized on the basis of OSATS and was demonstrated to be a good assessment of the technical  
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38 259 competency of surgeons. The operation scoring standard of the current research also refers to this  
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40 260 modified version of the scoring design. In addition, the current study utilized the NASA-TLX as  
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42 261 a subjective index to assess mental workload, which can reflect the surgeon's operating pressure,  
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44 262 which has attracted increasing attention in recent years [15, 27]. Given the results of the above  
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46 263 three indicators, the model is suggested to be able to effectively distinguish between the three  
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48 264 groups of physicians in terms of operating time, operating scores, and mental stress, further  
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50 265 indicating the effectiveness of the model. Among the groups, the attending group had a shorter  
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52 266 operating time than the fellow group ( $569.20 \pm 170.01$  vs.  $797.80 \pm 186.40$ ), however, this  
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54 267 difference was not statistically significant. This may be due to an insufficient number of enrolled  
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56 268 physicians. Additionally, there was no significant difference between the attending group and the  
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58 269 fellow group doctors in terms of stress scores, plausibly due to a better psychological tolerance in  
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60 270 the fellow group as the amount of surgery gradually increased. Furthermore, the mental stress of  
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272 attendings and fellows in the model training was significantly lower than that of the residents,

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3 272 suggesting that the model can effectively simulate mental stress. The results of the current study  
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5 273 demonstrate that the 3D printed PJ model has good simulation and effectiveness. It can help  
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7 274 distinguish pancreatic surgeons at various levels can roughly assess whether pancreatic surgeons  
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9 275 are prepared for surgery.

10  
11 276 Organ models cut from cadaver tissue have certain advantages in training young doctors in the  
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13 277 fields of trauma, plastic surgery, gynecology, general surgery, and vascular surgery. For  
14  
15 278 example, SIM Life, which is an emerging model that uses corpses as a template to have an  
16  
17 279 artificial heartbeat, circulation, and breathing, has been given high ratings by users. However, the  
18  
19 280 application of living tissues has many problems such as storage, production, and cost. The cost of  
20  
21 281 3D printed organizational models is greatly reduced and due to advances in technology and  
22  
23 282 materials, it has improved organizational similarity and training effects and it is easier to  
24  
25 283 promote and train economically. Simultaneously, it is easier to produce with a short production  
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27 284 cycle and it has a better prospect in clinical application.

28  
29 285 However, the current study has some disadvantages. I think one of the limitations or future  
30  
31 286 research could consider printing the pancreas model with inclusion of vessels such as splenic  
32  
33 287 artery, etc as this will allow for simulation of more realistic situation. And characteristics of  
34  
35 288 pancreatic tissue (consistency, elasticity, etc) are highly different from one patient to another,  
36  
37 289 and they influence both the technique and the results of pancreato-enteric anastomosis. In the  
38  
39 290 present study only one type of silicon model is used. And we selected soft silicone material to  
40  
41 291 simulate the pancreatic parenchyma and its hardness was still slightly higher than that of the  
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43 292 pancreatic tissue. we chose fifteen surgeons performed a PJ on the three-dimensional model. The  
44  
45 293 sample size could be larger. And In future studies, different materials should be tried to achieve  
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47 294 better material simulation and compare their different training effects and expert evaluation. We  
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49 295 also selected the open pancreaticoduodenal model for training and will use the laparoscopic  
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51 296 model for additional future research.

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## 55 298 **Conclusions**

56 299 The three-dimensional PJ model could mimic real surgical situations and can be used to  
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58 300 distinguish surgeons of various levels of experience. Therefore, prior to doing a

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3 301 pancreaticoduodenectomy, this model may be a convenient tool to let surgeons to evaluate  
4  
5 302 whether they are technically proficient to perform a high-quality and safe PJ on their patients.  
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23 310 like to thank all the colleagues at Sir Run Run Shaw Hospital who contributed to this research.  
24  
25 311

## 27 312 **Conflicts of interest**

30 313 All authors declares no conflicts of interest.  
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32 314

## 35 315 **Ethics Approval**

38 316 The Sir Run Run Shaw hospital granted Ethical approval to carry out the study within its  
39  
40 317 facilities (Ethical Application Ref: jm420-c5a3d).(See appendix S2).All procedures followed  
41  
42 318 were in accordance with the ethical standards of the responsible committee on human  
43  
44 319 experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised  
45  
46 320 in 2000 (5).  
47  
48 321

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31 341 **Figure 1.** The appearance of the 3D-printed PJ model. (A) The 3D printed PJ model is primarily  
32 342 composed of three parts: the pancreatic parenchyma, pancreatic duct, and intestinal duct. (B)  
33 343 Side view of the 3D printed PJ model.

36 344

37 345 **Figure 2.** Cattell-Warren anastomosis (A) Continuously suture the posterior margin of the  
38 346 pancreas and the seromuscular layer of the jejunum; 2/3 of the pancreatic tissue on the dorsal  
39 347 side of the pancreas should be sutured. The sutures should not be tightened temporarily to  
40 348 facilitate exposure of the posterior pancreatic duct wall. (B) Cut the full thickness of the jejunum  
41 349 wall corresponding to the position of the pancreatic duct. When suturing the posterior wall of the  
42 350 pancreatic duct, it should include 1/3 of the pancreatic tissue around it and knot it together. The  
43 351 knot should be on the outside of the anastomosis. (C) Suture the pancreatic duct and intestinal  
44 352 duct intermittently at 3, 6, 9, and 12 o'clock respectively to complete the anastomosis of the  
45 353 pancreatic duct and the jejunum wall. (D) The anterior wall of the pancreatic duct and its  
46 354 surrounding 1/3 of the pancreatic tissue and the entire anterior wall of the jejunum should be

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3 355 sutured continuously with the suture that was used when the posterior wall was sutured. (E)  
4  
5 356 Tighten the sutures to complete the anastomosis.  
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8 358 **Figure 3.** Panel A: The pancreas stiffness of the PJ model is measured by ultrasound with a 2D-  
9  
10 359 SWE value of  $10.08 \pm 6.50$  kPa. Panel B: General evaluation of the model. Panels C, D, E: The  
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12 360 appearance, elasticity, sense of tearing, and breakthrough degree evaluation of the different parts  
13  
14 361 of the model, including the pancreatic parenchyma, pancreatic duct, and the intestinal canal.

15 362 \*2D-SWE: Two-dimensional shear-wave elastography; OPD: Open pancreaticoduodenectomy;  
16  
17 363 LPD: Laparoscopic pancreaticoduodenectomy  
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19 364

20 365 **Figure 4.** Panel A: The operation time of the resident group was significantly longer than the fellow  
21  
22 366 group ( $1254.80 \pm 341.50$  vs.  $797.80 \pm 186.40$ ,  $p = 0.028$ ) and the attending group ( $1254.80 \pm 341.50$  vs.  
23  
24 367  $569.20 \pm 170.01$ ,  $p = 0.009$ ); Panel B: The operation score of the attending group was significantly higher  
25  
26 368 than the fellow group ( $18.80 \pm 0.84$  vs.  $17.20 \pm 0.84$ ,  $p = 0.023$ ) and the resident group ( $18.80 \pm 0.84$  vs.  
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28 369  $14.40 \pm 1.34$ ,  $p = 0.008$ ); Panel C: The NASA-TLX score of the resident group was significantly higher  
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30 370 than the fellow group ( $412.80 \pm 79.74$  vs.  $261.60 \pm 86.41$ ,  $p = 0.028$ ) and the attending group ( $412.80 \pm$   
31  
32 371  $79.74$  vs.  $265.40 \pm 99.02$ ,  $p = 0.047$ ). ( $*p < 0.05$ ,  $**p < 0.01$ ,  $***p < 0.001$ ).

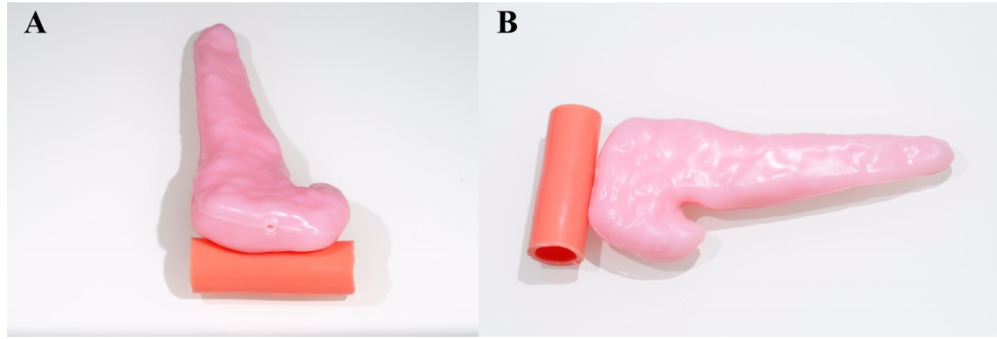
372 **References**

- 373 [1] Ecker, B.L., McMillan, M.T., Asbun, H.J., Ball, C.G., Bassi, C., Beane, J.D., Behrman, S.W.,  
374 Berger, A.C., Dickson, E.J., Bloomston, M., et al. 2018 Characterization and Optimal  
375 Management of High-risk Pancreatic Anastomoses During Pancreatoduodenectomy. *Annals of*  
376 *surgery* **267**, 608-616. (doi:10.1097/sla.0000000000002327).
- 377 [2] Besselink, M.G., van Rijssen, L.B., Bassi, C., Dervenis, C., Montorsi, M., Adham, M., Asbun,  
378 H.J., Bockhorn, M., Strobel, O., Büchler, M.W., et al. 2017 Definition and classification of chyle  
379 leak after pancreatic operation: A consensus statement by the International Study Group on  
380 Pancreatic Surgery. *Surgery* **161**, 365-372. (doi:10.1016/j.surg.2016.06.058).
- 381 [3] Suzuki, S., Kajiyama, H., Takemura, A., Shimazaki, J., Nishida, K. & Shimoda, M. 2017 The  
382 Clinical Outcomes after Total Pancreatectomy. *Digestive surgery* **34**, 142-150.  
383 (doi:10.1159/000449234).
- 384 [4] Szasz, P., Louridas, M., Harris, K.A., Aggarwal, R. & Grantcharov, T.P. 2015 Assessing  
385 Technical Competence in Surgical Trainees: A Systematic Review. *Annals of surgery* **261**,  
386 1046-1055. (doi:10.1097/sla.0000000000000866).
- 387 [5] Ziv, A., Wolpe, P.R., Small, S.D. & Glick, S. 2003 Simulation-based medical education: an  
388 ethical imperative. *Academic medicine : journal of the Association of American Medical Colleges*  
389 **78**, 783-788. (doi:10.1097/00001888-200308000-00006).
- 390 [6] Frank, J.R., Snell, L.S., Cate, O.T., Holmboe, E.S., Carraccio, C., Swing, S.R., Harris, P.,  
391 Glasgow, N.J., Campbell, C., Dath, D., et al. 2010 Competency-based medical education:  
392 theory to practice. *Medical teacher* **32**, 638-645. (doi:10.3109/0142159x.2010.501190).
- 393 [7] Tack, P., Victor, J., Gemmel, P. & Annemans, L. 2016 3D-printing techniques in a medical  
394 setting: a systematic literature review. *Biomedical engineering online* **15**, 115.  
395 (doi:10.1186/s12938-016-0236-4).
- 396 [8] Perica, E.R. & Sun, Z. 2018 A Systematic Review of Three-Dimensional Printing in Liver  
397 Disease. *Journal of digital imaging* **31**, 692-701. (doi:10.1007/s10278-018-0067-x).
- 398 [9] Sun, Z. & Lee, S.Y. 2017 A systematic review of 3-D printing in cardiovascular and  
399 cerebrovascular diseases. *Anatolian journal of cardiology* **17**, 423-435.  
400 (doi:10.14744/AnatolJCardiol.2017.7464).
- 401 [10] Kiely, D.J. 2014 Advancing surgical simulation in robotic gynecologic oncology.
- 402 [11] Tam, V., Zenati, M., Novak, S., Chen, Y., Zureikat, A.H., Zeh, H.J., 3rd & Hogg, M.E. 2017  
403 Robotic Pancreatoduodenectomy Biotissue Curriculum has Validity and Improves Technical  
404 Performance for Surgical Oncology Fellows. *Journal of surgical education* **74**, 1057-1065.  
405 (doi:10.1016/j.jsurg.2017.05.016).
- 406 [12] Maricic, M.A., Bailez, M.M. & Rodriguez, S.P. 2016 Validation of an inanimate low cost  
407 model for training minimal invasive surgery (MIS) of esophageal atresia with tracheoesophageal  
408 fistula (AE/TEF) repair. *Journal of pediatric surgery* **51**, 1429-1435.  
409 (doi:10.1016/j.jpedsurg.2016.04.018).
- 410 [13] Kiely, D.J., Gotlieb, W.H., Jardon, K., Lau, S. & Press, J.Z. 2015 Advancing surgical  
411 simulation in gynecologic oncology: robotic dissection of a novel pelvic lymphadenectomy  
412 model. *Simulation in healthcare : journal of the Society for Simulation in Healthcare* **10**, 38-42.  
413 (doi:10.1097/sih.0000000000000054).
- 414 [14] Wei, F., Xu, M., Lai, X., Zhang, J., Yiengpruksawan, A., Lu, Y., Liu, J. & Wang, Z. 2019  
415 Three-dimensional printed dry lab training models to simulate robotic-assisted  
416 pancreaticojejunostomy. *ANZ journal of surgery* **89**, 1631-1635. (doi:10.1111/ans.15544).
- 417 [15] Lowndes, B.R., Forsyth, K.L., Blocker, R.C., Dean, P.G., Truty, M.J., Heller, S.F.,  
418 Blackmon, S., Hallbeck, M.S. & Nelson, H. 2020 NASA-TLX Assessment of Surgeon Workload  
419 Variation Across Specialties. *Annals of surgery* **271**, 686-692.  
420 (doi:10.1097/sla.0000000000003058).



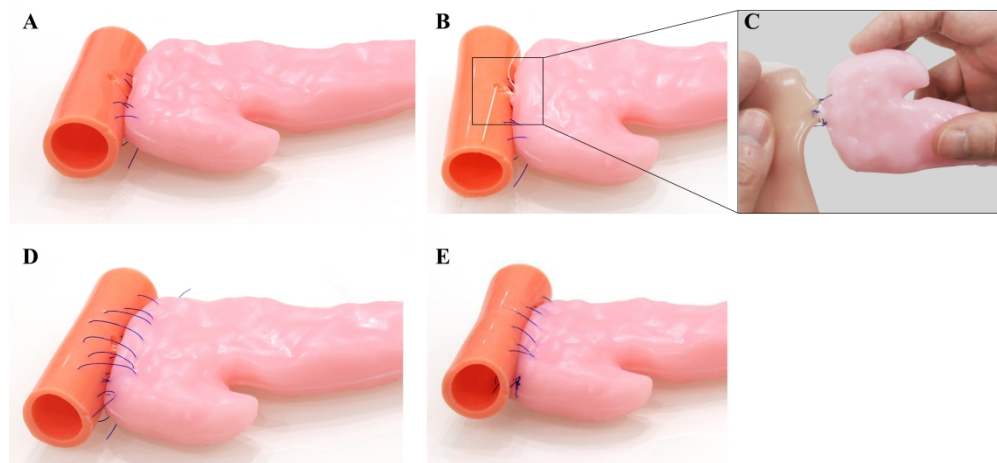
- 1  
2  
3 421 [16] Law, K.E., Lowndes, B.R., Kelley, S.R., Blocker, R.C., Larson, D.W., Hallbeck, M.S. &  
4 422 Nelson, H. 2020 NASA-Task Load Index Differentiates Surgical Approach: Opportunities for  
5 423 Improvement in Colon and Rectal Surgery. *Annals of surgery* **271**, 906-912.  
6 424 (doi:10.1097/sla.0000000000003173).  
7 425 [dataset] [17] Sezgin, O., Yaraş, S. & Özdoğan, O. 2021 The course and prognostic value of  
8 426 increased pancreas stiffness detected by ultrasound elastography during acute pancreatitis.  
9 427 *Pancreatology : official journal of the International Association of Pancreatology (IAP) ... [et al.]*.  
10 428 (doi:10.1016/j.pan.2021.07.006).  
11 429 [18] Werz, S.M., Zeichner, S.J., Berg, B.I., Zeilhofer, H.F. & Thieringer, F. 2018 3D Printed  
12 430 Surgical Simulation Models as educational tool by maxillofacial surgeons. *European journal of*  
13 431 *dental education : official journal of the Association for Dental Education in Europe* **22**, e500-  
14 432 e505. (doi:10.1111/eje.12332).  
15 433 [19] Bangeas, P., Drevelegas, K., Agorastou, C., Tzounis, L., Chorti, A., Paramythiotis, D.,  
16 434 Michalopoulos, A., Tsoulfas, G., Papadopoulos, V.N., Exadaktylos, A., et al. 2019 Three-  
17 435 dimensional printing as an educational tool in colorectal surgery. *Frontiers in bioscience (Elite*  
18 436 *edition)* **11**, 29-37. (doi:10.2741/e844).  
19 437 [20] Wang, C., Zhang, L., Qin, T., Xi, Z., Sun, L., Wu, H. & Li, D. 2020 3D printing in adult  
20 438 cardiovascular surgery and interventions: a systematic review. *Journal of thoracic disease* **12**,  
21 439 3227-3237. (doi:10.21037/jtd-20-455).  
22 440 [21] Weinstock, P., Rehder, R., Prabhu, S.P., Forbes, P.W., Roussin, C.J. & Cohen, A.R. 2017  
23 441 Creation of a novel simulator for minimally invasive neurosurgery: fusion of 3D printing and  
24 442 special effects. *Journal of neurosurgery. Pediatrics* **20**, 1-9. (doi:10.3171/2017.1.Peds16568).  
25 443 [22] Ophir, J., Céspedes, I., Ponnekanti, H., Yazdi, Y. & Li, X. 1991 Elastography: a quantitative  
26 444 method for imaging the elasticity of biological tissues. *Ultrasonic imaging* **13**, 111-134.  
27 445 (doi:10.1177/016173469101300201).  
28 446 [23] Kuwahara, T., Hirooka, Y., Kawashima, H., Ohno, E., Sugimoto, H., Hayashi, D.,  
29 447 Morishima, T., Kawai, M., Suhara, H., Takeyama, T., et al. 2016 Quantitative evaluation of  
30 448 pancreatic tumor fibrosis using shear wave elastography. *Pancreatology : official journal of the*  
31 449 *International Association of Pancreatology (IAP) ... [et al.]* **16**, 1063-1068.  
32 450 (doi:10.1016/j.pan.2016.09.012).  
33 451 [24] Pucci, J.U., Christophe, B.R., Sisti, J.A. & Connolly, E.S., Jr. 2017 Three-dimensional  
34 452 printing: technologies, applications, and limitations in neurosurgery. *Biotechnology advances* **35**,  
35 453 521-529. (doi:10.1016/j.biotechadv.2017.05.007).  
36 454 [25] Bartel, T., Rivard, A., Jimenez, A., Mestres, C.A. & Müller, S. 2018 Medical three-  
37 455 dimensional printing opens up new opportunities in cardiology and cardiac surgery. *European*  
38 456 *heart journal* **39**, 1246-1254. (doi:10.1093/eurheartj/ehx016).  
39 457 [26] Beard, J.D. 2005 Setting standards for the assessment of operative competence. *European*  
40 458 *journal of vascular and endovascular surgery : the official journal of the European Society for*  
41 459 *Vascular Surgery* **30**, 215-218. (doi:10.1016/j.ejvs.2005.01.032).  
42 460 [27] Abbott, E.F., Thompson, W., Pandian, T.K., Zendejas, B., Farley, D.R. & Cook, D.A. 2017  
43 461 Personalized Video Feedback and Repeated Task Practice Improve Laparoscopic Knot-Tying  
44 462 Skills: Two Controlled Trials. *Academic medicine : journal of the Association of American*  
45 463 *Medical Colleges* **92**, S26-s32. (doi:10.1097/acm.0000000000001924).

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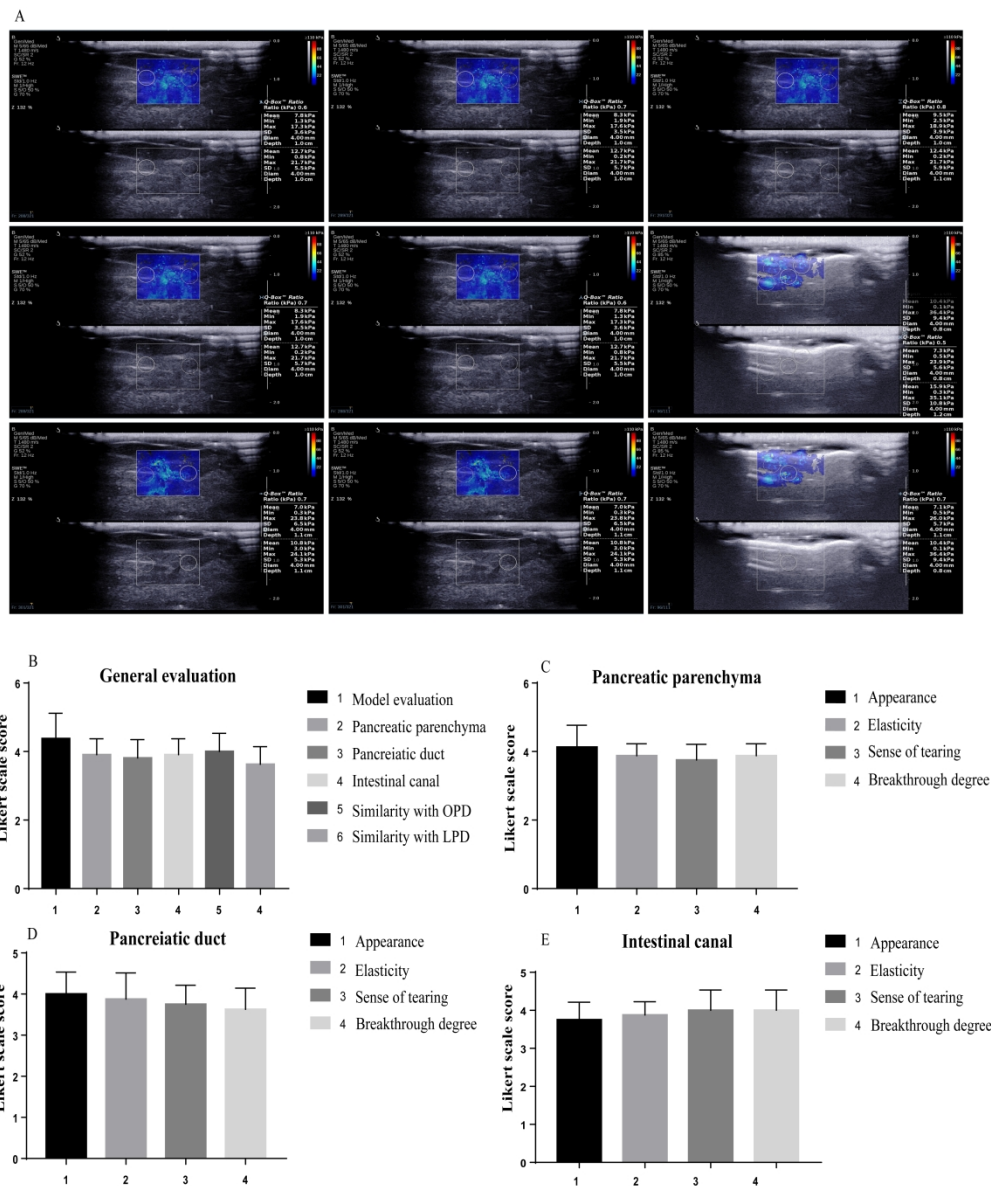
The appearance of the 3D-printed PJ model. (A) The 3D-printed PJ model is primarily composed of three parts: the pancreatic parenchyma, the pancreatic duct, and the intestinal duct. (B) Side view of the 3D-printed PJ model.





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.

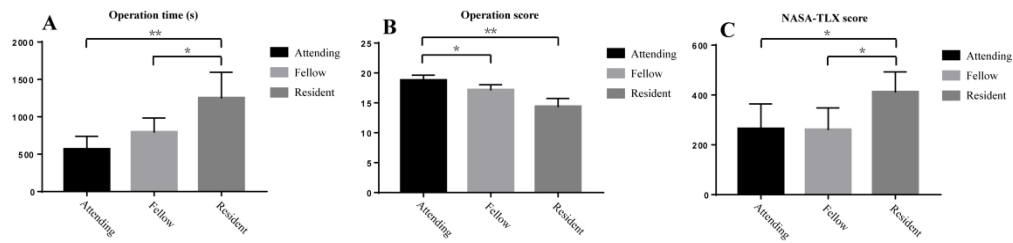
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Panel A: The pancreas stiffness of the PJ model was measured by ultrasound with a 2D-SWE value of  $10.08 \pm 6.50$  kPa. Panel B: General evaluation of the model. Panels C, D, and E: The appearance, elasticity, sense of tearing, and breakthrough degree 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 pancreaticoduodenectomy

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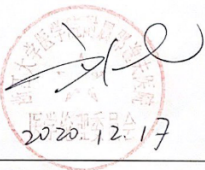


Panel A: The operation time of the resident group was significantly longer than either that of the fellow group ( $1254.80 \pm 341.50$  vs.  $797.80 \pm 186.40$ ,  $p = 0.028$ ) or the attending group ( $1254.80 \pm 341.50$  vs.  $569.20 \pm 170.01$ ,  $p = 0.009$ ); Panel B: The operation score of the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

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

## 浙江大学医学院附属邵逸夫医院医学伦理委员会 快速伦理批件

批件号：科研 20201217-41

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： <input checked="" type="checkbox"/> 初始审查 <input type="checkbox"/> 复审 <input type="checkbox"/> 修正案审查 <input type="checkbox"/> 年度跟踪审查	
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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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methods, interventions, results, conclusions

## Introduction

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4	<b>Introduction</b>		
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6	Problem	<a href="#">#3</a>	Nature and significance of the local problem
7			
8	description		
9			
10			
11	Available	<a href="#">#4</a>	Summary of what is currently known about the problem,
12			including relevant previous studies
13	knowledge		
14			
15			
16	Rationale	<a href="#">#5</a>	Informal or formal frameworks, models, concepts, and / or
17			theories used to explain the problem, any reasons or
18			assumptions that were used to develop the intervention(s), and
19			reasons why the intervention(s) was expected to work
20			
21			
22			
23	Specific aims	<a href="#">#6</a>	Purpose of the project and of this report
24			
25			
26	<b>Methods</b>		
27			
28			
29			
30	Context	<a href="#">#7</a>	Contextual elements considered important at the outset of
31			introducing the intervention(s)
32			
33			
34	Intervention(s)	<a href="#">#08a</a>	Description of the intervention(s) in sufficient detail that others
35			could reproduce it
36			
37			
38			
39	Intervention(s)	<a href="#">#08b</a>	Specifics of the team involved in the work
40			
41			
42	Study of the	<a href="#">#09a</a>	Approach chosen for assessing the impact of the intervention(s)
43			
44	Intervention(s)		
45			
46			
47	Study of the	<a href="#">#09b</a>	Approach used to establish whether the observed outcomes
48			were due to the intervention(s)
49	Intervention(s)		
50			
51			
52	Measures	<a href="#">#10a</a>	Measures chosen for studying processes and outcomes of the
53			intervention(s), including rationale for choosing them, their
54			operational definitions, and their validity and reliability
55			
56			
57			
58	Measures	<a href="#">#10b</a>	Description of the approach to the ongoing assessment of
59			
60			



contextual elements that contributed to the success, failure, efficiency, and cost

1			
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4			
5	Measures	<a href="#">#10c</a> Methods employed for assessing completeness and accuracy of data	4-7
6			
7			
8			
9	Analysis	<a href="#">#11a</a> Qualitative and quantitative methods used to draw inferences from the data	4-7
10			
11			
12			
13			
14	Analysis	<a href="#">#11b</a> Methods for understanding variation within the data, including the effects of time as a variable	4-7
15			
16			
17			
18	Ethical considerations	<a href="#">#12</a> 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
19			
20			
21			
22			
23			
24			
25	<b>Results</b>		
26			
27			
28		<a href="#">#13a</a> 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
29			
30			
31			
32			
33			
34		<a href="#">#13b</a> Details of the process measures and outcome	7-9
35			
36			
37		<a href="#">#13c</a> Contextual elements that interacted with the intervention(s)	7-9
38			
39			
40		<a href="#">#13d</a> Observed associations between outcomes, interventions, and relevant contextual elements	7-9
41			
42			
43			
44			
45		<a href="#">#13e</a> Unintended consequences such as unexpected benefits, problems, failures, or costs associated with the intervention(s).	7-9
46			
47			
48			
49			
50		<a href="#">#13f</a> Details about missing data	7-9
51			
52			
53	<b>Discussion</b>		
54			
55			
56	Summary	<a href="#">#14a</a> Key findings, including relevance to the rationale and specific aims	9-11
57			
58			
59			
60			

1	Summary	<a href="#">#14b</a>	Particular strengths of the project	9-11
2				
3				
4	Interpretation	<a href="#">#15a</a>	Nature of the association between the intervention(s) and the	9-11
5			outcomes	
6				
7				
8				
9	Interpretation	<a href="#">#15b</a>	Comparison of results with findings from other publications	9-11
10				
11				
12	Interpretation	<a href="#">#15c</a>	Impact of the project on people and systems	9-11
13				
14				
15	Interpretation	<a href="#">#15d</a>	Reasons for any differences between observed and anticipated	9-11
16			outcomes, including the influence of context	
17				
18				
19				
20	Interpretation	<a href="#">#15e</a>	Costs and strategic trade-offs, including opportunity costs	9-11
21				
22				
23	Limitations	<a href="#">#16a</a>	Limits to the generalizability of the work	11
24				
25				
26	Limitations	<a href="#">#16b</a>	Factors that might have limited internal validity such as	11
27			confounding, bias, or imprecision in the design, methods,	
28			measurement, or analysis	
29				
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32	Limitations	<a href="#">#16c</a>	Efforts made to minimize and adjust for limitations	11
33				
34				
35	Conclusion	<a href="#">#17a</a>	Usefulness of the work	11
36				
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38	Conclusion	<a href="#">#17b</a>	Sustainability	11
39				
40				
41	Conclusion	<a href="#">#17c</a>	Potential for spread to other contexts	11
42				
43				
44				
45	Conclusion	<a href="#">#17d</a>	Implications for practice and for further study in the field	11
46				
47				
48	Conclusion	<a href="#">#17e</a>	Suggested next steps	11
49				
50				
51	<b>Other</b>			
52	<b>information</b>			
53				
54				
55				
56	Funding	<a href="#">#18</a>	Sources of funding that supported this work. Role, if any, of the	12
57			funding organization in the design, implementation,	
58				
59				
60				

interpretation, and reporting

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# BMJ Open

## 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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### 33 Abstract

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

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

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

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

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

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

### 55 Strengths and limitations of this study

56 Strengths of this cross-sectional study include that:

- 57 1. The three-dimensional PJ model could mimic a real surgical situation, allowing it to be used as  
58 a portable teaching and learning tool, and;
- 59 2. The model is easier to store, therefore it can be used by students in the office or even at home.

60 Limitations of the study include that:

- 61 1. Although the current study used softer silicone material to simulate the pancreatic  
62 parenchyma, its structure was still slightly higher than that of the pancreatic tissue;
- 63 2. The PJ model in the current study didn't contain vessels such as the splenic artery, which  
64 would have allowed for the simulation of a more realistic situation, and;
- 65 3. The characteristics of the pancreatic tissue (consistency, elasticity, etc) are highly different  
66 from one patient to another, which may influence both the technique and the results of pancreato-  
67 enteric anastomosis, but in the current study only one type of silicon model was used.

## 68 **Introduction**

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

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

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

89 three-dimensional model could mimic a real surgical situation and distinguish between surgeons  
90 of various levels of experience.

91

## 92 **Materials & Methods**

### 93 **1 Study Design and Setting**

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

### 100 **2 3D-Printed Dry Lab PJ Model Production**

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

### 117 **3 Patient and Public Involvement**

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

#### 119 **4 Evaluation scale design**

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

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

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

#### 133 **5 Assessment scale issuance**

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

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

#### 145 **6 General Information of Pancreatic Surgeons**

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

1  
2  
3 164 The current study collected statistics on the overall settings and appearance, size, and tactile  
4  
5 165 similarity of the 3D printed pancreas model and the functional evaluation indicators of the model  
6  
7 166 (primarily including the surgical operation score, operation time, and NASA-TLX score).  
8  
9 167 Microsoft Excel (2016) was used to establish the scoring and evaluation table of each item in the  
10  
11 168 evaluation scale by experts. SPSS (Version 20.0, SPSS Inc, Chicago, IL, USA) software was  
12  
13 169 then used for the subsequent data analyses and processing. All tests were 2-tailed and  $p < 0.05$   
14  
15 170 was considered statistically significant. The results from the statistical analyses were entered into  
16  
17 171 Graphpad Prism 7.0 and related charts were drawn. Each score was calculated by the mean  $\pm$   
18  
19 172 standard deviation.

173

## 174 Results

### 175 1 Pancreatic surgery experts' anatomical evaluation of the model

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

#### 183 1.1 Appearance

184 The overall appearance of the 3D printed PJ dry laboratory model was evaluated at  $3.96 \pm$   
185  $0.55$ . The appearance of the pancreatic parenchyma was evaluated at  $4.13 \pm 0.64$ , the appearance  
186 of the pancreatic duct was evaluated at  $4.00 \pm 0.53$ , and the appearance of the intestinal canal  
187 was evaluated at  $3.75 \pm 0.46$ .

#### 188 1.2 Tactile Sensations

189 The pancreas was the primary component of the PJ model and its stiffness was measured via  
190 ultrasound with a two-dimensional shear-wave elastography (2D-SWE) value of  $10.08 \pm 6.50$   
191 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  $7.72 \pm 2.50$  kPa [17]. The overall tactile evaluation  
 193 of the 3D printed PJ dry laboratory model by experts was evaluated at  $3.85 \pm 0.46$ . The elasticity  
 194 of the model was evaluated at  $3.88 \pm 0.45$  and the elasticity of the pancreas parenchyma,  
 195 pancreatic duct, and intestinal duct of the model were equivalent. The ease of tearing of the  
 196 model was evaluated at  $3.83 \pm 0.48$  and the ease of tearing of the intestinal duct of the model was  
 197 slightly higher than the other two parts, at  $4.00 \pm 0.53$ . The suture breakthrough of the model was  
 198 evaluated at  $3.83 \pm 0.48$  and the pancreatic parenchyma of the model was slightly lower than the  
 199 other two, at  $3.88 \pm 0.35$ .

### 200 1.3 Education

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

## 203 2 Model functional evaluation

204 The functional evaluation of the 3D printed PJ dry laboratory model included three outcome  
 205 indicators selected for evaluation, including operation time, operation score, and the NASA Task  
 206 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  
 211 researchers ( $p = 0.003$ ) (shown in *Figure 4A*), where the operation time of the resident group  
 212 was significantly longer than either that of the fellow group ( $1254.80 \pm 341.50$  vs.  $797.80 \pm$   
 213  $186.40$ ,  $p = 0.028$ ) or the attending group ( $1254.80 \pm 341.50$  vs.  $569.20 \pm 170.01$ ;  $p = 0.009$ ), but  
 214 there was no significant statistical difference between the attending group and the fellow group  
 215 ( $569.20 \pm 170.01$  vs.  $797.80 \pm 186.40$ ,  $p = 0.175$ ).

### 216 2.2 Operation score

217 The operation score for the three groups of researchers was statistically significant ( $p <$   
 218  $0.001$ ), as shown in *Figure 4B*, where the operation score of the attending group is significantly



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

### 221 2.3 NASA-TLX score

222 The NASA-TLX mental load scores of the three groups of researchers were statistically  
223 significantly different ( $p = 0.031$ ), as shown in *Figure 4C*. The NASA-TLX score of the  
224 attending group was not significantly different from that of the fellow group ( $265.40 \pm 99.02$  vs.  
225  $261.60 \pm 86.41$ ,  $p = 0.754$ ), while the NASA-TLX score of the resident group was significantly  
226 higher than fellow group ( $412.80 \pm 79.74$  vs.  $261.60 \pm 86.41$ ,  $p = 0.028$ ) and the attending group  
227 ( $412.80 \pm 79.74$  vs.  $265.40 \pm 99.02$ ,  $p = 0.047$ ).

228 **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*

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

## 231 Discussion

232 Traditional surgical teaching and training methods are experiencing increasing learning costs  
233 under the modern background and pancreatic surgery is known for its relatively higher surgical  
234 difficulty. Within the digestive tract anastomosis, the PJ is the most complicated, which can lead  
235 to various postoperative complications. The PJ model based on biotissue[11] is considered to  
236 improve technical performance in surgical oncology fellows. However, to our knowledge,  
237 although they have been successfully applied to training in many fields of surgery, including  
238 head and neck surgery [18], colorectal surgery [19], vascular surgery [20], and neurosurgery  
239 [21], among others, there are few reports on PJ models using 3D printed models.

240 Elastography is an ultrasound imaging method that has been used to assess the stiffness of  
241 tissues. The concept of elastography was first proposed in 1991 [22]. During an elastography  
242 evaluation, the stiffness of the model can be estimated from the response of the model to  
243 compression. This process can be performed in two ways; shear wave elastography (SWE) or  
244 strain elastography [23]. The current study used soft silicone material to simulate the pancreatic  
245 parenchyma and its hardness, which was slightly higher than that of the pancreatic tissue. Our  
246 team has also studied hydrogel as a 3D printing material to print PJ models. Its hardness is very

247 close to that of the pancreas. But the moisture in hydrogel tends to evaporate over time, which  
248 causes difficulties with storage, thereby limiting its use. Future studies are planned to conduct in-  
249 depth research on this softer material. In the current study, eight pancreatic surgery experts were  
250 selected, all of whom exceeded the experience expectations for a pancreaticoduodenectomy, and  
251 a model evaluation scale was issued to these experts. The evaluation scale adopts the 5-point  
252 Likert scale [11-13], which comprehensively evaluates the appearance and touch of each  
253 component of the model, its similarity with real surgery, and its application in teaching. Experts  
254 rated the model highly on both appearance and touch, suggesting that the model has good  
255 simulation performance. All experts recommend it for teaching, suggesting a potential role of  
256 such models in surgical training.

257 The current study also selected three groups of surgeons to perform functional tests of the  
258 model. The selected research indicators primarily include operation time, operation score, and  
259 the NASA-TLX. There is a plethora of research on operation time and operation score, which  
260 can effectively reflect the operation level on the model [24, 25]. Additionally, Beard et al. [26]  
261 developed an objective structured assessment of technical skills (OSATS) scale based on the  
262 surgeon's technical competency evaluation. The research published by Wei et al. [14] was  
263 optimized on the basis of OSATS and was demonstrated to be a good assessment of the technical  
264 competency of surgeons. The operation scoring standard of the current research also refers to this  
265 modified version of the scoring design. In addition, the current study utilized the NASA-TLX as  
266 a subjective index to assess mental workload, which can reflect the surgeon's operating pressure,  
267 which has attracted increasing attention in recent years [15, 27]. Given the results of the above  
268 three indicators, the model is suggested to be able to effectively distinguish between the three  
269 groups of physicians in terms of operating time, operating scores, and mental stress, further  
270 indicating the effectiveness of the model. Among the groups, the attending group had a shorter  
271 operating time than the fellow group ( $569.20 \pm 170.01$  vs.  $797.80 \pm 186.40$ ), however, this  
272 difference was not statistically significant. This may be due to an insufficient number of enrolled  
273 physicians. Additionally, there was no significant difference between the attending group and the  
274 fellow group doctors in terms of stress scores, plausibly due to a better psychological tolerance in  
275 the fellow group as the amount of surgery gradually increased. Furthermore, the mental stress of  
276 attendings and fellows in the model training was significantly lower than that of the residents,  
277 suggesting that the model can effectively simulate mental stress. The results of the current study

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3 278 demonstrate that the 3D printed PJ model has good simulation and effectiveness. It can help  
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5 279 distinguish pancreatic surgeons at various levels can roughly assess whether pancreatic surgeons  
6  
7 280 are prepared for surgery.

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9 281 Organ models cut from cadaver tissue have certain advantages in training young doctors in the  
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11 282 fields of trauma, plastic surgery, gynecology, general surgery, and vascular surgery. For  
12  
13 283 example, SIM Life, which is an emerging model that uses corpses as a template to have an  
14  
15 284 artificial heartbeat, circulation, and breathing, has been given high ratings by users. However, the  
16  
17 285 application of living tissues has many problems such as storage, production, and cost. The cost of  
18  
19 286 3D printed organizational models is greatly reduced and due to advances in technology and  
20  
21 287 materials, it has improved organizational similarity and training effects and it is easier to  
22  
23 288 promote and train economically. Simultaneously, it is easier to produce with a short production  
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25 289 cycle and it has a better prospect in clinical application.

26  
27 290 However, the current study has some disadvantages. One of the limitations that future research  
28  
29 291 should consider is the printing of the pancreas model with the inclusion of vessels, such as the  
30  
31 292 splenic artery, as this will allow for the simulation of a more realistic situation. Additionally,  
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33 293 characteristics of the pancreatic tissue (consistency, elasticity, etc.) are highly different from one  
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35 294 patient to another and influence both the technique and the results of the pancreato-enteric  
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37 295 anastomosis. In the current study, only one type of silicon model was used. Furthermore, while a  
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39 296 soft silicone material was selected to simulate the pancreatic parenchyma, its hardness was still  
40  
41 297 slightly higher than that of the pancreatic tissue. Additionally, while we chose fifteen surgeons  
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43 298 performed a PJ on the three-dimensional model, the sample size could be larger. In future  
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45 299 studies, different materials should be tried to achieve better material simulation and compare  
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47 300 their different training effects and expert evaluation. We also selected the open  
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49 301 pancreaticoduodenal model for training and will use the laparoscopic model for additional future  
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51 302 research.

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## 54 304 **Conclusions**

55 305 The three-dimensional PJ model could mimic real surgical situations and can be used to  
56  
57 306 distinguish surgeons of various levels of experience. Therefore, prior to doing a

307 pancreaticoduodenectomy, this model may be a convenient tool to let surgeons to evaluate  
308 whether they are technically proficient to perform a high-quality and safe PJ on their patients.

309

### 310 **Author Contribution**

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

314

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320 Haiying Dong, Zhifei Wang, Jin Yang, and Tunan Yu for the reporting of the work. The authors  
321 would additionally like to thank all the colleagues at Sir Run Run Shaw Hospital who  
322 contributed to this research.

323

### 324 **Conflicts of interest**

325 All authors declare no conflicts of interest.

326

### 327 **Ethics Approval**

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

333

### 334 **Data availability statement**

335 All data that used in the writing of our article in the text are publicly available and the reference  
336 list were cited. See  
337 Doi: <https://doi.org/10.5281/zenodo.5842799>

338

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

360 **(B)** Side view of the 3D-printed PJ model.

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3 362 **Figure 2.** Cattell-Warren anastomosis instructions **(A)** Continuously suture the posterior margin  
4 363 of the pancreas and the seromuscular layer of the jejunum; 2/3 of the pancreatic tissue on the  
5 364 dorsal side of the pancreas should be sutured. The sutures should not be temporarily tightened to  
6 365 facilitate exposure of the posterior pancreatic duct wall. **(B)** Cut the full thickness of the jejunum  
7 366 wall corresponding to the position of the pancreatic duct. When suturing the posterior wall of the  
8 367 pancreatic duct, 1/3 of the surrounding pancreatic tissue should be included, then knot it  
9 368 together. The knot should be on the outside of the anastomosis. **(C)** Suture the pancreatic duct  
10 369 and the intestinal duct intermittently at 3, 6, 9, and 12 o'clock, respectively, to complete the  
11 370 anastomosis of the pancreatic duct and the jejunum wall. **(D)** The anterior wall of the pancreatic  
12 371 duct and its surrounding 1/3 of the pancreatic tissue and the entire anterior wall of the jejunum  
13 372 should be continuously sutured with the suture that was used when the posterior wall was  
14 373 sutured. **(E)** Tighten the sutures to complete the anastomosis.  
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25 375 **Figure 3.** Panel A: The pancreas stiffness of the PJ model was measured by ultrasound with a  
26 376 2D-SWE value of  $10.08 \pm 6.50$  kPa. Panel B: General evaluation of the model. Panels C, D, and  
27 377 E: The appearance, elasticity, sense of tearing, and breakthrough degree of evaluation of the  
28 378 various parts of the model, including the pancreatic parenchyma, pancreatic duct, and the  
29 379 intestinal canal.

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31 380 \*2D-SWE: Two-dimensional shear-wave elastography; OPD: Open pancreaticoduodenectomy;  
32 381 LPD: Laparoscopic pancreaticoduodenectomy  
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39 383 **Figure 4.** Panel A: The operation time of the resident group was significantly longer than either  
40 384 that of the fellow group ( $1254.80 \pm 341.50$  vs.  $797.80 \pm 186.40$ ,  $p = 0.028$ ) or the attending  
41 385 group ( $1254.80 \pm 341.50$  vs.  $569.20 \pm 170.01$ ,  $p = 0.009$ ); Panel B: The operation score of the  
42 386 attending group was significantly higher than either that of the fellow group ( $18.80 \pm 0.84$  vs.  
43 387  $17.20 \pm 0.84$ ,  $p = 0.023$ ) or the resident group ( $18.80 \pm 0.84$  vs.  $14.40 \pm 1.34$ ,  $p = 0.008$ ); Panel  
44 388 C: The NASA-TLX score of the resident group was significantly higher than either that of the  
45 389 fellow group ( $412.80 \pm 79.74$  vs.  $261.60 \pm 86.41$ ,  $p = 0.028$ ) or the attending group ( $412.80 \pm$   
46 390  $79.74$  vs.  $265.40 \pm 99.02$ ,  $p = 0.047$ ).

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51 391 \* $p < 0.05$ , \*\* $p < 0.01$ , \*\*\* $p < 0.001$   
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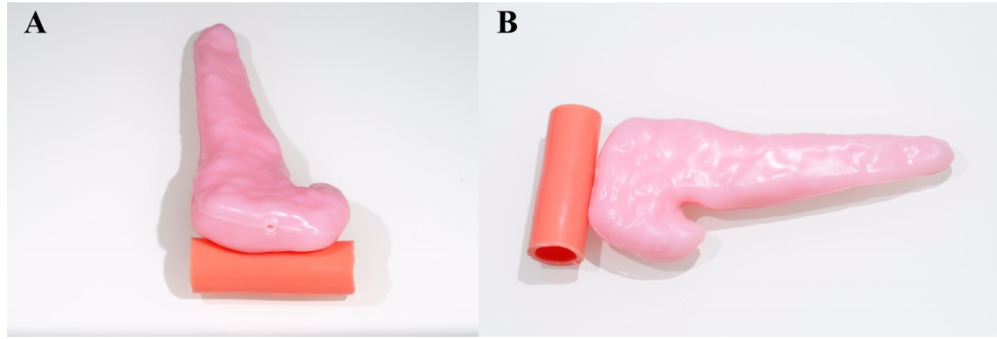
## 392 References

- 393 [1] Ecker, B.L., McMillan, M.T., Asbun, H.J., Ball, C.G., Bassi, C., Beane, J.D., Behrman, S.W.,  
394 Berger, A.C., Dickson, E.J., Bloomston, M., et al. 2018 Characterization and Optimal  
395 Management of High-risk Pancreatic Anastomoses During Pancreatoduodenectomy. *Annals of*  
396 *surgery* **267**, 608-616. (doi:10.1097/sla.0000000000002327).
- 397 [2] Besselink, M.G., van Rijssen, L.B., Bassi, C., Dervenis, C., Montorsi, M., Adham, M., Asbun,  
398 H.J., Bockhorn, M., Strobel, O., Büchler, M.W., et al. 2017 Definition and classification of chyle  
399 leak after pancreatic operation: A consensus statement by the International Study Group on  
400 Pancreatic Surgery. *Surgery* **161**, 365-372. (doi:10.1016/j.surg.2016.06.058).
- 401 [3] Suzuki, S., Kajiyama, H., Takemura, A., Shimazaki, J., Nishida, K. & Shimoda, M. 2017 The  
402 Clinical Outcomes after Total Pancreatectomy. *Digestive surgery* **34**, 142-150.  
403 (doi:10.1159/000449234).
- 404 [4] Szasz, P., Louridas, M., Harris, K.A., Aggarwal, R. & Grantcharov, T.P. 2015 Assessing  
405 Technical Competence in Surgical Trainees: A Systematic Review. *Annals of surgery* **261**,  
406 1046-1055. (doi:10.1097/sla.0000000000000866).
- 407 [5] Ziv, A., Wolpe, P.R., Small, S.D. & Glick, S. 2003 Simulation-based medical education: an  
408 ethical imperative. *Academic medicine : journal of the Association of American Medical Colleges*  
409 **78**, 783-788. (doi:10.1097/00001888-200308000-00006).
- 410 [6] Frank, J.R., Snell, L.S., Cate, O.T., Holmboe, E.S., Carraccio, C., Swing, S.R., Harris, P.,  
411 Glasgow, N.J., Campbell, C., Dath, D., et al. 2010 Competency-based medical education:  
412 theory to practice. *Medical teacher* **32**, 638-645. (doi:10.3109/0142159x.2010.501190).
- 413 [7] Tack, P., Victor, J., Gemmel, P. & Annemans, L. 2016 3D-printing techniques in a medical  
414 setting: a systematic literature review. *Biomedical engineering online* **15**, 115.  
415 (doi:10.1186/s12938-016-0236-4).
- 416 [8] Perica, E.R. & Sun, Z. 2018 A Systematic Review of Three-Dimensional Printing in Liver  
417 Disease. *Journal of digital imaging* **31**, 692-701. (doi:10.1007/s10278-018-0067-x).
- 418 [9] Sun, Z. & Lee, S.Y. 2017 A systematic review of 3-D printing in cardiovascular and  
419 cerebrovascular diseases. *Anatolian journal of cardiology* **17**, 423-435.  
420 (doi:10.14744/AnatolJCardiol.2017.7464).
- 421 [10] Kiely, D.J. 2014 Advancing surgical simulation in robotic gynecologic oncology.
- 422 [11] Tam, V., Zenati, M., Novak, S., Chen, Y., Zureikat, A.H., Zeh, H.J., 3rd & Hogg, M.E. 2017  
423 Robotic Pancreatoduodenectomy Biotissue Curriculum has Validity and Improves Technical  
424 Performance for Surgical Oncology Fellows. *Journal of surgical education* **74**, 1057-1065.  
425 (doi:10.1016/j.jsurg.2017.05.016).
- 426 [12] Maricic, M.A., Bailez, M.M. & Rodriguez, S.P. 2016 Validation of an inanimate low cost  
427 model for training minimal invasive surgery (MIS) of esophageal atresia with tracheoesophageal  
428 fistula (AE/TEF) repair. *Journal of pediatric surgery* **51**, 1429-1435.  
429 (doi:10.1016/j.jpedsurg.2016.04.018).
- 430 [13] Kiely, D.J., Gotlieb, W.H., Jardon, K., Lau, S. & Press, J.Z. 2015 Advancing surgical  
431 simulation in gynecologic oncology: robotic dissection of a novel pelvic lymphadenectomy  
432 model. *Simulation in healthcare : journal of the Society for Simulation in Healthcare* **10**, 38-42.  
433 (doi:10.1097/sih.0000000000000054).
- 434 [14] Wei, F., Xu, M., Lai, X., Zhang, J., Yiengpruksawan, A., Lu, Y., Liu, J. & Wang, Z. 2019  
435 Three-dimensional printed dry lab training models to simulate robotic-assisted  
436 pancreaticojejunostomy. *ANZ journal of surgery* **89**, 1631-1635. (doi:10.1111/ans.15544).
- 437 [15] Lowndes, B.R., Forsyth, K.L., Blocker, R.C., Dean, P.G., Truty, M.J., Heller, S.F.,  
438 Blackmon, S., Hallbeck, M.S. & Nelson, H. 2020 NASA-TLX Assessment of Surgeon Workload  
439 Variation Across Specialties. *Annals of surgery* **271**, 686-692.  
440 (doi:10.1097/sla.0000000000003058).

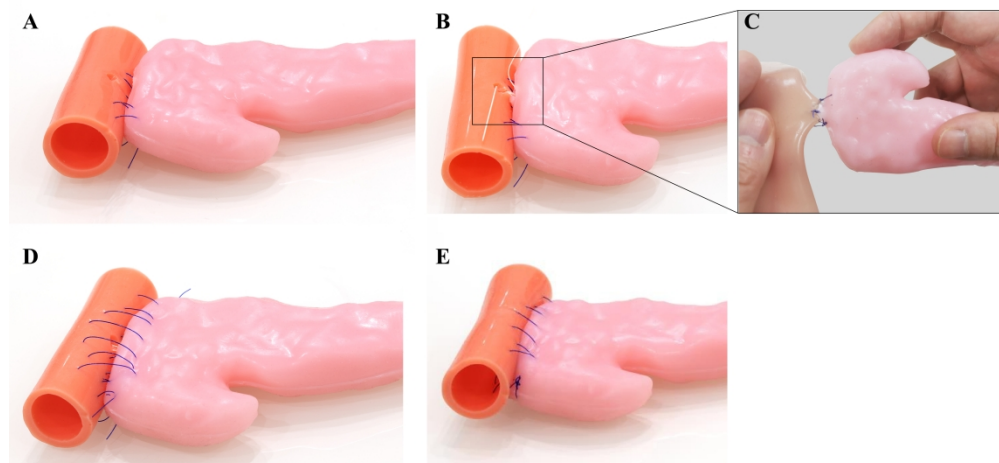


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2  
3 441 [16] Law, K.E., Lowndes, B.R., Kelley, S.R., Blocker, R.C., Larson, D.W., Hallbeck, M.S. &  
4 442 Nelson, H. 2020 NASA-Task Load Index Differentiates Surgical Approach: Opportunities for  
5 443 Improvement in Colon and Rectal Surgery. *Annals of surgery* **271**, 906-912.  
6 444 (doi:10.1097/sla.0000000000003173).  
7 445 [dataset] [17] Sezgin, O., Yaraş, S. & Özdoğan, O. 2021 The course and prognostic value of  
8 446 increased pancreas stiffness detected by ultrasound elastography during acute pancreatitis.  
9 447 *Pancreatology : official journal of the International Association of Pancreatology (IAP) ... [et al.]*.  
10 448 (doi:10.1016/j.pan.2021.07.006).  
11 449 [18] Werz, S.M., Zeichner, S.J., Berg, B.I., Zeilhofer, H.F. & Thieringer, F. 2018 3D Printed  
12 450 Surgical Simulation Models as educational tool by maxillofacial surgeons. *European journal of*  
13 451 *dental education : official journal of the Association for Dental Education in Europe* **22**, e500-  
14 452 e505. (doi:10.1111/eje.12332).  
15 453 [19] Bangeas, P., Drevelegas, K., Agorastou, C., Tzounis, L., Chorti, A., Paramythiotis, D.,  
16 454 Michalopoulos, A., Tsoulfas, G., Papadopoulos, V.N., Exadaktylos, A., et al. 2019 Three-  
17 455 dimensional printing as an educational tool in colorectal surgery. *Frontiers in bioscience (Elite*  
18 456 *edition)* **11**, 29-37. (doi:10.2741/e844).  
19 457 [20] Wang, C., Zhang, L., Qin, T., Xi, Z., Sun, L., Wu, H. & Li, D. 2020 3D printing in adult  
20 458 cardiovascular surgery and interventions: a systematic review. *Journal of thoracic disease* **12**,  
21 459 3227-3237. (doi:10.21037/jtd-20-455).  
22 460 [21] Weinstock, P., Rehder, R., Prabhu, S.P., Forbes, P.W., Roussin, C.J. & Cohen, A.R. 2017  
23 461 Creation of a novel simulator for minimally invasive neurosurgery: fusion of 3D printing and  
24 462 special effects. *Journal of neurosurgery. Pediatrics* **20**, 1-9. (doi:10.3171/2017.1.Peds16568).  
25 463 [22] Ophir, J., Céspedes, I., Ponnekanti, H., Yazdi, Y. & Li, X. 1991 Elastography: a quantitative  
26 464 method for imaging the elasticity of biological tissues. *Ultrasonic imaging* **13**, 111-134.  
27 465 (doi:10.1177/016173469101300201).  
28 466 [23] Kuwahara, T., Hirooka, Y., Kawashima, H., Ohno, E., Sugimoto, H., Hayashi, D.,  
29 467 Morishima, T., Kawai, M., Suhara, H., Takeyama, T., et al. 2016 Quantitative evaluation of  
30 468 pancreatic tumor fibrosis using shear wave elastography. *Pancreatology : official journal of the*  
31 469 *International Association of Pancreatology (IAP) ... [et al.]* **16**, 1063-1068.  
32 470 (doi:10.1016/j.pan.2016.09.012).  
33 471 [24] Pucci, J.U., Christophe, B.R., Sisti, J.A. & Connolly, E.S., Jr. 2017 Three-dimensional  
34 472 printing: technologies, applications, and limitations in neurosurgery. *Biotechnology advances* **35**,  
35 473 521-529. (doi:10.1016/j.biotechadv.2017.05.007).  
36 474 [25] Bartel, T., Rivard, A., Jimenez, A., Mestres, C.A. & Müller, S. 2018 Medical three-  
37 475 dimensional printing opens up new opportunities in cardiology and cardiac surgery. *European*  
38 476 *heart journal* **39**, 1246-1254. (doi:10.1093/eurheartj/ehx016).  
39 477 [26] Beard, J.D. 2005 Setting standards for the assessment of operative competence. *European*  
40 478 *journal of vascular and endovascular surgery : the official journal of the European Society for*  
41 479 *Vascular Surgery* **30**, 215-218. (doi:10.1016/j.ejvs.2005.01.032).  
42 480 [27] Abbott, E.F., Thompson, W., Pandian, T.K., Zendejas, B., Farley, D.R. & Cook, D.A. 2017  
43 481 Personalized Video Feedback and Repeated Task Practice Improve Laparoscopic Knot-Tying  
44 482 Skills: Two Controlled Trials. *Academic medicine : journal of the Association of American*  
45 483 *Medical Colleges* **92**, S26-s32. (doi:10.1097/acm.0000000000001924).

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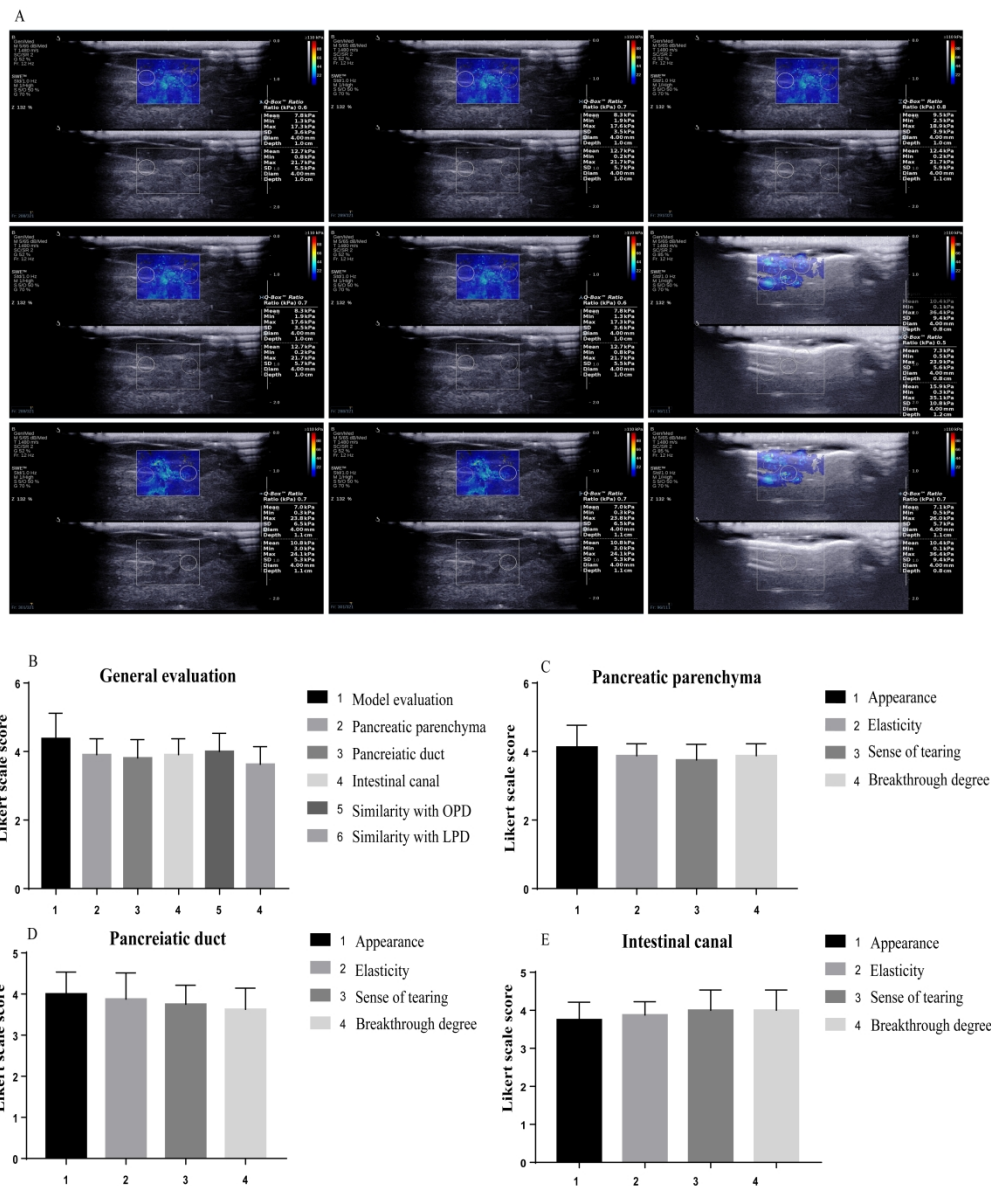


The appearance of the 3D-printed PJ model. (A) The 3D-printed PJ model is primarily composed of three parts: the pancreatic parenchyma, the pancreatic duct, and the intestinal duct. (B) Side view of the 3D-printed PJ model.



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.

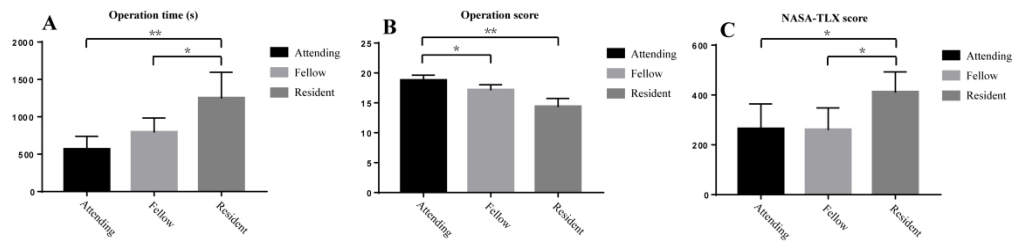
578x314mm (300 x 300 DPI)



Panel A: The pancreas stiffness of the PJ model was measured by ultrasound with a 2D-SWE value of  $10.08 \pm 6.50$  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 pancreaticoduodenectomy

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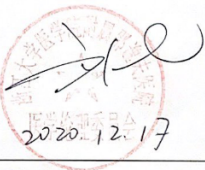
Panel A: The operation time of the resident group was significantly longer than either that of the fellow group ( $1254.80 \pm 341.50$  vs.  $797.80 \pm 186.40$ ,  $p = 0.028$ ) or the attending group ( $1254.80 \pm 341.50$  vs.  $569.20 \pm 170.01$ ,  $p = 0.009$ ); Panel B: The operation score of the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

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



## 浙江大学医学院附属邵逸夫医院医学伦理委员会 快速伦理批件

批件号：科研 20201217-41

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： <input checked="" type="checkbox"/> 初始审查 <input type="checkbox"/> 复审 <input type="checkbox"/> 修正案审查 <input type="checkbox"/> 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	
审查结果： <input checked="" type="checkbox"/> 同意 <input type="checkbox"/> 修正后同意 <input type="checkbox"/> 终止或暂停已批准的研究 <input type="checkbox"/> 不同意	
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## 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.

## Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

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	Reporting Item	Page Number
<b>Title</b>		
	<a href="#">#1</a> 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
<b>Abstract</b>		
	<a href="#">#02a</a> Provide adequate information to aid in searching and indexing	2
	<a href="#">#02b</a> 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	<a href="#">#3</a>	Nature and significance of the local problem	3
Available knowledge	<a href="#">#4</a>	Summary of what is currently known about the problem, including relevant previous studies	3
Rationale	<a href="#">#5</a>	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	<a href="#">#6</a>	Purpose of the project and of this report	3

## Methods

Context	<a href="#">#7</a>	Contextual elements considered important at the outset of introducing the intervention(s)	3
Intervention(s)	<a href="#">#08a</a>	Description of the intervention(s) in sufficient detail that others could reproduce it	4-7
Intervention(s)	<a href="#">#08b</a>	Specifics of the team involved in the work	4-7
Study of the Intervention(s)	<a href="#">#09a</a>	Approach chosen for assessing the impact of the intervention(s)	4-7
Study of the Intervention(s)	<a href="#">#09b</a>	Approach used to establish whether the observed outcomes were due to the intervention(s)	4-7
Measures	<a href="#">#10a</a>	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	<a href="#">#10b</a>	Description of the approach to the ongoing assessment of	4-7

contextual elements that contributed to the success, failure, efficiency, and cost

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2			
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5	Measures	<a href="#">#10c</a> Methods employed for assessing completeness and accuracy of data	4-7
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7			
8			
9	Analysis	<a href="#">#11a</a> Qualitative and quantitative methods used to draw inferences from the data	4-7
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12			
13			
14	Analysis	<a href="#">#11b</a> Methods for understanding variation within the data, including the effects of time as a variable	4-7
15			
16			
17			
18	Ethical considerations	<a href="#">#12</a> 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
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25	<b>Results</b>		
26			
27			
28		<a href="#">#13a</a> 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
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34		<a href="#">#13b</a> Details of the process measures and outcome	7-9
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37		<a href="#">#13c</a> Contextual elements that interacted with the intervention(s)	7-9
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40		<a href="#">#13d</a> Observed associations between outcomes, interventions, and relevant contextual elements	7-9
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45		<a href="#">#13e</a> Unintended consequences such as unexpected benefits, problems, failures, or costs associated with the intervention(s).	7-9
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50		<a href="#">#13f</a> Details about missing data	7-9
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53	<b>Discussion</b>		
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56	Summary	<a href="#">#14a</a> Key findings, including relevance to the rationale and specific aims	9-11
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1	Summary	<a href="#">#14b</a>	Particular strengths of the project	9-11
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4	Interpretation	<a href="#">#15a</a>	Nature of the association between the intervention(s) and the	9-11
5			outcomes	
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9	Interpretation	<a href="#">#15b</a>	Comparison of results with findings from other publications	9-11
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12	Interpretation	<a href="#">#15c</a>	Impact of the project on people and systems	9-11
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15	Interpretation	<a href="#">#15d</a>	Reasons for any differences between observed and anticipated	9-11
16			outcomes, including the influence of context	
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20	Interpretation	<a href="#">#15e</a>	Costs and strategic trade-offs, including opportunity costs	9-11
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23	Limitations	<a href="#">#16a</a>	Limits to the generalizability of the work	11
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26	Limitations	<a href="#">#16b</a>	Factors that might have limited internal validity such as	11
27			confounding, bias, or imprecision in the design, methods,	
28			measurement, or analysis	
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32	Limitations	<a href="#">#16c</a>	Efforts made to minimize and adjust for limitations	11
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35	Conclusion	<a href="#">#17a</a>	Usefulness of the work	11
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38	Conclusion	<a href="#">#17b</a>	Sustainability	11
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41	Conclusion	<a href="#">#17c</a>	Potential for spread to other contexts	11
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44	Conclusion	<a href="#">#17d</a>	Implications for practice and for further study in the field	11
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47	Conclusion	<a href="#">#17e</a>	Suggested next steps	11
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51	<b>Other</b>			
52	<b>information</b>			
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56	Funding	<a href="#">#18</a>	Sources of funding that supported this work. Role, if any, of the	12
57			funding organization in the design, implementation,	
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interpretation, and reporting

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