ORIGINAL ARTICLE

Added value of 3D-vision during laparoscopic biotissue pancreatico- and hepaticojejunostomy (LAELAPS 3D2D): an international randomized cross-over trial

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Abstract

Background: It is currently unclear what the added value is of 3D-laparoscopy during pancreatic and biliary surgery. 3D-laparoscopy could improve procedure time and/or surgical performance, for instance in demanding anastomoses such as pancreatico- and hepaticojejunostomy. The impact of 3D-laparoscopy could be negligible in more experienced surgeons.

Methods: We conducted a randomized controlled cross-over trial including 20 expert laparoscopic surgeons and 20 surgical residents from 9 countries (Argentina, Estonia, Israel, Italy, the Netherlands, South Africa, Spain, UK, USA). All participants performed a pancreaticojejunostomy (PJ) and a hepaticojejunostomy (HJ) using 3D- and 2D-laparoscopy on biotissue organ models according to the Pittsburgh method. Primary endpoint was the time required to complete both anastomoses. Secondary endpoint was the objective structured assessment of technical skill (OSATS; range 12–60) rating. Observers were blinded for 3D/2D and expertise.

Results: A total of 40 participants completed 144 PJs and HJs. 3D-laparoscopy reduced the operative time with 15.5 min (95%CI 10.2–24.5 min), from 81.0 to 64.4 min, p = 0.001. This reduction was observed for both experts and residents (13.0 vs 22.2 min, intergroup significance p = 0.354). The OSATS improved with 5.1 points, SD ± 6.3, with 3D-laparoscopy, p = 0.001. This improvement was observed for both experts and residents (4.6 vs 5.6 points, p = 0.519). Of all participants, 37/39 participants stated to prefer 3D laparoscopy whereas 14/39 reported side effects. Minor side effects were reported by 10/39 participants whereas 2/39 participants reported severe side effects (both severe eye strain).

Conclusion: 3D-laparoscopy, as compared to 2D-laparoscopy, reduced the operative time and improved surgical performance for PJ and HJ anastomoses in both experts and residents with mostly minor side effects.

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Introduction

Pancreatoduodenectomy (PD) carries a morbidity rate around 50% which is, to a large extent, caused by postoperative pancreatic fistula and, to a lesser extent, biliary leakage from the hepatico-jejunostomy.[1,2] In recent years, laparoscopic PD has been studied as a means to minimize the surgical impact of surgery and thus enhance postoperative recovery.[3] Laparoscopic PD is, however, technically challenging and associated with a learning curve effect.[4,5] Lack of 3D vision, reduced haptic feedback, and limitation in range of motion importantly contribute to the increased difficulty of laparoscopic procedures, and possibly carries the risk of increased postoperative pancreatic fistula- and bile leaks rates.[6–8] The 2018 EAES consensus development conference for 3D laparoscopy concluded that no prospective study or RCT dealing directly with the pancreas surgery could be found.[9] Hence, no statement made relating to the use of 3D systems in HPB surgery could be made.[9]

Previous studies assessing 3D-laparoscopy used simulated settings with simple laparoscopic tasks such as knot tying. The impact of 3D-vision in complex surgery, such as laparoscopic PD, is unknown.[10] Some of these studies suggest there is only limited additional benefit of 3D-laparoscopy for expert laparoscopic surgeons.[9,11,12] Moreover, it is unclear to what extent 3D-vision may give rise to negative side effects.[13]

The aim of this study was to assess the potential benefits and side effects of 3D-laparoscopy when creating pancreatojejunostomy (PJ) and hepaticojejunostomy (HJ) anastomoses by experts and residents in a simulated environment.

Materials and methods

Study design

We conducted a randomized cross-over study. The Consolidated Standards of Reporting Trials (CONSORT) guidelines where followed were possible.[14] All participants were asked to complete a PJ and a HJ twice in a simulated setting using biotissue; once with 3D- and once with 2D-laparoscopy (see Supplementary material 1 for more detail on the procedures). The cross-over design with randomization was intended to minimize interobserver differences and the impact of familiarity. The study was approved by the local ethics committee and performed in accordance with the Declaration of Helsinki.

Participants

Participants were invited from all 17 centers participating in the Dutch Pancreatic Cancer Group as well as from international collaborating centers. As it is known that the benefits of 3D vision rely on both the surgeon's laparoscopic experience and stereoptic capabilities,[15] both experts and surgical residents were invited. A total of 40 participants were included in two groups: 20 surgeons experienced in advanced laparoscopic gastrointestinal surgery, defined as laparoscopic surgery beyond appendectomy and cholecystectomy, and 20 trained surgical residents, from all residency years, but capable of laparoscopic suturing. Experience with minimally invasive PD was not required because inclusion would be limited by the low amount of surgeons capable of performing minimally invasive PD. Although it was assumed all participants had 3D-vision abilities, participants were excluded if they had no 3D-vision abilities. Stereoptic abilities, *i.e.* 3D-vision capabilities, ware assessed using a Randot Test (Stereo optical, Chicago, IL, USA). Reported side effects and preferences, and baseline demographics were collected using questionnaires (see Supplementary figure 1).

Intervention

The study was performed at the department of experimental surgery at the Amsterdam UMC, University of Amsterdam. All exercises were performed during day-time hours. Participants watched a 10 min instruction video and had an oral instruction before the start of the experiment.

A standardized patient setting was simulated using inanimate artificial, biotissue, organs according to the Pittsburgh method (See Fig. 1).[16] Several minimally invasive training programs have incorporated these synthetic artificial organs, one of which shows face- and construct validity training PD.[16] Polarization 3D screens are generally used in 3D laparoscopic surgery.[17] Therefore, a 3D HD camera, the ENDOEYE FLEX 3D (Olympus, Tokyo, Japan) 10-mm articulating laparoscope was used. Participants used the same identical set of instruments and camera for all corresponding cross-over exercises. Artificial organs were obtained from LifeLike BioTissue (Ontario, Canada) *i.e.,* long pancreas, long double layer small bowel, bile duct, vessel holder, and skin holder. The box trainer, LapStar (Camtronics B.V., Ekkersrijt, the Netherlands) and suture material were provided by Ethicon Endo-Surgery (Johnson & Johnson, New Brunswick, New Jersey, United States). Laparoscopic video imaging of the exercises was recorded using the FireStore-4High-Definition recorder (Focus Enhancements Inc., Sunnyvale, CA, US). A trained laparoscopic camera assistant was provided. Ergonomic conditions were adjusted in advance and constant for all subjects. Before the experiment, the height of the surgical table was set, and the monitor was placed at a comfortable, optimal for polarization 3D, level for each participant. The anastomoses were photographed in high-definition (HD) after completion of the exercise.

Rating

All imaging material presented to a rater and a validation rater was anonymized, thus blinded for both the performing participant and for 3D/2D. The rater training was performed at University of Pittsburgh Medical Center. The validation rater was an experienced laparoscopic surgeon and received crash course in rating and a random sample of 30 anastomoses. Performance was graded using an objective structured assessment of technical skill

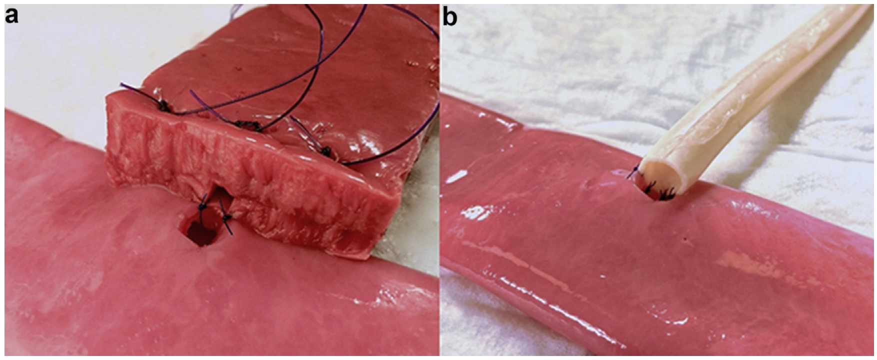

Figure 1 Biotissue anastomoses. (a) Pancreaticojejunostomy completed halfway, (b) hepaticojejunostomy completed halfway

(OSATS) validated by Birkmeyer *et al.*, that we modified for static surgical environments by replacing 'flow of operation' by 'ambidexterity' (see Table 1).[18,19]

Randomization

Randomization was done with SPSS (SPSS Inc., Chicago, IL, USA). Randomization was performed by the study coordinator. Participant data were anonymized by using a 4 digit code, and the principal investigator and study coordinators were the only one with access to the decoding document.

Outcomes

The primary outcome was the difference in total operative time expressed in minutes and percentages. Secondary outcome was surgical performance according to the OSATS score (attainable range 12–60). Other outcomes were the difference in operative time for the PJ and HJ; correlation between quality and speed differences between interventions; participant's preference for 3D or 2D, side effects of 3D vision.

Table 1 OSATS

Grading Definition	
1	Deficient/Traumatic
2	Lacking/Lacks finesse
3	Average
4	Skilled
5	Master/Flawless
Grading aspects and elucidation	
Summary Score	Overall assessment of technical skill
Ambidexterity	Use of both hands
Knot Tying	Fluidity, granny knots, square knots, sliding knots, suture tail length
Instrument Handling	Fluid use of instruments without awkwardness
Time and Motion	Economy of motion, maximum efficiency
Gentleness	Gentle tissue handling that does not result in injury

5-Point rating scale modified for static surgical environments.[14]

Statistical methods

The sample size estimation for this trial was based on a previous study looking at basic motor skill improvement with 3D-laparoscopy.[20] In this trial operative time reduction was 10 min (SD ± 15) over approximately 50 min. Using a power of 80% and alpha of 0.05 a sample size of 19 per group was required.

Data were analyzed using IBM SPSS statistics for Windows version 24 (IBM Corp, Armonk, NY, USA). Normally distributed continuous data were presented as means and standard deviations (SDs). Non-normally distributed continuous data were presented as medians and interquartile ranges (IQRs) or 95% confidence intervals (95% CI). Categorical (binary, nominal, and ordinal) data were presented as frequencies and percentages. Likert-Scale ordinal data were also presented in means and standard deviations, as this allows more insight into the effect size.[21] A two-tailed p value < 0.05 was considered statistically significant. Missing data were corrected by excluding the corresponding missing part of the video of both the intervention and control procedure into the analysis. Differences in anastomosis times were analyzed paired-wise according to the performing participant.

Baseline demographics were compared with Student's t-test for normally distributed data, Chi-squared test for frequencies in one or more categories, and Mann–Whitney U test for non-normally distributed data. Primary outcomes were analyzed using the Wilcoxon signed-rank test, since the comparison was paired-wise. Participants who completed one anastomosis only were excluded from primary outcome analysis. Secondary outcomes were analyzed using Wilcoxon signed-rank test and sub score analysis was performed with a Student's t-test after normality was assessed. Other outcomes were analyzed using the Wilcoxon signed-rank test for non-normally distributed data, Pearson coefficient correlation, Kendall's tau coefficient correlation, and interrater reliability was analyzed using intraclass correlation coefficient in two-way mixed effects model after normalizing data with z-scores.

Results

Participants

In the months December 2017 and January 2018, over 80 surgeons and surgical residents were invited, resulting in a final 40 participants. Data of one PJ in 3D was partially lost due to an accidentally damaged file. To prevent learning curve interference, this procedure was not repeated. For detailed information on the numbers of participants randomly assigned, their performed procedures, and data analyzed, see Fig. 2.

Baseline demographics

Surgeons and residents from 9 countries (Argentina, Estonia, Israel, Italy, the Netherlands, South Africa, Spain, UK, USA) participated. The two groups of randomization, *i.e.* start with 3D or 2D, were comparable, without statistical differences for baseline characteristics, laparoscopic experience, hand dominance, vision correction and 3D-vision abilities (see Table 2) Mean age was 45 years (SD ± 9) for experts and 33 years (SD ± 5) for residents (see Supplementary table 1).

Primary outcome

The 40 participants completed 72 PJs and 72 HJs. Four participants had time to complete one anastomosis, only, and were distributed equally between both intervention groups. One participant left to perform an emergency procedure after randomization and was not able to complete the experiment. The median operative time to complete both anastomoses was 64.4 min (IQR 54.0–82.4) using 3D-laparoscopy and 81.0 min (IQR 64.3–95.0) using 2D-laparoscopy (p = 0.001). The median reduction in operative time with 3D was 15.5 min, 95%CI 10.2–24.5, p = 0.001. This reduction was 13.0 min for experts, 95% CI 3.0–16.1, p = 0.034 versus 22.2 min for residents, 95% CI 12.4–36.5, p = 0.020. The reduction in operative time with 3D did not differ significantly between experts and residents: 13.0 vs 22.2 min, (p = 0.354) (see Fig. 3). For experts, the relative reduction in operative time was 16.0%, 95%CI 8.3–27.0 (p = 0·034). For residents, the relative reduction in operative time was 25.8%, 95%CI 10·4–32·0 (p = 0·020).

Secondary outcomes

The mean overall improvement in the OSATS for both anastomoses with 3D-laparoscopy was 5.1 points with attainable scores between 12 and 60 points, SD ± 6.3, p = 0.001. For the expert group this was a 4.6 points improvement, SD ± 4.8, p = 0.007, and for the resident group a 5.6 points improvement, SD ± 7.7, p = 0.023. The improvements did not differ significantly between

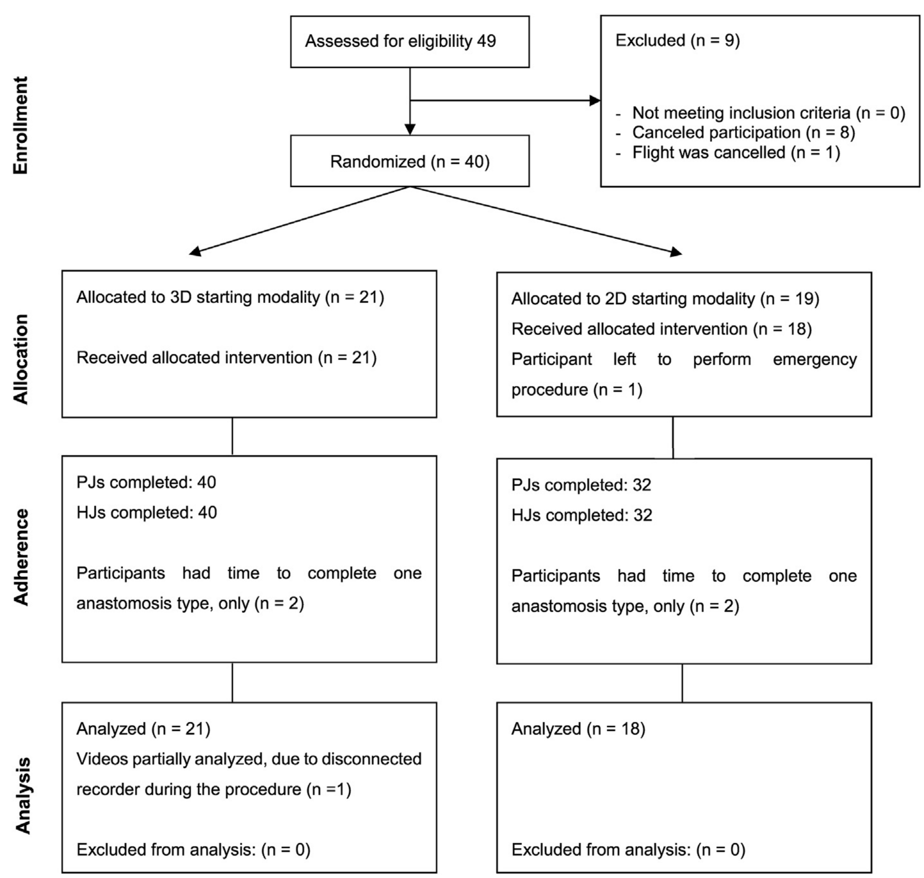

Figure 2 CONSORT flowchart

Table 2 Participant group characteristics

Starting modality	Total (N = 40)	3D (N = 21)	2D (N = 19)	p
Characteristics				
Age	39 ± 10	40 ± 8	39 ± 11	0.72[a]
Male	31 (77.5)	16 (76.2)	15 (78.9)	0.70[b] (X_2 = 0.303)
Laparoscopic experience				
Years of laparoscopic experience	6.5 (4–13)	7 (4–14)	6 (5–12)	0.86[c]
Number of advanced laparoscopic procedures performed annually	40 (10–93)	40 (10–85)	40 (10–100)	0.91[c]
Number of laparoscopic pancreato-duodenectomies performed	0 (0–3)	0 (0–0)	0 (0–23)	0.26[c]
Hand dominance				0.57[b] (X_2 = 1.109)
Right	31 (77.5)	16 (76.2)	14 (73.7)	
Left	5 (12.5)	2 (9.5)	3 (15.8)	
Ambidextrous	4 (10.0)	3 (14.3)	1 (5.3)	
Vision correction	18 (45.0)	7 (33.3)	11 (57.9)	0.10[b] (X_2 = 3.709)
Minimal degrees of stereopsis	30 (25–40)	30 (25–48)	30 (25–40)	0.98[c]

Values are mean ± SD, median (quartile 1 to quartile 3) or n (percentage).
[a] Students T-test.
[b] Chi-square test.
[c] Mann–Whitney U Test.

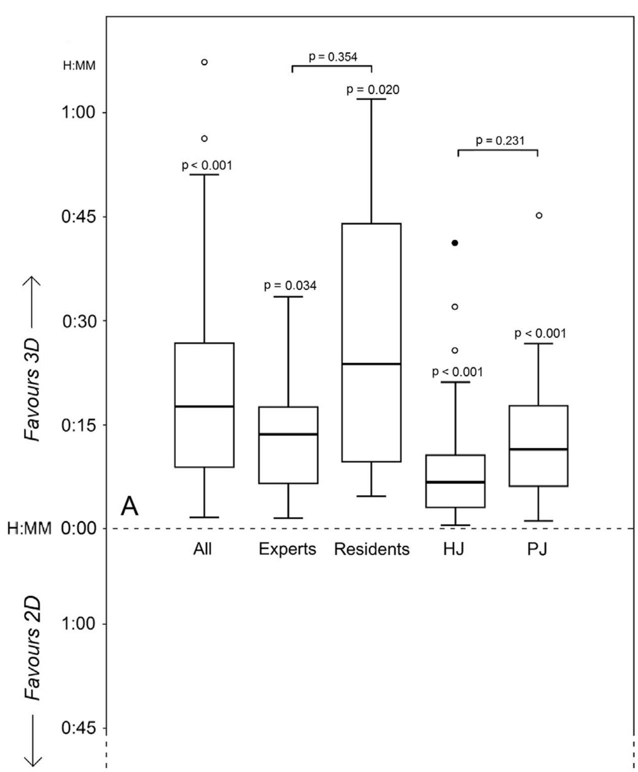

Figure 3 **Time advantage by 3D.** Primary outcome expressed in median advantage in operative time by 3D vision expressed in minutes

groups; p = 0.519 (see Table 3). For more detailed OSATS outcomes see Supplementary figure 2.

Other outcomes

The median operative time for the PJ was 41.3 min (IQR 33.4–50.2) in 3D and 48.5 min (IQR 37.2–59.0) in 2D. The median reduction in PJ operative time with 3D was 9.1 min, 95%CI 3.1–12.5 (p = 0.001). The median operative time for the HJ was 24.3 min (IQR 18.2–33.3) in 3D and 30.1 min (IQR 21.6–42.3) in 2D. The median reduction in HJ operative time in 3D was 4.4 min, 95%CI 1.4–9.5 (p = 0.001). The two anastomosis did not differ significantly in the benefit of time by 3D (p = 0.231) (see Fig. 3). The relative improvements in operative time were 19.4%, 95%CI 4.0–22.9 (p = 0.001), for PJ, and 21.1%, 95%CI 6.5–24.0 (p = 0.001), for HJ.

The Pearson coefficient showed 1% increase in sum of OSATS scores correlated with a 0.205% reduction in operative time in 3D (p = 0.296). Suggesting both an increased quality and a decrease operative time when using 3D laparoscopy compared to 2D laparoscopy.

Of all participants, 37/39 participants stated to prefer 3D laparoscopy whereas 14/39 reported side effects. Minor side effects, *e.g.*, minor headache, were reported by 10/39 participants and 2/39 participants reported severe side effects (both in severe eye strain) (see Supplementary table 2).

Table 3 Differences in summarized OSATS scores

	3D	2D	Δ	p	
Total, SD	43.7 ± 7.1	38.5 ± 8.1	5.1 ± 6.3	0.001	
Experts, SD	47.1 ± 7.2	42.5 ± 6.2	4.6 ± 4.8	0.007	0.519[a]
Residents, SD	40.2 ± 5.3	34.6 ± 8.0	5.6 ± 7.7	0.023	

Values in parentheses are percentages. Wilcoxon Signed-Rank Test.
[a] Significance intergroup difference. OSATS: objective structured assessment of technical skill, SD: Standard deviation, 3D: mean summarized OSATS scores for 3D anastomoses, 2D: mean summarized OSATS scores for 2D anastomoses, Δ: Mean difference 3D vs 2D.

Validation rating of 28, randomly assigned, individual procedures was performed by a laparoscopic surgeon with experience with laparoscopic PD. Sums of scores of the rater and the validation rater showed an interclass correlation coefficient of 0.616, p = 0.007 based on average measures.

Discussion

In this randomized controlled crossover trial using biotissue, 3D-laparoscopy, as compared to 2D-laparoscopy, demonstrated substantial reduction in operative time of completing both PJ and HJ and improved surgical performance for both experts and trained surgical residents.

This is the first study to examine the impact of 3D-laparoscopy with biotissue simulated PJ and HJ anastomoses. A recent systematic review on 3D-laparoscopy found 28 randomized experimental studies, which used operative time reduction as the primary outcome, mostly in a suturing course.[10] Overall, 17 out of 31 (clinical (2/3) and experimental (15/28)) studies reported a reduction in both operative time and surgical error with the use of 3D laparoscopic vision.[10] Of the 28 previous randomized experimental studies, 17 included both experts and residents. In 5 out of 17 studies, outcome improved with 3D-laparoscopy in both groups.[10] More recently, two randomized clinical trials with 3D-laparoscopy concerning abdominal surgery were published.[22,23] The first trial compared 3D-with 2D-laparoscopy in 36 patients undergoing hiatal hernia repair and found 22.4% operative time reduction with 3D-laparoscopy (p = 0.006).[23] The second trial studied 3D-laparoscopy compared to 2D-laparoscopy in 438 patients undergoing gastrectomy and found similar operative times in both groups.[22]

Interestingly, a recent retrospective study found similar operative times for 3D laparoscopic PD versus open PD.[24] Currently, three randomized clinical trials have been performed comparing laparoscopic versus open PD.[25–27] All reported longer operative times for laparoscopy, with the multicenter Dutch LEOPARD-2 trial by using 3D for anastomoses in some centers and the PADULAP using 3D routinely[26,27]

Birkmeyer *et al.* demonstrated that when surgical performance improves, the complication rates nearly halves for one point increase in summary rating.[18] Also, a lower OSATS score was shown to be predictive of postoperative pancreatic fistulas in robot-assisted pancreatoduodenectomy.[13] In this study, 3D-laparoscopy improved both the surgical performance and operative time suggesting that 3D-laparoscopy in PD could potentially reduce the impact of the learning curve for laparoscopic pancreatoduodenectomy. Clearly, clinical studies will have to affirm these suggestions.

Are there downsides to 3D-laparoscopy? As confirmed in this study, some surgeons report discomfort when using 3D-laparoscopy. 3D polarization systems allegedly have the highest comfort compared to other systems, such as head-mounted displays.[28] In this study, 10 participants reported minor side effects, although 37 out of 39 participants stated to prefer 3D-laparoscopy. Thereby indicating that the majority of participants felt comfortable in tolerating experienced side effects in order to obtain the experienced benefit of 3D-laparoscopy. It has only recently been demonstrated that the benefits of stereovision are greatly subjective to interpersonal variation in stereovision capabilities. For example, 10% of people are unable to see stereoptically and experience adverse effects of nausea and eye strain.[29] Previous 3D laparoscopic vision systems are reported to have caused additional fatigue and nausea through an unaligned horizon in susceptible users.[28] Recent systems use polarization to minimize additional fatigue but nausea through horizon misalignment could remain a problem, thus the question remains if these side effects can be tolerated if 3D surgery is performed on a daily basis.[28,30] Interestingly, robotic systems such as the da Vinci® (Intuitive Surgical, Sunnyvale, CA, USA) inherently use 3D-laparoscopy. It would be interesting to compare 3D with 2D robot assisted anastomoses in PD, and compare the results with 3D-laparoscopy without robot-assistance.

This study has some limitations. First, this was a randomized trial in an experimental and not in a clinical setting. A randomized trial in a clinical setting comparing the benefits for both experts and residents would, however, seem unlikely. Nevertheless, to determine the true benefit of 3D-laparosocpy in the clinical setting a randomized controlled trial would be needed. Second, participants were recruited on an invitational basis. This could have caused a selection bias toward participants with better skills or better stereoptic capabilities. This was reflected by a relatively high mean seconds of arc of stereopsis of 30 (IQR 25–40).[31] The improved skills, however, could theoretically have caused an underestimation of the impact of 3D-laparoscopy. Third, blinding for intervention was not possible, even in this experimental setting. However, the raters were blinded for 2D and 3D-laparoscopy which will essentially have eliminated observer bias. Fourth, not all participants were able to complete both anastomoses. Later completion was not attempted, as it might interfere with the attempt to eliminate the learning curve.

Strengths of the current study include the randomized design, the use of both experts and trained surgical residents for multiple countries, the rater blinding for OSATS outcomes, and good description of stereoptic capabilities. Overall, we measured a reduction in operative time and increased OSATS by 3D-laparoscopy in a simulated clinical setting of pancreatoduodenectomy. With the use of artificial organs, confounders of patient variables are eliminated, *e.g.*, blood loss. Furthermore, the current study examines the correlation between the measured reduction in operative time and increased OSATS by 3D-laparoscopy, and found a positive correlation. Although the significance of this correlation was low, the results suggest that reduction of operative time through 3D-laparoscopy correlates with an increase in Birkmeyer rating.

In conclusion, 3D-laparoscopy, as compared to 2D, demonstrated substantial reduction in operative time of completing both PJ and HJ in biotissue, and improved results in OSATS for both experts and trained residents. The use of 3D-laparoscopy may improve surgical performance and, ultimately, reduce postoperative pancreatic fistula rates.

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Disclosures

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Conflicts of interest

None declared.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.hpb.2019.04.012.

