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ORIGINAL ARTICLE

Development of biotissue training models for anastomotic suturing in pancreatic surgery

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Abstract

Background: Anastomotic suturing is the Achilles heel of pancreatic surgery. Especially in laparoscopic and robotically assisted surgery, the pancreatic anastomosis should first be trained outside the operating room. Realistic training models are therefore needed.

Methods: Models of the pancreas, small bowel, stomach, bile duct, and a realistic training torso were developed for training of anastomoses in pancreatic surgery. Pancreas models with soft and hard textures, small and large ducts were incrementally developed and evaluated. Experienced pancreatic surgeons ($n = 44$) evaluated haptic realism, rigidity, fragility of tissues, and realism of suturing and knot tying.

Results: In the iterative development process the pancreas models showed high haptic realism and highest realism in suturing (4.6 ± 0.7 and 4.9 ± 0.5 on 1−5 Likert scale, soft pancreas). The small bowel model showed highest haptic realism (4.8 ± 0.4) and optimal wall thickness (0.1 ± 0.4 on −2 to +2 Likert scale) and suturing behavior (0.1 ± 0.4). The bile duct models showed optimal wall thickness (0.3 ± 0.8 and 0.4 ± 0.8 on −2 to +2 Likert scale) and optimal tissue fragility (0 ± 0.9 and 0.3 ± 0.7).

Conclusion: The biotissue training models showed high haptic realism and realistic suturing behavior. They are suitable for realistic training of anastomoses in pancreatic surgery which may improve patient outcomes.

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Introduction

Pancreatic surgeons perform highly complex operations with considerable morbidity rates even in high volume centers.[1] Since the first laparoscopic pancreatoduodenectomy in 1994,[2] minimally invasive pancreatic surgery (MIPS) has gained much popularity and is currently also performed robotically in specialized centers across the world. Robotic pancreatoduodenectomy has been shown to be a suitable and safe approach to pancreatic surgery.[3−5] The first studies regarding robotic pancreatoduodenectomy mainly focused on safety, comparability to open and laparoscopic approaches, and patient outcomes. Whether open, laparoscopic, or robotic pancreatoduodenectomy is the procedure of choice is still being discussed.[6,7] An important factor to consider is patient selection. A thin ampullary patient may be easier than a borderline patient which may need portal vein reconstruction. Thus, patient selection will play a crucial role in the choice of approach as well. Despite the smaller incisions with MIPS, still the most crucial part of the procedure is the pancreatico-jejunostomy and therefor the need to master the technique. In recent years, the learning curves for MIPS have been recognized and MIPS training curricula have been established.[5,8] The goal of training outside the operating room is to reduce patient morbidity and mortality associated with the adoption of new techniques. Another goal of simulation is efficient learning of techniques in order to reduce operation time.[8,9] Both laparoscopic and robotic surgery have been shown to require distinct skills.[10] Structured training programs accelerate the learning curve in robotic[11] as well as laparoscopic surgery[12,13] and are feasible and safe.[11,14–16] Implementation of MIPS can be optimized by a stepwise introduction that includes basic skill training, virtual simulation,[17] biotissue drills (Biotissue: synthetic tissue imitating human tissue), video analysis, proctoring of first cases, and fellowships to reach competency, proficiency, and mastery level.[8]

An important feature mentioned in various training curricula is training on synthetic biotissue models simulating human tissue.[8,11,18–20] Thus far, various studies have shown that training outside of the operating room improves surgical skills and accelerates the learning curve before operating on patients, both for minimally invasive and open surgery.[20,21] Basic technical skills, like suturing and knot tying, especially can easily be trained using simple suture pads made of various materials. For a more realistic training experience and more complex procedural steps, biotissue models can be used. Biotissue training models are specifically useful for MIPS due to the limited haptic feedback with laparoscopic and current robotic systems.[8,11] They also offer various advantages compared to training on animal models and cadavers. The latter suffer from rapid degradation of tissue and high maintenance and costs,[22] whereas biotissue models are easy to use, storage and transport is simple, and models can often be used multiple times. The aim of this project was to develop a training setup with biotissue models for anastomoses after pancreatoduodenectomy with realistic tissue properties and suturing behavior for use in MIPS and open surgical training.

Methods

Model development

Molding: The molds used for model casting were developed and constructed using 3D modelling software and 3D printing technology with standard PLA filament. The mold for the pancreas models was designed using segmented and deidentified Computed Tomography imaging data from a patient. After virtual pancreatic head resection, the 3D model of the remaining pancreatic tail was used as a template for the mold design (Fig. 1). For the stomach, small bowel, and biliary duct models, the molds were designed using realistic organ dimensions.

Silicone casting: The material used for organ model casting was liquid silicone rubber with additives that influence and change the tissue properties depending on the desired hardness, fragility, and haptic properties of the organ model. Color pigment was added for a more realistic visual appearance. Different silicone and additive mixtures were prepared to provide variability in tissue properties.

Pancreas and pancreatic ducts: The pancreas model size was 65 × 40 × 15 mm. Two different duct sizes with 3 mm and 4 mm inner diameter, each with 1 mm duct wall thickness, were produced. The duct was produced separately from the pancreas model and placed centrally and slightly dorsal for anatomical correctness. After the first silicone tests, 8 different pancreas models with 4 soft and 4 hard silicone mixtures were produced for the first expert evaluation round. Later in the development process, a pancreatic capsule made of a thin silicone layer was added (Fig. 1). The commercially available pancreas models used for comparison were purchased from LifeLike Biotissue Inc (London, Canada).

Small bowel: All versions of the small bowel models had the same length of 200 mm and an inner diameter of 18 mm. For the first evaluation round, a two-layered small bowel model was produced with a total wall thickness of 2 mm and 3 mm, generating outer diameters of 22 and 24 mm. Different silicone mixtures were used for the inner and outer bowel layer. In the further development process, a version with 2.5 mm wall thickness and improved silicone mixture was used (Fig. 1).

Stomach: The stomach model was produced with two layers. At first, two stomach models were produced with 2 and 4 mm wall thickness. Later, a version with 5 mm wall thickness and improved silicone mixture was added.

Bile duct: The bile duct models were designed to be single layered with 1 mm wall thickness and had various inner diameters ranging from 3 to 9 mm. For evaluation, two 6 mm models were used with different silicone mixtures (one hard and one soft), representing a soft and a hard duct wall (Fig. 1).

Training torso: The training torso was designed for mounting the biotissue organ models in an anatomically correct position in a realistic environment. The torso size was chosen to be large enough for open surgical training and small enough to fit in a standard laparoscopic box trainer. The laparotomy size of the first prototype proved to be slightly too small, therefore in the further development process a larger version was produced for the expert evaluation. A silicone liver was integrated in the cranial part of the laparotomy, where the bile duct is mounted. Silicone models of the relevant blood vessels for pancreatoduodenectomy (abdominal aorta; coeliac trunk with hepatic, splenic, left gastric artery, clipped gastroduodenal artery; superior mesenteric artery; vena cava; portomesenteric vein; splenic vein; and inferior mesenteric vein) were placed as background for the surgical field (Figs. 2 and 3). For open surgical training, the surrounding abdominal cavity was covered with abdominal cloths (Fig. 2).

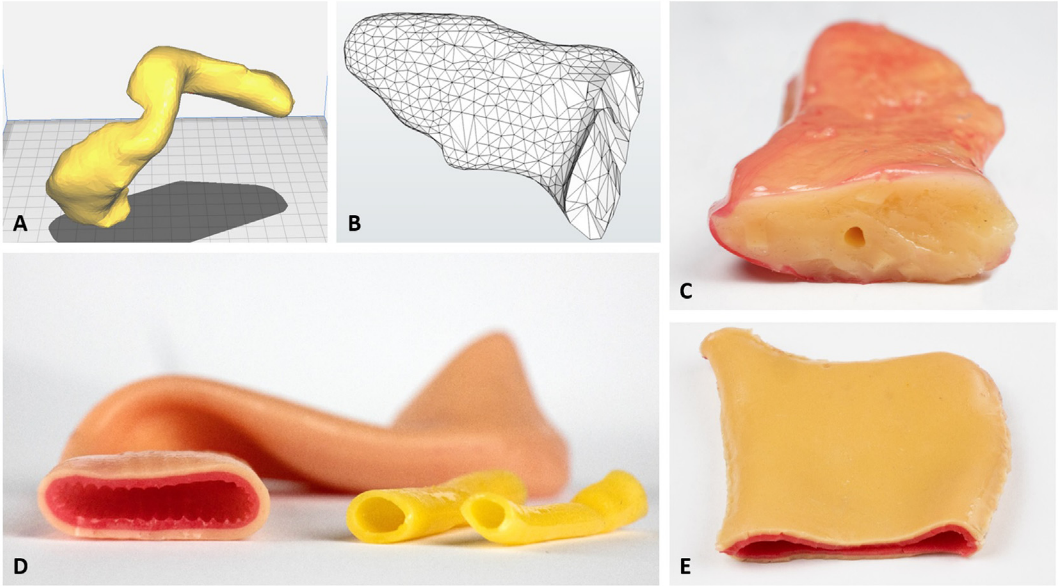

Figure 1 *Silicone organ models.* A: Pancreas 3D reconstruction of CT imaging. B: Final 3D pancreas model after virtual pancreatic head resection. C: Soft pancreas model with 3 mm duct. D: Small bowel with 2.5 mm wall thickness and soft bile ducts with 6 mm and 4 mm inner diameter. E: Stomach with 5 mm wall thickness

Evaluation process

The first evaluations were performed in September–November 2018 with highly experienced pancreatic surgeons at University Hospital Heidelberg. Each surgeon evaluated 10 different pancreas models (5 soft and 5 hard, including one soft and one hard commercial model), 2 small bowel models with 2 and 3 mm wall thickness, 2 stomach models with 2 mm and 4 mm wall thickness, and 2 bile duct models (soft and hard version). After the first evaluation phase, the best models were chosen and improved before further evaluations were performed with participants at the German Society of Surgery Congress in March 2019 in Munich/Germany, participants at the Austrian Surgeons Congress in June 2019 in Vienna/Austria, participants at a Minimally invasive and robotic pancreatic surgery training course at Amsterdam UMC/Netherlands in December 2019, and pancreas experts at the World Pancreas Forum in Bern/Switzerland in February 2020. At these congresses and training courses, highly experienced pancreatic surgeons were selected for organ model evaluation. In total 44 pancreas experts evaluated the models.

Evaluation criteria

For organ model evaluation, the participants were interviewed using a questionnaire. Evaluation criteria for the pancreas models were realism in haptic feedback, tissue rigidity, fragility of

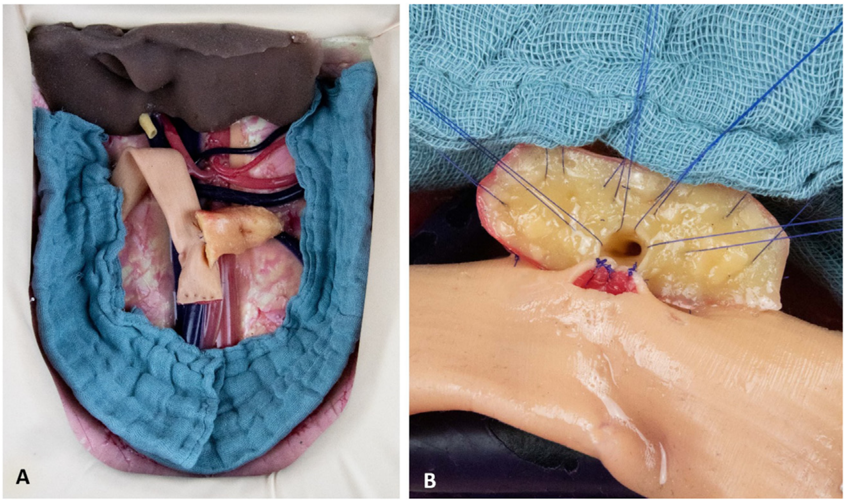

Figure 2 A: *Organ models mounted in training torso ready for surgical training. B: Pancreatico-jejunostomy with duct-to-mucosa technique*

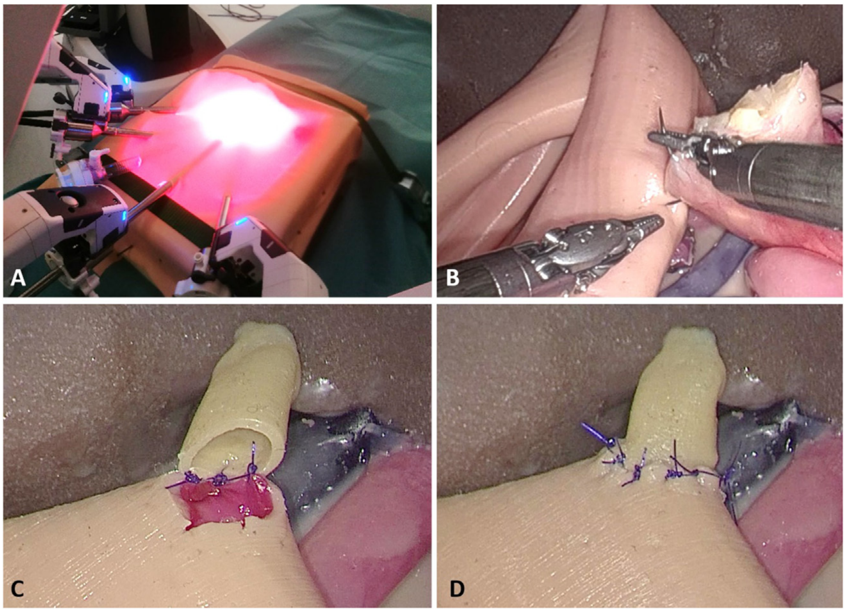

Figure 3 *Training torso used at the E-MIPS robotic pancreatic anastomosis course at Amsterdam UMC/Netherlands.* Participant performing pancreatic anastomosis (B) with modified Blumgart's technique and hepatico-jejunostomy (C, D) with single interrupted stitches using the DaVinci Xi Surgical System (A) (Intuitive Inc., Sunnyvale California

tissue, fragility of tissue including duct, and realism in suture behavior and knot tying at pancreatico-jejunostomy. The criteria for the stomach, small bowel, and bile duct models were realism in haptic feedback, wall thickness, and fragility. Fragility testing for all models was performed by stitching through the tissue and pulling on the suture. To avoid bias in fragility testing of the pancreas model, care was taken to ensure that stitching was done through the same amount of tissue when testing with or without the duct. The participants used surgical gloves and lubricant for higher realism. According to the Heidelberg in-house standard, PDS II 5-0 JRB-1™ sutures (Johnson & Johnson Medical, New Brunswick, New Jersey, USA) were used. Concerning the training torso, the participants rated the laparotomy size, anatomical organ position, appearance of the operation field, appearance of the whole training setup, and the general suitability of the training setup as an anastomosis training tool. For rating of haptic realism and realism in suturing and knot tying, Likert scales ranging from 1 to 5 were used, scored as "very unrealistic^{1}", "rather unrealistic^{2}", "moderate^{3}", "rather realistic^{4}" and "very realistic/like human tissue^{5}". For rigidity, fragility, and wall thickness, Likert scales ranging from −2 to +2 were used, scored as "too soft/fragile/thin (−2)", "rather soft/fragile/thin (−1)", "optimal (0)", "rather hard/tearproof/thick (+1)" and "too hard/tearproof/thick (+2)".

Statistics

For statistical analysis, the software GraphPad Prism Version 9.3.1. (GraphPad Software, San Diego, California) was used. For the data analysis of the first evaluation round with 10 surgeons from University Hospital Heidelberg, the Friedman test (nonparametric; matched data) followed by uncorrected Dunn's test was used. After adding the data from the following evaluation rounds, the Kruskal-Wallis-Test (nonparametric; no matching or pairing) followed by uncorrected Dunn's test was used.

Results

Pancreas: In the first evaluation round with pancreatic surgeons from University Hospital Heidelberg (n = 10, average 242 Whipple procedures as 1st surgeon), all four of the developed soft pancreas models P1−P4 showed significantly higher haptic realism compared to the commercially available soft pancreas model P5 (Fig. 4). Concerning realism of suture behavior and knot tying, the soft pancreas models P1−P4 showed rather realistic suture behavior, while the commercial model P5 showed moderate suture behavior. The evaluation of the tissue rigidity for the soft models P1−P4 showed nearly optimal results for the models P1 and P3 (mean: 0.2 ± 1.2, 0.4 ± 1.1; median: 1, 0.5) and optimal to rather soft for P2 and P4 (mean: −0.6 ± 0.8, −0.6 ± 1.1; median: 0, 0). The commercial soft model was rated rather hard with a mean value of 1.2 ± 0.9 (median: 1.5). Tissue fragility was tested both for the tissue alone and for tissue including duct. Each model was rated similarly both with and without the duct, with no statistically significant differences depending on duct presence (Fig. 4). For the soft models, P2 showed overall optimal tissue fragility and superiority to the commercial model P5 (p = 0.0164), which was rated rather tearproof (Fig. 4). Evaluation results for the hard pancreas models can be seen in Fig. 4. Hard pancreas model P9 showed high realism in suture behavior and optimal tissue fragility. The commercial model P10 was rated moderate in suture behavior, and optimal in haptic realism and rigidity.

As data from the first evaluation showed, soft pancreas model P2 and hard model P9 were rated as the most realistic pancreas models in various evaluation criteria. Models P2 and P9 were thus selected for further evaluation without modifications in the second evaluation round by additional pancreas experts (n = 12 for soft pancreas, n = 7 for hard pancreas, average 314 Whipple procedures as 1st surgeon) at the German Society of Surgery (DGCH) congress 2019 in Munich/Germany. Pooling the data with the prior evaluation resulted in a mean haptic realism rating of 4.1 ± 1.3 (median: 5), changing the rating from moderate to rather realistic, to rather realistic. The suturing behavior rating improved slightly from a mean value of 4.1 ± 1.2 to a pooled mean value of 4.3 ± 1.1. Rigidity and tissue fragility did not change remarkably.

For further improvement of haptics and suturing behavior, as well as a more realistic visual appearance, a pancreatic capsule was added to the pancreas models for the third, multicentric evaluation round with 22 additional experts at the Austrian Surgeons Congress 2019 in Innsbruck/Austria (n = 4, average 95 Whipple procedures as 1st surgeon), the E-MIPS Minimally Invasive Pancreatic Surgery Course 2019 at Amsterdam UMC/ Netherlands (n = 11, average 226 Whipple procedures as 1st surgeon), as well as the World Pancreas Forum 2020 in Bern/

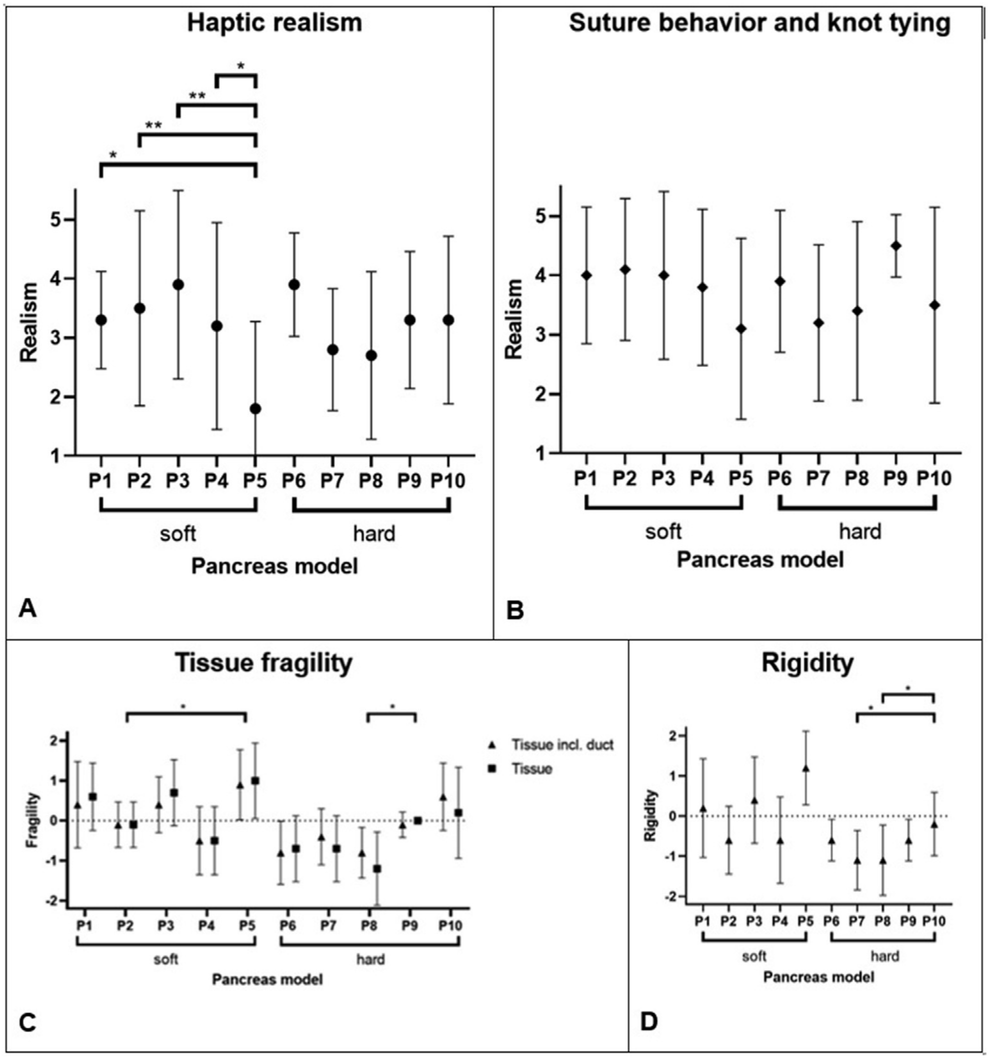

Figure 4 *First evaluation round of pancreatic biotissue models: Haptic realism* (A), *suture behavior and knot tying (B), Tissue fragility (C) and Rigidity (D) in soft pancreas models P1–P5 (P5: commercial model) and hard pancreas models P6-10 (P10: commercial model).* Likert scales from "very unrealistic"[1] over "moderate"[3] to "very realistic/like human tissue"[5] in A and B. Likert scale from "too fragile" (–2) over "optimal" (0) to "too tear proof" (+2) in C. Likert scale from "too soft" (–2) over "optimal" (0) to "too hard" (+2) in D. *p < 0.05; **p < 0.01

Switzerland (n = 7, average 633 Whipple procedures as 1st surgeon). Addition of the pancreatic capsule resulted in slightly higher haptic realism for the soft pancreas model with a mean value of 4.6 ± 0.7 vs. 4.1 ± 1.3 (median: 5 and 5) (Fig. 5A). The developed soft pancreas model showed higher haptic realism compared to the commercial soft model (mean: 4.6 ± 0.7 vs. 1.8 ± 1.5; $p < 0.0001$; median: 5 vs. 1). The realism in suturing changed from 4.3 ± 1.1 to 4.9 ± 0.5 and showed superiority to the commercial soft model (mean: 4.9 ± 0.5 vs. 3.1 ± 1.5; $p = 0.0001$; median: 5 vs. 3.5) (Fig. 5B). Haptic realism of the hard pancreas model improved from 3.8 ± 1.1 to 4.7 ± 0.7 (median: 4, 5) and showed significantly higher haptic realism compared to the commercial model (mean: 4.7 ± 0.7 vs. 3.3 ± 1.4; $p = 0.011$; median: 5 vs. 4) and to the first evaluation of haptic realism (mean: 4.7 ± 0.7 vs. 3.3 ± 1.2; $p = 0.0074$; median: 5 vs. 4). The pancreatic capsule did not change tissue fragility neither for the soft (mean: 0.3 ± 0.6 vs. 0.1 ± 0.5; median: 0 vs. 0) nor the hard model (mean: 0.2 ± 0.5 vs. 0 ± 0.4; median: 0 vs. 0).

Small bowel: In the first evaluation round, two two-layered bowel models with 2 mm and 3 mm wall thickness and the same silicone mixture were evaluated by experienced pancreatic surgeons in Heidelberg (n = 10). The models were rated in haptic realism, wall thickness, and tissue fragility. The haptic realism was initially rated moderate for both models. Wall thickness was rated rather thin (mean: −0.8 ± 0.9; median: −0.5) for the 2 mm model and optimal to rather thick for the 3 mm model (mean: 0.6 ± 1.2; median: 1). Tissue fragility was rated optimal to rather tear proof for the 2 mm model and too tear proof for the 3 mm model. Tissue properties were adjusted for the second evaluation round (n = 45; Munich, Innsbruck, Amsterdam, Bern). A softer and more fragile silicone mixture was used, and the wall thickness was changed to 2.5 mm. These changes led to improvements in haptic realism, wall thickness, and tissue fragility. Haptic realism ratings improved from means of 3.6 ± 1.2 (2 mm model) and 3.1 ± 1.2 (3 mm model) to 4.8 ± 0.4 (median: 4 and 3 to 5; p-values: $p = 0.0002$ and $p < 0.0001$) (Fig. 5). Wall thickness improved from rather thin (mean: −0.8 ± 0.9; median: −0.5) to optimal (mean: 0.1 ± 0.4; median: 0) compared to the 2 mm model ($p = 0.018$). Compared to the 3 mm model, no significant improvement in wall thickness ratings was measured. As seen in Fig. 5C, tissue fragility improved from rather tear proof (2 mm) and too tear proof (3 mm) to optimal, with a mean rating of −0.1 ± 0.4 (median: 0; p-values: $p = 0.0036$ and $p < 0.0001$).

Stomach: Stomach models with 2 mm and 4 mm wall thickness and the same silicone mixture were evaluated in the first evaluation round. Haptic realism was rated rather unrealistic for the 2 mm model and moderate for the 4 mm model (Fig. 5). The wall thickness was rated too thin for the 2 mm model (mean: −1.6 ± 0.7) and optimal for the 4 mm model (mean: −0.1 ± 1.4), with superiority of the 4 mm model ($p = 0.0243$). The tissue fragility was rated rather tear proof to optimal with mean ratings of 0.5 ± 1.2 (2 mm) and 0.6 ± 1 (4 mm). For improvement of haptic realism and tissue properties, the wall thickness was changed to 5 mm and a softer and slightly more fragile silicone mixture was developed for the second evaluation round (Munich, Innsbruck, Amsterdam, Bern). These changes improved haptic realism from rather unrealistic and moderate with mean ratings of 2.6 ± 1.5 and 3.5 ± 1.2 to very realistic with a mean of 4.5 ± 0.8 (p-values: $p_2 = 0.0005$, $p_4 = 0.0251$) (Fig. 5). The adjusted wall thickness was rated optimal with a mean value of 0.2 ± 0.5. Tissue fragility was rated optimal with a mean value of 0.06 ± 0.5.

Bile duct: Two different bile duct versions were evaluated in the first evaluation round. Two bile ducts with 6 mm inner diameter and 1 mm wall thickness were produced, one with a soft and one with a harder silicone mixture. The models were evaluated by 27 general or visceral surgeons, including 16 pancreas experts. There were no differences in ratings between the soft and the hard model. Haptic realism was rated moderate for both models with mean values of 3.6 ± 1.1 (median: 4) and 3.7 ± 0.9 (median: 3). Wall thickness was rated optimal for both models with 0.3 ± 0.8 (median: 0) and 0.4 ± 0.8 (median: 0). Tissue fragility was optimal for both models, with mean values of 0 ± 0.9 (median: 0) and 0.3 ± 0.7 (median: 0). To improve the haptic realism, a slightly softer and more flexible silicone mixture was developed. In the second evaluation round with 15 additional pancreas experts, the new silicone mixture resulted in a change in haptic realism from moderate to rather realistic (3.6 ± 1.1 and 3.7 ± 0.9) to very realistic with a mean value of 4.7 ± 0.6 (median: 5), while preserving the optimal wall thickness (mean: 0.1 ± 0.4; median: 0) and tissue fragility (mean: 0.3 ± 0.6; median: 0) (Fig. 5).

Training torso: The training torso was used in laparoscopic, robotic, and open pancreas anastomosis courses, where experienced pancreas experts were interviewed about their training experience. 23 Participants took part in the evaluation. The laparotomy size was rated optimal by 16 of in total 23 participants, whereas 6 rated it rather small and 1 rather large. The organ position of the bile duct as well as of the splenic vein was found to be slightly anatomically incorrect, which was corrected after the first few evaluations. The positions of the pancreas, small bowel, stomach, and colonic mesentery were rated as anatomically correct. All participants stated that there were no training disadvantages resulting from the lack of small bowel mesentery and 1 stated that there were no training disadvantages resulting from the lack of pancreatic tissue bleeding. Performing anastomosis inside the torso was rated very realistic by 20 participants for pancreatico-jejunostomy, 23 for hepatico-jejunostomy, and 22 for gastro-jejunostomy. The direct surgical environment (surrounding tissue like blood vessels and surrounding organs) was rated rather realistic by 13, very realistic by 9, and moderate by 1 participant. The reality of the whole training setup was rated very realistic by 12 participants and rather realistic by 11. All participants rated the training setup as very suitable and would recommend it for surgical training.

Discussion

In the present study international pancreatic surgeons tested realistic biotissue training models for minimally invasive and open surgery pancreatoduodenectomy. To our knowledge this is the first comprehensive anatomically complete pancreaticoduodenectomy suture training setup. Following an iterative development and evaluation process, the biotissue training models for pancreatoduodenectomy showed high haptic realism, optimal tissue rigidity, optimal tissue fragility, and high realism in suturing and knot tying. The models for soft and hard pancreas displayed superior haptics and tissue properties compared to commercially available models and included different duct sizes and a pancreatic capsule. The small bowel and stomach models were improved significantly by changing the silicone mixtures and wall thicknesses, resulting in high haptic realism, optimal tissue fragility, and wall thickness for both. The bile duct models displayed optimal tissue properties regarding fragility and wall

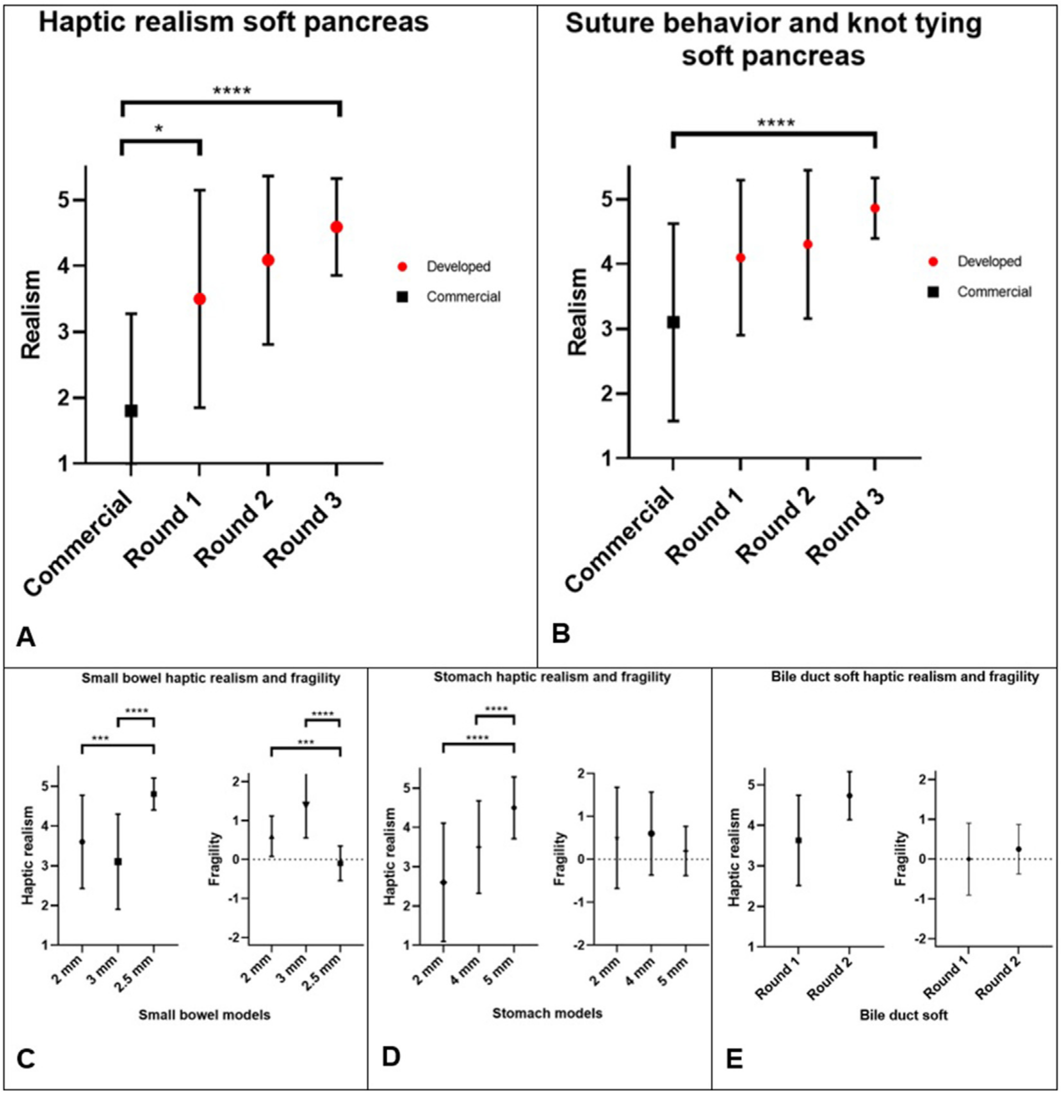

Figure 5 *Final evaluation of soft pancreas (A, B), small bowel (C), stomach (D) and soft bile duct (E) in haptic realism, suture behavior and knot tying, and tissue fragility.* Likert scales from "very unrealistic"^{1} over "moderate"^{3} to "very realistic/like human tissue"^{5} and from "too fragile" (–2) over "optimal" (0) to "too tear proof" (+2). A, B: Improvement of haptic realism (A) and suture behavior and knot tying (B) of soft pancreas model after adding pancreatic capsule. Evaluations over time performed in Heidelberg (HD), Munich (MU), Innsbruck (IB), Amsterdam (AM) and Bern (BE). Round 1: Evaluations from HD. Round 2: Pooled evaluations from HD + MU. Round 3: Pooled evaluations from IB + AM + BE. C, D, E: Round 1: Pooled evaluations from HD + MU. Round 2: Pooled evaluations from AM + BE after tissue adjustment. $^{*}p < 0.05$; $^{***}p \leq 0.001$; $^{****}p \leq 0.0001$

thickness. For improvement of haptic realism, the silicone mixture was adjusted. The training torso was rated realistic and highly suitable for open, laparoscopic, and robotic anastomotic suturing training. The models were considered an adequate and realistic training tool for suturing training of anastomoses after pancreatoduodenectomy.

The commercial pancreas model has already been widely used by other research groups in their training curricula.[11,14,18,23,24] The biotissue training models developed in the present study are being used in the recently started LEARNBOT project,[25,26] a pan-European training program for robotic pancreatoduodenectomy including 20 European centers with 40 surgeons as participants. The project is comparing patient outcomes after surgeries performed by surgeons who participated in a multimodal training curriculum with one-on-one personal training using biotissue models to the outcomes after surgeries performed by surgeons without structured training on models (Netherlands Trial Register, Trial Nr. 8898: Impact of a European training program for robot pancreatoduodenectomy using a video databank, da Vinci® simulator and robot biotissue anastomoses on clinical outcomes (LEARNBOT): a pan-European prospective study[25]). LEARNBOT follows the previous LAELAPS studies 1–3,[12–14] LAELAPS 3D2D[24] and LAEBOT 3D2D[23] from the Dutch Pancreatic Cancer Group. The first LAELAPS study described the outcome of a nationwide implementation of a minimally invasive distal pancreatectomy training curriculum, which showed feasibility, an increase in performed minimally invasive pancreatic procedures, and a reduction in conversion rates. The LAELAPS-2 study assessed feasibility and outcomes of a multicentric training curriculum for laparoscopic pancreatoduodenectomy. The training curriculum showed positive effects on outcomes and learning curves in all centers. In the LAELAPS-3 study, the implementation and the outcomes of a multicentric training curriculum for robotic pancreatoduodenectomy were assessed. In high volume centers, the training curriculum (biotissue training combined with robotic simulation training and on-site proctoring to train surgical skills) showed feasibility without a negative impact of learning curves on surgical outcomes. LAELAPS 3D2D[24] and LAEBOT 3D2D[23] showed advantages of 3D vision compared to 2D vision in laparoscopic and robotic training of pancreatico-jejunostomy and hepatico-jejunostomy on biotissue models. In the LEARNBOT study the training models of the current study are adding a realistic training experience for surgical training.

Few other research groups have developed or are developing training models for surgical training in pancreatoduodenectomy. Wei et al. used silicon and 3D printing for a pancreas suturing model, measuring performance of three surgeons performing repeated pancreatico-jejunostomy.[27] The realism of tissue properties was not described. Furthermore, the same group 3D printed a choledochojejunostomy training model,[28] a modular training setup with reusable and replaceable key modules including bile ducts, biliary lesions, and cystic sheaths. The system can be perfused using a pump to simulate blood and bile flow. The setup was evaluated by three experienced resident surgeons and three fellows and appeared to be a feasible training tool with interesting features and potential for surgical training. Following the present study, our research group is working on incorporation of a perfusion setup into the existing training system. Other research groups have used commercially available training models to show feasibility of anastomosis training and assessment of learning curves in surgical training.[11,14,20] Simulation in surgical training helps compensate for limited operating room practice time. However, it must be kept in mind that simulation can only address partial aspects of a whole surgical procedure. Surgical simulation in general can only train specific skills and parts of procedures. It cannot replace the training on real patients, but it is adding valuable prework and preparation for training of surgeries on real patients. Therefore its incorporation into a full training curriculum is very important.[29]

Biotissue drills in general have been shown to improve technical skills.[5,11,14,23,30] At present, there is little literature available addressing biotissue training for hepatico-jejunostomy. Patients with hepatico-jejunostomy leaks after pancreatoduodenectomy are at high risk of major surgical morbidity and mortality, although hepatico-jejunostomy leaks are rarer than pancreatico-jejunostomy leaks.[31] Training of hepatico-jejunostomy on realistic models could reduce the occurrence of hepatico-jejunostomy leakage and thus reduce patient morbidity and mortality. In addition, anastomotic leak testing after hepatico-jejunostomy has been shown to effectively prevent hepatico-jejunostomy leakage after surgery.[32] To examine the quality of the anastomosis and to provide feedback of the surgical result, leakage testing can also be performed in the training setting using the developed training models.

The small bowel and stomach models had moderate tissue properties initially and were improved significantly by adjusting the silicone mixtures and the wall thicknesses. The stomach design was chosen to be used for gastro-jejunostomy. For simulation of duodeno-jejunostomy after pylorus-preserving pancreatoduodenectomy, a second small bowel model can be used. A pylorus training model for increased realism is currently in development. The small bowel models are easy to use, and linear as well as circular stapler devices can be applied. The models can be used in combination with validated and structured surgical performance scoring systems to monitor training progress, to give specific feedback on areas of potential improvement, and for certification purposes.[33–37] There are currently other bowel models on the market, for example from LifeLike Biotissue Inc. (London, Canada) and Limbs & Things Ltd (Bristol, United Kingdom), but there is little literature available on the quality and realism of these models. The bowel model from LifeLike Biotissue Inc (London, Canada) was used with the pancreas training model in robotic pancreas training curriculums mentioned above .[5,11] Oxford et al. designed a prototype of a simple, single-layered silicone bowel model for surgical training that was tested and evaluated by three senior residents (postgraduate year 4 or 5) and six staff general surgeons.[38] The overall quality of the model (face validity) was rated with a mean value of 3.58 on a Likert scale from 1 (strongly disagree) to 5 (strongly agree). The subcategories regarding overall quality were flexibility (3.77/5), texture (3.77/5), size (4.44/5), color (4.44/5), wall thickness (3/5), and layers (2.11/5). The overall training potential (content validity) was rated with a mean value of 3.98/5. The model is available open source for reproduction. Our developed two-layered small bowel model showed higher realism in comparable categories like texture (4.8 vs. 3.77/5), and wall thickness (5 vs. 3/5; adjusted to different Likert scales). Regarding stomach training models, a few others have been described in the current literature for different applications. Botden et al. designed a laparoscopic dry lab setup for Nissen fundoplication training as an alternative to animal tissue, which can be used to train the main steps of the surgical procedure.[39] However, their stomach model could not be wrapped adequately because it was too rigid. Further published stomach training models include pyloromyotomy models,[40,41] an esophagogastric anastomosis training model,[42] and a gastroenterostomy training model.[43] Barreira et al. used self-developed gastric and jejunal silicone rubber models to show improvement of technical skills and reduced operation time in laparoscopic anastomosis suturing training.[43] Our developed stomach model can be used for training of gastro-jejunostomy as well for pancreatico-gastrostomy.

Evaluations of the training torso in the present study showed high suitability for training. The laparotomy size was sufficient for an adequate training experience, as 70% of experts rated it as optimal. Currently, commercially available training setups often do not include a realistic surrounding surgical field. Instead, most setups only include simple holders and clamps, which do not represent the surgical environment and intraoperative context sufficiently. Most available studies and training curricula have also only used simple clamps and holding mechanisms for biotissue training.[11,14,20,22,27] The operation field in the developed training torso was designed to contain the main vascular structures relevant for pancreatoduodenectomy and the liver, where the bile duct is placed for training. The evaluations resulted in good overall realism. Keeping in mind that a simulation device can never be as realistic as a human body, the evaluation outcome can be considered satisfactory. The torso is easily adjusted for use with laparoscopic and robotic surgery and can be placed in current box trainers (Fig. 3). Compared to a simple holding mechanism, the training torso provides a very realistic training environment for training of open, laparoscopic, and robotic surgery. Future studies will investigate the potential positive impact of a realistic training environment in surgical training.

The results of this study should be interpreted with some limitations in mind. First, the initial group of ten surgeons from Heidelberg University Hospital did not re-evaluate the organ models after tissue adjustments following the first evaluation round. Second, there was no direct comparison made after adding the pancreatic capsule and adjusting tissue properties from small bowel, stomach, and bile duct with ratings performed by the same surgeons, which would have resulted in a higher total number of evaluations. Nevertheless, due to the high surgical experience of the participating evaluators, the total number of n = 44 (soft pancreas model) expert surgeons appeared to be sufficient and is not regarded as a possible selection bias. Third, the bowel, stomach, and bile duct models were not compared to commercially available models. The main focus of the project however was the development of realistic pancreas models. The bowel, stomach and bile duct models as well as the torso were added for further realism and to provide complete training for reconstruction after pancreatic resection. The critical part clinically is certainly believed to be the pancreatic anastomosis and the pancreas was deemed more difficult to be developed as a realistic biotissue model. Therefore, this was prioritized in the current research project. For the participating experts, there was no need to compare directly to human tissue in the evaluation setting, as human tissue was their daily business. In addition, comparison to human specimens would not have been possible due to logistical challenges regarding gathering specimens, quality, storage, and safety reasons.

Conclusion

Realistic biotissue models for anastomotic suturing in pancreatoduodenectomy were developed using 3D printing and silicone casting and iteratively improved with expert evaluations. The developed suture training models scored “very realistic” evaluations and had similar tissue properties to human tissue regarding haptic realism, rigidity, tissue fragility, and realism in suture behavior and knot tying. Especially for robotic training, realistic tissue properties are important for training of visual haptics outside the operating room, due to the absence of haptic feedback in robotic surgery. The developed training model setup is a valid and realistic anastomotic training tool for pancreatic surgery. To our knowledge this is the first comprehensive anatomically complete pancreaticoduodenectomy suture training setup. It is being implemented in training curricula to improve patient outcomes and surgical training methods. Further organ models that include blood vessels for training of vascular resections are currently in development and will soon be evaluated and validated for use in routine surgical training. As minimally invasive pancreatic surgery is evolving worldwide, more surgeons are gaining experience in this technically challenging surgical procedure, which should be practiced in a multimodal way before operating on a patient to reach best possible patient safety. It has been shown that surgeons' technical skills affect complication rates and oncological outcomes,[37,44,45] underlining the importance of training outside the operation room.[37] Realistic suture training models are becoming an important part of surgical training. The main focus of future research on biotissue models will be on fastening learning curves, improving patient outcomes, and further translational research using digital technologies to improve training.[46–49]

Conflict of Interest

None declared.

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