Randomised Controlled Trial

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Simulation training of laparoscopic biliary-enteric anastomosis with a three-dimensional-printed model leads to better skill transfer: a randomized controlled trial

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Aim: A new simulation model and training curriculum for laparoscopic bilioenteric anastomosis has been developed. Currently, this concept lacks evidence for the transfer of skills from simulation to clinical settings. This study was conducted to determine whether training with a three-dimensional (3D) bilioenteric anastomosis model result in greater transfer of skills than traditional training methods involving video observation and a general suture model.

Methods: Fifteen general surgeons with no prior experience in laparoscopic biliary-enteric anastomosis were included in this study and randomised into three training groups: video observation only, practice using a general suture model, and practice using a 3D-printed biliary-enteric anastomosis model. Following five training sessions, each surgeon was asked to perform a laparoscopic biliary-enteric anastomosis procedure on an isolated swine organ model. The operative time and performance scores of the procedure were recorded and compared among the three training groups.

Results: The operation time in the 3D-printed model group was significantly shorter than the suture and video observation groups ($P = 0.040$). Furthermore, the performance score of the 3D-printed model group was significantly higher than those of the suture and video observation groups ($P = 0.001$). Finally, the goal score for laparoscopic biliary-enteric anastomosis in the isolated swine organ model was significantly higher in the 3D model group than in the suture and video observation groups ($P = 0.004$).

Conclusions: The utilisation of a novel 3D-printed model for simulation training in laparoscopic biliary-enteric anastomosis facilitates improved skill acquisition and transferability to an animal setting compared with traditional training techniques.

Keywords: Biliary-enteric anastomosis, laparoscopic, simulation training, skill transfer, training model

Introduction

Biliary-enteric anastomosis is a critical surgical intervention for the treatment of biliary stricture, cholangiocarcinoma, and pancreatoduodenectomy[1–3]. Laparoscopic surgical techniques have become increasingly popular in general surgical procedures because of their associated benefits[4–6], including the safety and efficacy of laparoscopic biliary-enteric anastomosis. However, the procedure is complex and requires extensive training[7]. Without proper training, postoperative bile leakage or biliary stricture may develop, leading to a prolonged hospital stay[8–10]. In clinical practice, junior surgeons frequently begin laparoscopy training as assistants or camera operators before being entrusted with autonomous operations[11]. For more intricate procedures, junior surgeons may repetitively practice their techniques on animal models to improve their technical skills and enhance

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muscle memory. Nevertheless, acquiring animal models for surgical training can be an elaborate and time-consuming process[12], and not all surgical training centres have access to them. Consequently, relying solely on this learning pattern may impede junior surgeons' proficiency.

Basic training models, like One Track Transfer, One Tunnel Pass, High and Low Pillars basic, as well as Simple Wound Closure, have been widely used for rudimentary laparoscopic surgical procedures encompassing separation, grasping, and suturing. However, these models may be insufficient when it comes to training for intricate surgical skills. Recently, three-dimensional (3D) and virtual reality simulations have been employed in the training of surgical skills[13–16]. While computer simulators, such as virtual reality (VR), have been widely used in various surgical domains[17] but still lack of providing enhanced sensory and haptic feedback. 3D printing models, which replicate the anatomical features of patients and provide enhanced sensory and haptic feedback. An overview of 3D printing for abdominal surgery have proven its effectiveness in surgical simulation training[18]. Simulation training provides an advantage over animal model-based training in terms of decreasing working hours and budgetary constraints[19,20]. Additionally, simulation training facilitates a better understanding of certain abilities within the surgical community than traditional approaches[21–23]. High-resolution simulation models that feature authentic tissues for training force application, in conjunction with complex 3D vascular networks and accurate representations of surgical anatomy, have the potential to provide a heightened sense of realism and engage a greater number of trainees during the training process[24–26]. A simulation with a high degree of authenticity and realism may ultimately lead to greater success in transferring skills to a therapeutic setting.

To the best of our knowledge, a dependable simulation model for training in laparoscopic biliary-enteric anastomosis has not yet been developed. To fill this gap, we created a 3D-printed model for laparoscopic biliary-enteric anastomosis training[27]. In a previous study, the same model was used in a stepwise training program for laparoscopic pancreaticojejunostomy[28]. The primary goal of the present study was to assess the transferability of biliary-enteric anastomosis skills using our simulation-based training model. The transfer of skills acquired through simulation-based training to clinical practice is crucial for evaluating the efficacy of such training modalities[29]. General surgeons were divided into three distinct training groups to explore the research objectives. After simulation training, each surgeon performed a laparoscopic biliary-enteric anastomosis procedure using an isolated swine organ model. The performance of each surgeon was evaluated and compared among the three distinct training groups. Our hypothesis posited that the 3D-printed model of laparoscopic biliary-enteric anastomosis would provide greater skill transferability than the other two simulation model.

HIGHLIGHTS

- A reliable simulation training model was developed to focused on laparoscopic bilioenteric anastomosis.
- This study's findings suggest that simulation training on laparoscopic bilioenteric anastomosis with a new three-dimensional-printed model showed a better skill transfer to clinic compared with video watching and general suture training.

Methods

The ethics committee at our centre authorised this randomized controlled experiment. (NO. 2022-469-01). This study was filed at http://www.chictr.org.cn. and conducted in line with Consolidated Standards of Reporting Trials (CONSORT) Guidelines[30], Supplemental Digital Content 1, http://links.lww.com/JS9/B675.

Surgeons and randomisation

All surgeons recruited for this study were from the department of General Surgery at our centre. Surgeons were required to meet this inclusion requirement; they had completed more 50 laparoscopic cholecystectomy procedures but without open or laparoscopic biliary-enteric anastomosis experience in clinical practice.

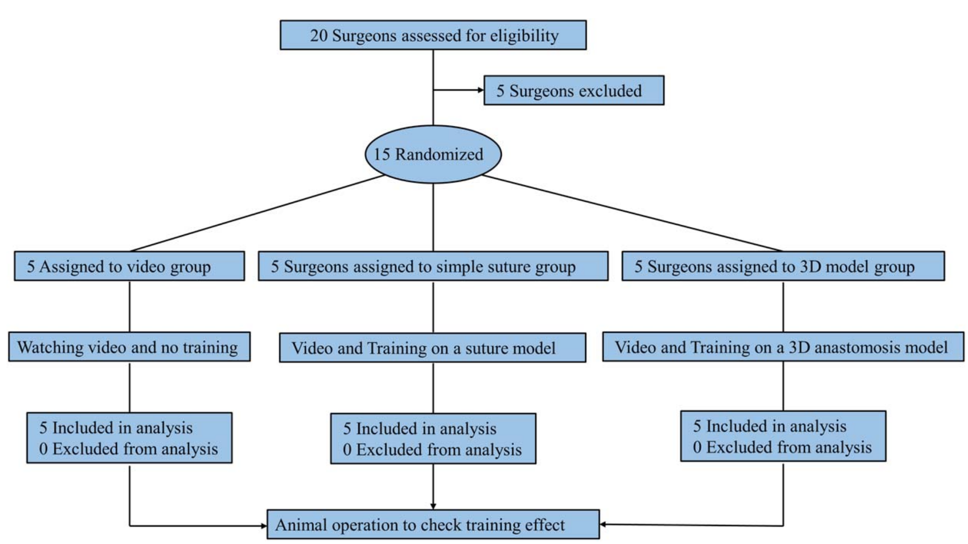
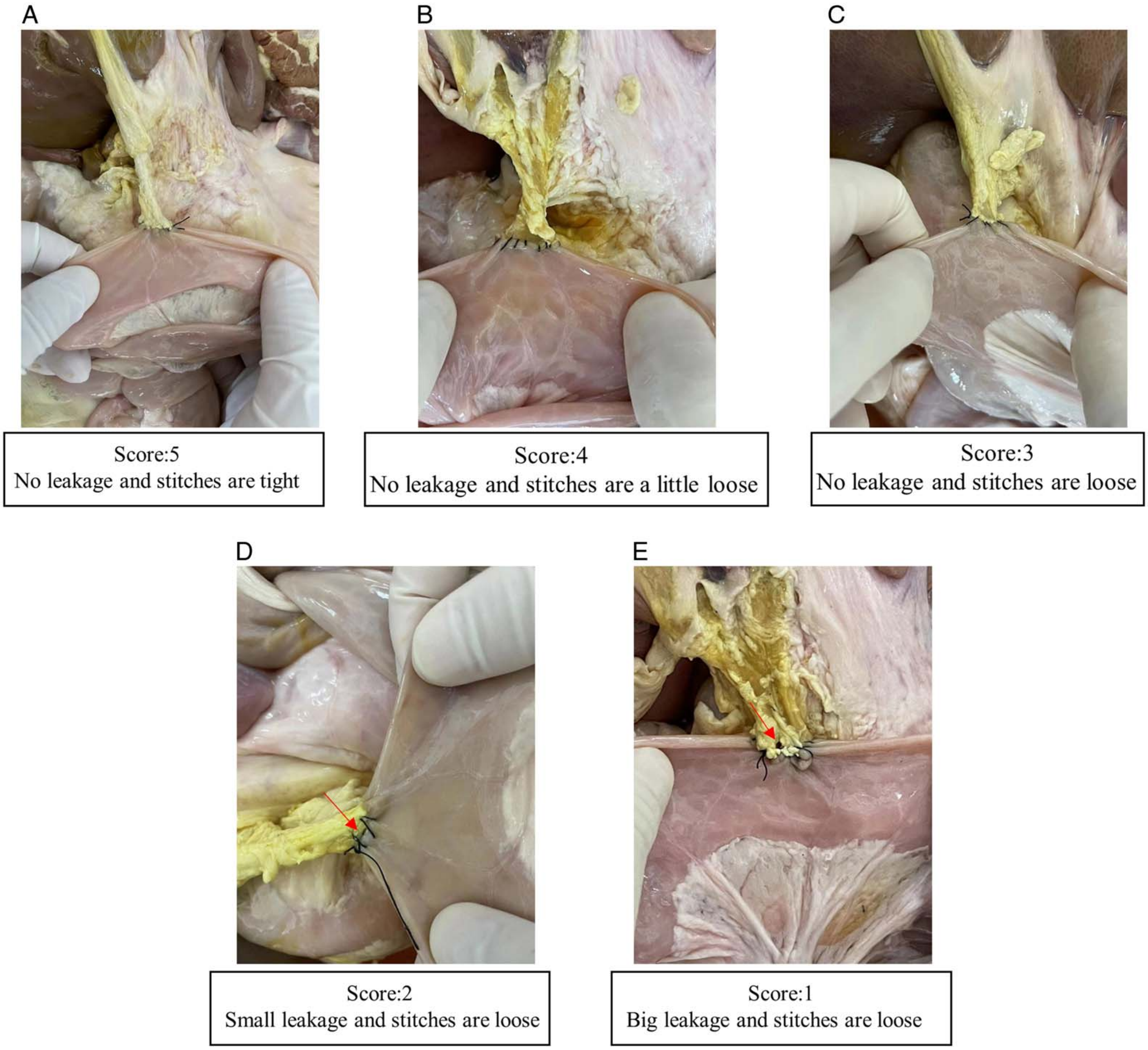


Figure 1. Participant recruitment flowchart. 3D, three dimensional.



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Items	Scores
leakage and stitches	1~5
Anterior wall of the anastomosis	A
Posterior wall of the anastomosis	B
Total score for the anastomosis	A+B

Figure 2. Criteria and scoring details for anastomosis. (A) No leakage, and tight stitches = 5 points; (B) no leakage and slightly loose stitches = 4 points; (C) no leakage and loose stitches = 3 points; (D) minor leakage and loose stitches = 2 points; (E) major leakage and loose stitches = 1 point; (F) anastomotic leakage and stitch loosening were markers of our scores and were rated on a 5-point Likert scale; the anterior and posterior walls of each anastomosis were scored using the same approach, and the sum of the anterior and posterior wall scores was the final score for anastomosis.

Twenty surgeons who met this requirement were selected from about 80 surgeons in our department of general surgery. Four surgeons were excluded as they have the experiences of simulation training on other 3D models and one surgeon was excluded due to time conflict. Eventually, 15 surgeons were recruited for the study. They were divided into three training groups: video, simple suture, and 3D model. Randomisation was performed using a computer-generated, internet-based random sequence.

Figure 1 depicts the participant recruitment flowchart and training programs.

Blinding

Group allocation was concealed by the study coordinators, and instructors were notified 12 h in advance for scheduling purposes. Surgeons recruited were not informed of the training purpose. Training programs and transfer tests on the animal model were finished in one day. Each group completed trainings and tests in separated room to avoid intergroup communications. There was a study coordinator in each room to avoid intergroup communication.

3D simulation training model

We devised a 3D-printed biliary-enteric anastomosis model, manufactured by XIMOUWEIXUN Medical Technology. The liver, bile duct, and small intestine were produced on the model using a silicone printer. The material was made of silicone specialized for 3D printing. The liver and small intestine were printed in pink colour, and the bile duct was printed in yellow. The liver and intestines were supported using a plastic platform to facilitate surgical manipulation. Figure S1, Supplemental Digital Content 2, http://links.lww.com/JS9/B676 depicts the 3D simulation training model for the laparoscopic biliary-enteric anastomosis. The detailed steps of the laparoscopic biliary anastomosis in the 3D model are depicted in Figure S2, Supplemental Digital Content 3, http://links.lww.com/JS9/B677. A senior attending surgeon performed and explained the surgical steps, which were captured in standard training videos. This film was used to instruct all participants on the precise operational procedures.

Training interventions

Surgeons were randomly assigned to one of three training groups: video, basic suture, and 3D model. The video group was required to view a typical instructional video, but there was no opportunity for hands-on training. The simple-suture group was required to watch the same typical instructional video and practice using a basic suture model. In the simple-suture group, a silicone model designed for suturing at multiple angles was used for wound closure (Figure S3, Supplemental Digital Content 4, http://links.lww.com/JS9/B678). Surgeons in the 3D model started training first and the average training duration (157 min: the five simulated training time) of the trainers was calculated. Then, each surgeon in the simple-suture group commenced training for an equivalent overall duration (157 min). Multiple-angle suture instructions were regarded as standard training. Before receiving simulation training on the laparoscopic biliary-enteric anastomosis model for five training sessions, the 3D model group was required to view the typical instructional video too and practice using the 3D model. Figure S4, Supplemental Digital Content 5, http://links.lww.com/JS9/B679 depicts the detailed training flowchart.

Transfer test on the animal model

By employing an animal model, portions of a pig's liver, stomach, intestines, pancreas, and spleen were used to examine the transferability of skills. The animal abdominal multi-organ was placed according to the normal physiological and anatomical position in Darwin laparoscopic systems by a study coordinator. The isolated swine organs were placed in wet simulators (Darwin, WeiXiao Medical Technology). After finishing the training phase, each participant was required to perform a laparoscopic biliary-enteric anastomosis in the animal model according to the standard teaching video instructions (Figure S5, Supplemental Digital Content 6, http://links.lww.com/JS9/B680). The operation time and performance scores were recorded to assess the effectiveness of the various training programs.

Table 1

Parameters of the different groups ($N = 5$ each group).

	Group			
	3D model	Simple-suture	Video	*P*
Sex (male), *n* (%)	5 (100)	5 (100)	4 (80)	1
Age	33.0 ± 1.4	34.0 ± 1.6	33.8 ± 2.4	0.671
Working years	6.8 ± 3.0	6.6 ± 1.8	6.4 ± 2.6	0.969
LC number	230.0 ± 120.4	336.0 ± 210.9	300.0 ± 169.6	0.620
LCBDE number	23.0 ± 20.5	30.0 ± 24.2	28.0 ± 18.2	0.866

LC, laparoscopic cholecystectomy; LCBDE, laparoscopic common bile duct exploration.

Performance score

The performance rating was based on the GOALS score and the quality of the anastomosis. The evaluation form was formulated by three professionals in surgery who were required to evaluate the quality of the anastomosis. The front and back of the anastomoses were also evaluated. Anastomotic leakage and knot-tying security were used to evaluate quality on each side. On a 5-point Likert scale, two general surgery specialists who were blinded to the identities of the participants, were asked to evaluate their performance on a five-point Likert scale. A score of 5 indicates flawless performance on one side of the anastomosis, a total score of 10 indicates flawless function during the entire anastomosis (Fig. 2).

Statistical analysis

Descriptive statistics are presented as follows: for continuous data: mean ± standard deviation; for categorical data, frequencies, and percentages. The Fisher's exact test was used to compare group proportions. Continuous data were analysed using ANOVA-tests for means. All analyses were conducted using the statistical software SPSS 26.0 (IBM).

Table 2

Operation time of each trainee in the 3D model group ($N = 5$).

	Training time for each trainee (min)				
	Trainee1#	Trainee2#	Trainee3#	Trainee4#	Trainee5#
1st training	49	45	46	44	43
2nd training	37	34	42	39	34
3rd training	29	27	33	32	27
4th training	23	24	19	25	19
5th training	25	26	17	23	24
Total time	163	156	157	163	147
Average training time for each trainee (min)					157.2

3D, three dimensional.

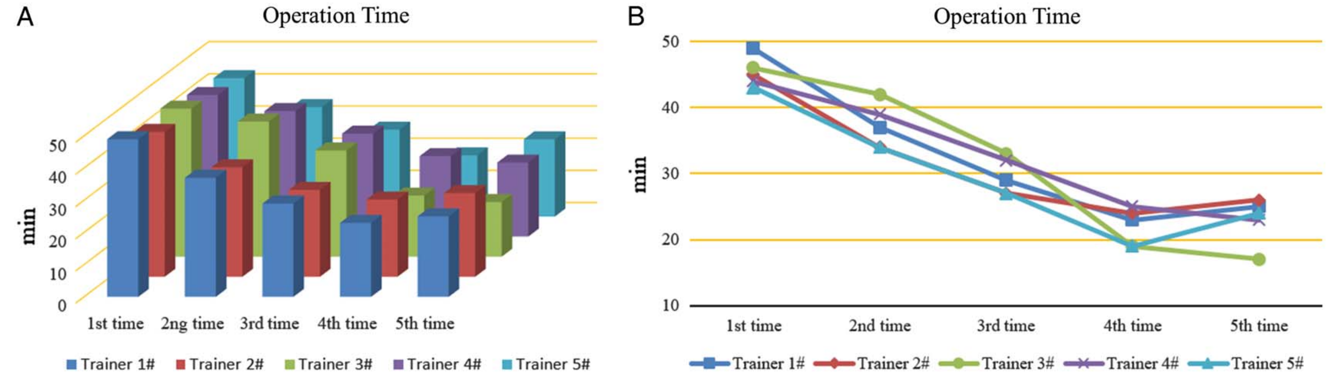

Figure 3. Operation time for trainers in the three-dimensional (3D) model group was shown, indicating that surgical time can be significantly reduced through repeated training. (A) The operation time histogram for the five trainers of 3D model group in the five-time training; (B) the operation time curve for the five trainers of 3D model group in the five-time training.

Results

Baseline characteristics

The baseline characteristics of the study participants are presented in Table 1. Standardised training years for residents were included in the working years. There were no statistically significant differences in sex between every two groups. The average age of the 3D model group, simple-suture group, and video group were 33.0 ± 1.4, 34.0 ± 1.6, and 33.8 ± 2.4, respectively. The average working years of the 3D model group, simple-suture group and video group were 6.8 ± 3.0, 6.6 ± 1.8, and 6.4 ± 2.6, respectively. The average age and years of work experience in every two groups were comparable. The number of laparoscopic cholecystectomies (LCs) and laparoscopic common bile duct explorations (LCBDEs) r was recorded and compared to represent their experience in laparoscopic procedures and suturing ability. LC numbers of the 3D model group, simple-suture group, and video group were 230.0 ± 120.4, 336.0 ± 210.9, and 300.0 ± 169.6, respectively. LCBDE numbers of 3D model group, simple-suture group, and video group were 23.0 ± 20.5, 30.0 ± 24.2, and 28.0 ± 18.2, respectively. There were no appreciable differences in the LC or LCBDE numbers in the three groups. Overall, there were no significant differences in baseline data between the three.

Surgical performance of simulation training

Participants in the 3D model group were required to perform the biliary-enteric anastomosis five times. Each surgical time for these surgeons was logged, and the average duration of the five simulated training sessions was 157.2 min (Table 2).

The participants in the simple-suture group were required to practice for 157 min. The operation time for each participant during the five training sessions on the 3D model group was provided in Fig. 3. The operation time of the participants in the 3D model was reduced during the training phase (Fig. 3A and B).

Surgical performance on animals

The operation time, operative score, and GOALS score of the isolated swine organs models performed by participants from the three different training groups were recorded and compared (Table 3). The average operation time of the 3D model group, simple-suture group, and video group was 29.4 ± 2.3 min, 42.4 ± 9.7 min, and 45.2 ± 12.3 min, respectively. The operation time in the 3D model group tended to be shorter than that in the other two groups ($P = 0.040$). The mean operative score was used to quantitatively evaluate the quality of the anastomosis. Average operative scores of the 3D model group, simple-suture group, and video group were 8.2 ± 0.8, 6.8 ± 0.5, and 5.2 ± 1.3, respectively. There was a significant difference in operative scores among the three groups ($P = 0.001$). The operative score in the 3D model group showed a higher score compared to the other two groups. Operative score in simple-suture group was higher than that in the video group ($P = 0.019$). The GOALS score was used for e to quantitatively evaluate the surgical performance. The average GOALS score of the 3D model group, simple-suture group and video group were 21.2 ± 1.8, 17.8 ± 1.6, and 15.6 ± 2.7, respectively. There was a significant difference in GOALS scores among the three groups ($P = 0.004$); the 3D group showed the best GOALS score compared with the other two groups.

Table 3

Surgical performance of the various groups ($N = 5$ each group).

	Group				*P* (LSD)		
	3D model	Simple-suture	Video	*P*	3D vs suture	3D vs video	Suture vs video
Operation time	29.4 ± 2.3	42.4 ± 9.7	45.4 ± 12.3	**0.040**	**0.044**	**0.018**	0.637
Operation score	8.2 ± 0.8	6.8 ± 0.5	5.2 ± 1.3	**0.001**	**0.035**	**< 0.001**	**0.019**
GOALS score	21.2 ± 1.8	17.8 ± 1.6	15.6 ± 2.7	**0.004**	**0.025**	**0.001**	0.123

Partial Eta Squared values of operation time, operation score and GOALS score were 0.415, 0.684 and 0.601.
Bold values are statistical significance $P < 0.05$
3D, three dimensional; LSD, a method of post-hoc ANOVA.

Discussion

Young or inexperienced physicians who directly perform laparoscopic biliary-enteric anastomosis in the clinical setting may be taking an unnecessary risk[7]. Simulation training has been successful in aiding students' comprehension and mastery of specific abilities[21,23]. However, studies analysing the efficacy of simulation training with respect to laparoscopic biliary-enteric anastomosis have been scarce. In a recent study[25], we developed a 3D-printed simulation model for laparoscopic biliary-enteric anastomosis training. Our findings in this study validated our research premise, with the 3D model group outperforming the other two groups (those who viewed instructional videos and the basic suture group) in the testing of isolated swine organ models.

Consistent with the results of our previous study[25], the operating time of the 3D model group decreased significantly with repeated training sessions and reached a relatively stable plateau after the fifth session. Thus, frequent simulation training enables surgeons to develop skills that can significantly enhance their overall surgical performance.

In this study, the video group merely viewed a conventional instructional film on laparoscopic biliary-enteric anastomosis and did not receive any hands-on training. The basic suture group viewed a conventional instructional film on laparoscopic biliary-enteric anastomosis and received simple suturing training. The 3D group viewed a conventional instructional film on laparoscopic biliary-enteric anastomosis and received a 3D model training. Finally, the 3D group showed the best training effect compared with the other two groups. Surgeons undergoing simple suturing training may improve their laparoscopic suture quality, enabling them to successfully execute suture techniques such as accurate needle adjustments and correct knot-tying[31]. However, they were unable to use these suturing methods in the specific scenarios. The 3D model not only allowed surgeons the opportunity to practice suturing in a milieu resembling actual patient anatomy but also required them to constantly maintain tautness throughout the continuous suturing process. Failure to do so could result in suture loosening and subsequent leakage after completion of the biliary-enteric anastomosis. Moreover, achieving appropriate suture spacing at the anastomotic stoma site is critical. Short distances between stitches may result in overly dense sutures that lengthen the surgical duration, whereas excessively large spacing may increase the likelihood of fistula formation in the anastomotic stoma. In contrast, these skills and abilities could not be exercised or homed in the basic suture training group. Hence, the surgeons in 3D model group performed significantly better than those in the other two groups.

There are numerous options for medical education through simulation training, including virtual reality (VR) and augmented reality (AR) simulations, as well as animal models. The use of computer-simulated interactive environments to mimic medical scenarios defines VR simulation. However, VR lacks the ability to provide learners with a tactile experience of virtual objects, thus hindering the replication of the sensory minutiae that may arise during medical procedures[32]. Conversely, AR simulation involves superimposing digital information onto real-world objects, allowing for immersive and lifelike practice of procedures in an interactive setting[33] Nevertheless, it requires the creation of software with adequate display of the laparoscopic biliary-enteric anastomosis scenario in addition to the design and production of relevant virtual objects.

Although often considered the best standard for surgical training, animal models provide a more realistic simulation of surgical procedures. This allows surgeons to train under circumstances that closely resemble those encountered in actual medical procedures[12]. The preparation of animal models is frequently more complicated and involves ethical approval, cooperation with anesthesiologists and nurses before surgery, and correct treatment of animals following surgery.

Compared to an animal model, a 3D-printed model may not match the level of simulation offered by actual surgery; nonetheless, it presents several advantages[18]. The 3D model training preparation is simpler and more convenient. By leveraging patient-specific imaging data, 3D models can be generated, which offer customised surgical training and preoperative preparation. In some cases, 3D models can be configured to replicate intricate surgical contexts that are difficult to reproduce using animal models. Additionally, they can be remotely accessed and employed for training purposes, which is particularly valuable in regions with limited access to animal models or where physical separation is required. Although 3D-printed model provides a good model for clinical practice, animal study or real clinical practice are important approaches that cannot be substituted. 3D-printed model is difficult in replicating the physical properties of soft tissues. Besides, in animal study or real clinical practice, factors such as blood perfusion, exposure of surgery region, the mental and physical status of surgeon facing with real scenarios may also affect operation time and operative quality.

This study had some limitations. First, the data in this study were obtained from a single centre; the sample size was also limited as we chose surgeons with certain degree of laparoscopic experience but lack of open or laparoscopic biliary-enteric anastomosis experience. Only 20 surgeons out of about 80 surgeons in our department met this inclusion requirement. Although the powers of sensitivity analysis in this study (operation time, $\eta 2 = 0.415$; operation score, $\eta 2 = 0.\ 684$ and GOALS score, $\eta 2 = 0.601$) are enough, the results could be strengthened by a bigger sample size through multicenter investigations. If the sample size could be larger, the findings would yield far greater significance. Second, although a swine model provides an anatomy close to that of humans in the upper abdominal compartment, the anatomy still differs in size and spatial structure feature of the bile duct, hepatic artery, and portal vein. The mental and physical status of surgeon facing with an animal study, or a real clinical practice may be different. The transfer of examination abilities from animals to human patients was not even close to being adequate. Caution is required when translating our findings directly into laparoscopic biliary-enteric anastomosis in human patients during surgical practice.

Conclusions

Using 3D printing techniques, we were able to establish an intricately detailed simulation model for biliary-enteric anastomosis training that exhibits striking fidelity to the surgical anatomy. In contrast to conventional training methods, simulation training using the 3D-printed model yielded amplified proficiency acquisition and seamless transfer of skills in a clinical setting.

Ethical approval

The study was reviewed and approved by the Institutional Review Board (IRB) of Sir Run-Run Shaw Hospital, Hangzhou, Zhejiang Province, China (NO. 2022-469-01), And the study was in accordance with Helsinki Declaration of 1964 and later versions.

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Author contribution

J.Y. and B.Z. designed the study. B.Z., C.L., J.C. and M.C. collected the data; J.S., Y.Z. analysed and interpreted the data; J.S., Y.Z. wrote the manuscript; J.S. revised the manuscript. All authors made final approval of the version of the manuscript.

Conflicts of interest disclosure

All the authors have completed the ICMJE uniform disclosure form. The authors have no conflicts of interest to declare.

Research registration unique identifying number (UIN)

The study has been registered in the Chinese Clinical Trial Registry. (ChiCTR2200060275). https://www.chictr.org.cn/showproj.aspx?proj=170091.

Guarantor

Jin Yang.

Data statement

All original data are available upon reasonable request to the corresponding authors.

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