TO COMPARE THE EFFICACY OF 3D PRINTED SILS PORT VERSUS CONVENTIONAL SILS PORT IN TAMIS (TRANSANAL MINIMALLY INVASIVE SURGERY) – A RANDOMISED CONTROL TRIAL

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Abstract:

Background: 3D printing is an additive manufacturing process that uses incrementally timed layers of materials to build 3D objects. Colorectal cancer is the second most frequent cancer, affecting over one million people each year. Over the past decade, TAMIS (transanal minimally invasive surgery) has gained interest for resection of early rectal carcinoma. However the conventional SILS (single-incision laparoscopic surgery) port used in TAMIS had a few drawbacks. To date there are no studies evaluating the 3D printing of SILS port. The purpose of this study is to evaluate the clinical safety and operability of 3D printed SILS port and compare the efficacy of same over conventional SILS port in TAMIS.

Methods: This is a randomised control study conducted in Victoria Hospital Bengaluru from October 2022 to March 2023 included 36 patients who underwent TAMIS using conventional SILS port and 3D printed SILS port. Data on technical aspects of 3D printed SILS port over conventional port were assessed using various parameters.

Results: In our study the port placement using 3D printed port was very easy in 38.9% of the patients as compared to conventional port where it was 11.1%. Similarly, easy instrumentation and good insufflation was found in 55.6% with 3D printed port as compared to conventional port (5.6%) ,whereas durability of conventional port was good in 50% of cases compared to 3D printed port which was only 11.1%.

Conclusion:We infer from our study that the 3D printing of SILS port is technically a feasible procedure and demonstrates potential advantages over the conventional port in terms of port placement, instrumentation and insufflation with a better surgical outcome.

Keywords:3D printing, Early carcinoma rectum, SILS port, TAMIS.

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1. INTRODUCTION

Transanal minimally invasive surgery (TAMIS) is a widely used technique in the field of colorectal surgery. In this procedure, a single incision laparoscopic surgery (SILS) port is used to perform resection of the rectal lesions like polyps, early carcinoma rectum. However, the traditional SILS port has some limitations such as poor maneuverability and lack of customization. Recently, 3D printing technology has emerged as a promising solution to overcome these limitations by 3D printing customised SILS port by making necessary design iterations.In this study, the efficacy of a 3D printed SILS port for TAMIS is compared to the conventional SILS port in a randomized controlled trial. The results of this study may provide valuable insights into the effectiveness of 3D printed surgical tools in improving patient outcomes in TAMIS.

The rectum and sigmoid colon are the most common locations for polyps and cancer in the gastrointestinal tract. Colorectal cancer is the second most frequent cancer, affecting over one million people each year, with 70% of those affected being 70 or older.[1] Screening programmes, improved technology, and more trained workers have resulted in the discovery of more rectal lesions and cancer at an earlier stage.[2] The treatment of benign and malignant rectal cancers entails more invasive treatments that necessitate an anastomosis or an ostomy.

Traditional techniques, such as TAE (Traditional transanal excision), have several disadvantages, such as restricted access to specific tumour areas.[3] TEMS (Trans anal endoscopic microsurgery) includes budgetary constraints, specialised equipment requirements, and a high learning curve.[4] This resulted in the creation of TAMIS,[5] a more cost-effective procedure that employs a SILS (single incision laparoscopic surgery) port and laparoscopic equipment.[6],[7],[8] Intraluminal full thickness excision of a rectal neoplastic lesion was accomplished despite the limitations of the conventional SILS port, such as difficulty in insertion due to its fixed width and dimension, overcrowding of instruments, and leakage of CO2 insufflation gas, which resulted in improper port fixation, visualisation of lesions, and resection. This resulted in the development of a novel process known as three-dimensional printing of SILS ports.

3D printing technology has been adopted by surgeons at an impressive rate and in a large variety of applications. Nearly every part of human anatomy that can be operated on, has had a 3D model printed of it. Furthermore, surgeons have gone beyond printing these impressive patient-specific anatomic models to printing patient-specific medical hardware, such as implants, prosthetics, external fixators, splints, surgical instruments, and surgical cutting guides.[9],[10],[11] The recent explosion in popularity of 3D printing is a testament to the promise of this technology and its profound utility in surgery.

To date there are no studies evaluating the 3D printing of SILS port and its application in surgery. The purpose of this study is to evaluate the clinical safety and operability of 3D printed SILS port.

OBJECTIVES OF THE STUDY: To compare the efficacy of 3D printed SILS port versus conventional SILS port for TAMIS based on ease of

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- Port placement
- Instrumentation
- Insufflation
- Durability of port

2. MATERIALS AND METHODS:

2.1 Study design:

A randomized controlled trial was conducted from October 2022 to March 2023 in the Department of General Surgery in Victoria hospital attached to Bangalore Medical College and Research Institute, Bengaluru.

2.2 Sample size and patient selection

Based on a pilot study, the assessment of instrumentation in 3D printed SILS ports and conventional SILS ports was 3.6 ± 0.9 and 2.8 ± 0.8, respectively. The sample size was calculated using the G*Power software, assuming a power of 80%, a significance level of 5%, and an effect size of 0.8. The calculated sample size was 36, with 18 patients in each group.

Inclusion criteria:

- Patients willing to give informed written consent.
- Patients more than or equal to 18 years of age.
- Patients with benign rectal conditions and early carcinoma rectum.

Exclusion criteria:

- Patients with advanced rectal malignancies.
- Patients with coagulopathies and wound healing disorders
- Patient not willing to give informed consent.

2.3 Randomization and blinding:

The study participants were randomized into two groups using a computer-generated random number table. The data analyst was blinded to the group allocation.

2.4 Process of 3D printing

3D printing of SILS ports is done by Polyjet printer using liquid photopolymer with shore value of 95A. The design of the SILS ports was based on data collected from existing SILS ports in the market, which was scanned and processed to create modified designs. A CAD(Computer aided design) model is developed with required design iterations and finally printed using polyjet printer. The printed SILS ports were sterilized using chemical disinfectant(2% glutaraldehyde). Material used is biologically inert and does not react with human tissue.

Figure 1: CAD models of 3D printed SILS port with required design iteration and measurements.

Figure 2: 3D printed SILS port

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Figure 3. Conventional SILS port

Figure 4: Flowchart of 3D printing process

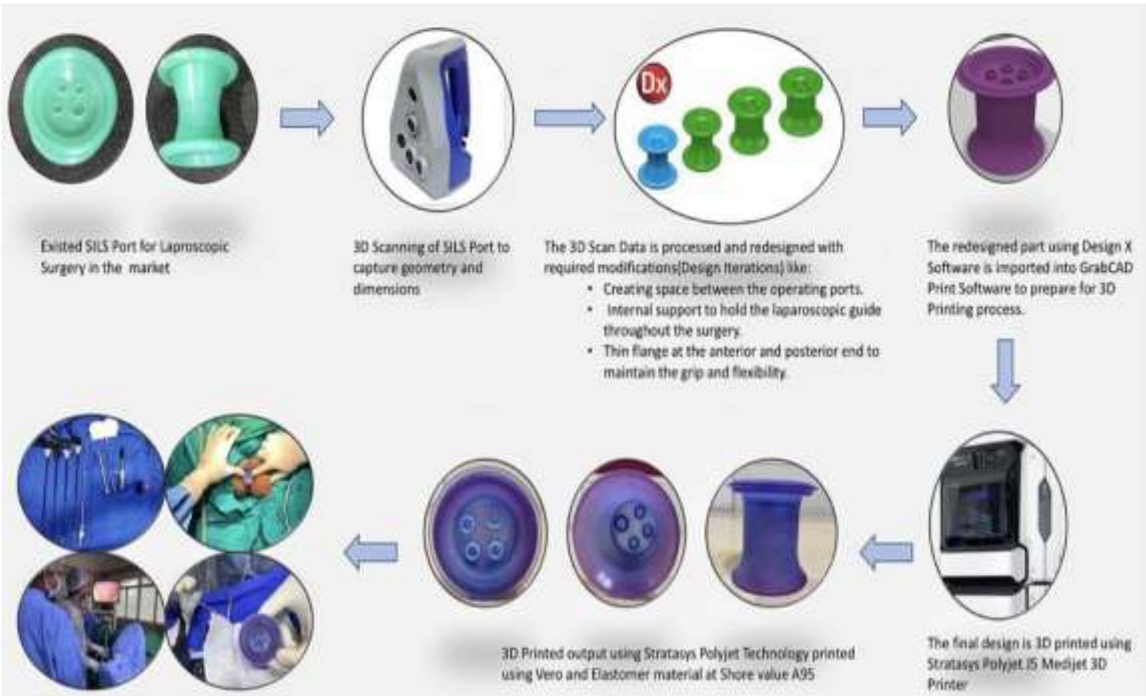

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Table 1. Comparasion between conventional and 3D printed SILS port.

Characteristics	Conventional port	3D printed port
Material	**Rubber**	**Liquid photopolymer with shore value of 95A**
Elasticity	**Soft flexible**	**Rigid**
Design	**Fixed**	**Design iterations : 1. Space between access points in port increased for maximal manoeuvrability of instruments 2.Internal funneling of port to avoid rectal collapse 3.Thin flange at the anterior and posterior end to maintain the grip and flexibility of port**
Cost	**Less expensive**	**Expensive**
Availability	**Easily available**	**Limited**

2.5 Surgical technique and assessment of efficacy of ports

The study enrolled patients with rectal disease who are admitted to the department of general surgery at BMCRI. Patients had to undergo evaluation using colonoscopy and, when necessary, imaging modalities. Preoperative preparation was done for all eligible patients. Patients were placed in lithotomy position under general anaesthesia had to undergo TAMIS procedure -A complete excision of rectal lesion using SILS port and basic laparoscopic instruments. The study group underwent TAMIS using 3D printed SILS ports and the control group underwent TAMIS using conventional SILS ports. The surgical procedures were performed by experienced surgeons using standardized techniques. The technical aspects of using 3D printed SILS port over the conventional SILS port were studied using assessment tools based on port placement, handling of laparoscopic instruments, insufflation and durability of the port.

A structured performa was prepared by qualified professionals for assessment of the parameters. Based on ease of port placement and handling of instruments, operating surgeon rates it as very difficult, difficult, moderate, easy and very easy. Adequate insufflation and durability of port rated from average, good, excellent, poor, very poor.

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Figure 5. Intraoperative images of TAMIS procedure

A.Port placement. B.Instrumentation and insufflation

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2.6 Data collection and analysis:

Data was collected using a standardized data collection form. Statistical analysis was performed using SPSS software, and p-value less than 0.05 was considered significant.

3. RESULTS

Table 2. Demographic and diagnostic distribution of patients

		Group						
		3D Port		Conventional Port		Total		
		Count	Column N %	Count	Column N %	Count	Column N %	p-value
Age	24-33	4	22.22%	4	22.22%	8	22.22%	0.263
	34-43	4	22.22%	4	22.22%	8	22.22%	
	44-53	2	11.11%	5	27.78%	7	19.44%	
	54-63	6	33.33%	3	16.67%	9	25.00%	
	64-73	2	11.11%	1	5.56%	3	8.33%	
	74-83		0.00%	1	5.56%	1	2.78%	
Gender (M/F)	F	5	27.80%	5	27.80%	10	27.80%	1
	M	13	72.20%	13	72.20%	26	72.20%	

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Diagnosis	Ca rectum	6	33.30%	5	27.80%	11	30.60%	0.321
	Foreign body rectum	0	0.00%	2	11.10%	2	5.60%	
	Grade 2 haemorrhoids	1	5.60%	2	11.10%	3	8.30%	
	Grade 3 haemorrhoids	2	11.10%	1	5.60%	3	8.30%	
	Pelvic abscess	0	0.00%	2	11.10%	2	5.60%	
	Perianal fistula	1	5.60%	0	0.00%	1	2.80%	
	Rectal polyp	3	16.70%	5	27.80%	8	22.20%	
	Rectal stricture	2	11.10%	0	0.00%	2	5.60%	
	Solitary rectal ulcer	3	16.70%	1	5.60%	4	11.10%	

The distribution of patients by age groups showed a relatively even distribution, with the largest group being patients aged 54-63 years (25% of the total patients). There was no significant difference in age distribution between the two groups (p=0.263).

The majority of patients were male (72.2%), and there was no significant difference in gender distribution between the two groups (p=1).

Regarding the diagnosis, the most common indication for TAMIS was rectal cancer (30.6%), followed by rectal polyp (22.2%), and solitary rectal ulcer (11.1%). There was no significant difference in diagnosis distribution between the two groups (p=0.321).
Overall, the demographic and diagnostic distribution of patients in the study appears to be balanced between the two groups, suggesting that any differences observed in the study outcomes are less likely to be due to demographic or diagnostic factors.

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Table 3. Statistical analysis of parameters

		Group						
		3D Port		Conventional Port		Total		
		Count	Column N %	Count	Column N %	Count	Column N %	p-value
Port placement	Very easy	7	38.90%	2	11.10%	9	25.00%	0.001
	Easy	9	50.00%	1	5.60%	10	27.80%	
	Moderate	2	11.10%	4	22.20%	6	16.70%	
	Difficult	0	0.00%	6	33.30%	6	16.70%	
	Very difficult	0	0.00%	5	27.80%	5	13.90%	
Instrumentation	Very easy	2	11.10%	0	0.00%	2	5.60%	0.003
	Easy	10	55.60%	1	5.60%	11	30.60%	
	Moderate	4	22.20%	6	33.30%	10	27.80%	
	Difficult	2	11.10%	8	44.40%	10	27.80%	
	Very difficult	0	0.00%	3	16.70%	3	8.30%	
Insufflation	Average	2	11.10%	4	22.20%	6	16.70%	0.001
	Good	10	55.60%	3	16.70%	13	36.10%	
	Excellent	6	33.30%	1	5.60%	7	19.40%	
	Poor	0	0.00%	7	38.90%	7	19.40%	
	Very poor	0	0.00%	3	16.70%	3	8.30%	
Durability of the port	Average	4	22.20%	1	5.60%	5	13.90%	0.001
	Good	2	11.10%	9	50.00%	11	30.60%	
	Excellent	0	0.00%	8	44.50%	8	22.20%	
	Poor	9	50.00%	0	0.00%	9	25.00%	
	Very poor	3	16.70%	0	0.00%	3	8.30%	

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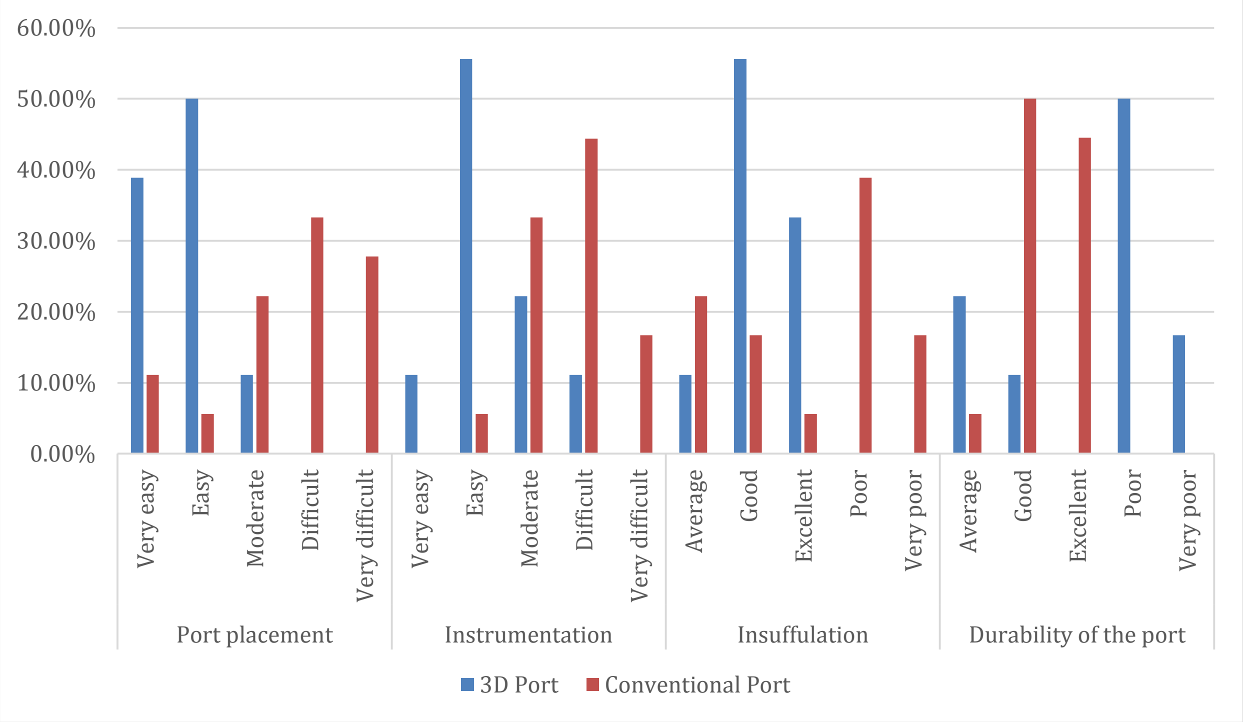
Graph 1. Graphical represention of analysis of various parameters comparing 3D printed versus conventional port



Port Placement:

The results indicate that a significantly higher percentage of surgeons found port placement very easy (38.90%) or easy (50.00%) with 3D ports compared to conventional ports, where only 11.10% and 5.60% of surgeons found it very easy and easy, respectively. In contrast, a higher percentage of surgeons found port placement to be difficult (33.30%) or very difficult (27.80%) with conventional ports compared to 3D ports. The p-value for this finding was 0.001, indicating that the difference between the ease of port placement with 3D and conventional ports is statistically significant.

Instrumentation:

The results indicate that a higher percentage of surgeons found instrumentation to be easy (55.60%) with 3D ports compared to conventional ports, where only 5.60% of surgeons found it easy. In contrast, a higher percentage of surgeons found instrumentation to be difficult (44.40%) or very difficult (16.70%) with conventional ports compared to 3D ports, where only 11.10% of surgeons found it difficult.

The p-value for this finding was 0.003, indicating that the difference between the ease of instrumentation with 3D and conventional ports is statistically significant.

Insufflation:

The results indicate that a higher percentage of surgeons found insufflation to be good (55.60%) or excellent (33.30%) with 3D ports compared to conventional ports, where only 16.70% found it good and 5.60% found it excellent. In contrast, a higher percentage of surgeons found insufflation to be poor (38.90%) or very poor (16.70%) with conventional

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ports compared to 3D ports. The p-value for this finding was 0.001, indicating that the difference between the insufflation performance of 3D and conventional ports is statistically significant.

Durability:

In the 3D port group, 22.20% of surgeons rated the durability of the port as average, 11.10% as good, 50.00% as poor, and 16.70% as very poor.In the conventional port group, 5.60% of surgeons rated the durability of the port as average, 50.00% as good, 44.50% as excellent. The statistical analysis showed a significant difference between the two groups with a p-value of 0.001. Based on the ratings given by the surgeons , the conventional port group received higher ratings for the durability of the port compared to the 3D port group. Therefore, one can conclude that the conventional port may be a better option in terms of port durability.

Overall, the findings suggest that the 3D printed SILS port is more effective than the conventional SILS port for TAMIS, particularly in terms of ease of placement, instrumentation, and insufflation.

4. DISCUSSION

3D printing is an additive manufacturing method that uses incrementally timed layers of materials to build 3D objects. Most surgical departments currently use 3D printing in some form or another, ranging from visual tactile assistance for surgery preparation to comprehensive virtual surgery planning and personalised surgical guides, as well as patient-specific implants.[12],[13]

Historically, the concept of using 3D medical imaging, specifically computed tomography (CT) data, to reconstruct a physical model was first suggested in 1979.[14] At that time, there were no 3D printing systems available, however subtractive manufacturing, or milling, was a possibility. Prior to the advent of 3D printers, the main method of fabricating a unique part for prototyping was with the use of Computer Numerical Controlled (CNC) machine. The first anatomic model constructed with the use of medical imaging was done that same year. It was a model pelvis that was milled from a polystyrene block.[15] With the introduction of the first commercial 3D printing machine in addition to increasing access to 3D medical imaging techniques in the late 1980s, applications for 3D printing in the medical field began to be seriously considered. Stereolithography (SLA) is the technique by which a computer controlled laser beam is used to harden a liquid polymer or resin, creating a structure layer by layer. SLA was the first 3D printing technique available and the first used in the biomedical field, in 1994.[16]Orthopedic surgery and Oral and Maxillofacial surgery were among the first specialties to adopt this technology.[17],[18] It has been suggested this is largely because, 3D printing is more suitable to fields that handle hard tissue since the first 3D printers could only print with hard materials.[19]

3D printing of SILS ports is done by Polyjet J5 printer using liquid photopolymer material with shore value of 95A. Material used was selected based on elastomer(shore) value. The port is biologically inert and does not react with human tissue.

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The study conducted to compare the efficacy of 3D printed SILS ports and conventional SILS ports for TAMIS. The study found that there were significant differences between the two types of ports in terms of ease of port placement, instrumentation, insufflation and durability.

The results showed that a significantly higher percentage of surgeons found port placement very easy or easy with 3D printed ports compared to conventional ports. In contrast, a higher percentage of surgeons found port placement to be difficult or very difficult with conventional ports. The findings suggest that the 3D printed SILS port may be a better option for ease of port placement in TAMIS.

In terms of instrumentation, a higher percentage of surgeons found handling of instruments to be easy with 3D printed ports compared to conventional ports. In contrast, a higher percentage of surgeons found instrumentation to be difficult or very difficult with conventional ports. This finding indicates that the use of 3D printed SILS ports may facilitate the easy handling of instruments during TAMIS.

The study also compared the insufflation performance of the two types of ports. The results showed that a higher percentage of surgeons found insufflation to be good or excellent with 3D printed ports compared to conventional ports. In contrast, a higher percentage of surgeons found insufflation to be poor or very poor with conventional ports. The findings suggest that the use of 3D printed SILS ports may improve the insufflation performance in TAMIS.

However, the study found that the conventional port group received higher ratings for the durability of the port compared to the 3D printed port group. Therefore, the conventional port may be a better option in terms of port durability.

Nevertheless, it is important to note that the process of 3D printing the SILS port needs refinement and standardization to optimize the quality and consistency of the printed product. Additionally, some surgeons reported dissatisfaction with the size and shape of the 3D printed port, suggesting that further customization may be necessary.

Another important consideration is the cost-effectiveness of 3D printing surgical instruments.[20]While the initial cost of 3D printing equipment and materials may be high, the potential cost savings associated with improved surgical outcomes and reduced complications may outweigh these initial costs in the long run. Future studies should aim to evaluate the cost-effectiveness of 3D printed surgical instruments and equipment to determine whether they are a viable option for widespread use in the healthcare industry.

3D printing in the medical field requires a multidisciplinary team. Most surgeons are not familiar with the techniques involved in 3D printing and most affordable printers require some engineering background for troubleshooting and CAD design.

The specific advantage of 3D printed SILS port over conventional SILS port is improved precision, use of flexible and variable sizes of ports compared to patient factors, reduced duration of operation, proper port fixation, avoids leakage of co2 insufflation gas, avoids overcrowding of instruments, and better visualisation of operating field.

5. CONCLUSION

In conclusion, the findings of this study suggest that the 3D printing of SILS port is technically feasible procedure and demonstrates potential advantages over the conventional port in terms of port placement, instrumentation, insufflation. However, further refinement and standardization of the 3D printing process are needed to optimize the quality and consistency of the printed product. With continued development, the 3D printed SILS port has the potential to revolutionize surgical port design and improve surgical outcomes.

Limitations

One of the main limitations of this study is the small sample size, which may limit the generalizability of the findings. Additionally, the 3D printed SILS port used in this study was not standardized and was not printed on a case-by-case basis, which could lead to variability in the quality and design of the port.

To address these limitations, future research should focus on standardizing the design and production of 3D printed surgical instruments, including SILS ports, to ensure consistency in quality and performance. This could involve the development of standardized templates or software programs that allow for the customization of 3D printed surgical instruments based on patient-specific needs.

Ethics:

The study was conducted in accordance with the principles of the Declaration of Helsinki. Ethical clearance was obtained from the institutional review board before the start of the study. Informed consent was obtained from all the study participants before enrollment.

Declaration of competing interest

No conflict of interest

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