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Design, manufacturing and initial evaluation of a 3D printed biliary anastomosis surgical simulator

Diseño, fabricación y evaluación inicial de un simulador quirúrgico de anastomosis biliar con impresión 3D

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Summary

Introduction: Medical simulation has been shown to improve surgeons' surgical skills in a safe environment. 3D printing offers a low-cost alternative for technical learning. The aim of this work was to describe the creation of a biliary anastomosis simulator with additive manufacturing and evaluate it by surgeons at various stages of training. Methods: Retrospective, descriptive, observational study with non-probabilistic sampling. The biliary anastomosis simulator was created with 3D printing and liquid silicone molding. It was evaluated using a Likert-type survey. Fidelity, functionality, and educational quality were measured. The total cost of the device was calculated. Descriptive statistics were applied. Results: Twelve people evaluated the simulator: 3 HPB surgeons, 4 HPB residents, and 5 general surgeons in training. The average age was 35.33 ± 11.02 years. 75% had experience with inorganic simulators and 50% with biliary anastomoses. The average previous surgical experience was 9.75 ± 11.01 years. Anatomical accuracy (2.58/5) and similarity to the bile duct (2.67/5) were the weakest points. Functionality (3.83/5) and durability (4.83/5) were highly rated. Educational quality received 4.67/5. Self-efficacy varied by experience: HPB surgeons (1.11/5), residents (3.42/5) and rotating surgeons (5/5). The overall evaluation was 4.5/5. Conclusions: Our study confirmed the feasibility of a 3D biliary anastomosis simulator using additive manufacturing and silicone molding. This accessible model facilitates the learning of biliary anastomosis in surgeons in training. Future research should demonstrate its educational efficacy and validity.

Keywords: bile ducts; simulated training; surgical anastomosis; surgical simulation

Abstract:

Background: Medical simulation has proven to enhance surgeons' skills in a safe environment. 3D printing offers a low-cost alternative for technical learning. This study describes the creation of a biliary anastomosis simulator using additive manufacturing and its initial evaluation by surgeons at various training stages. Methods: A retrospective, descriptive, observational study with non-probabilistic sampling was conducted. The biliary anastomosis simulator was created using 3D printing and liquid silicone molding. It was evaluated through a Likert-type survey, measuring fidelity, functionality, and educational quality. The total cost of the device was calculated. Descriptive statistics were applied. Results: Twelve participants evaluated the simulator: 3 HPB surgeons, 4 HPB residents, and 5 general surgery residents. The average age was 35.33 ± 11.02 years. Of the sample, 75% had experience with inorganic simulators, and 50% had experience in biliary anastomoses. The average surgical exposure was 9.75 ± 11.01 years. The weakest points were anatomical accuracy (2.58/5) and similarity to the bile duct (2.67/5). Functionality (3.83/5) and durability (4.83/5) were highly rated. Educational quality received a score of 4.67/5. Self-efficacy varied by experience: HPB surgeons (1.11/5), residents (3.42/5), and rotating residents (5/5). The overall evaluation was 4.5/5. Conclusions: Our study confirmed the feasibility of a 3D biliary anastomosis simulator using additive manufacturing and silicone molding. This accessible model facilitates the learning of biliary anastomoses among surgeons in training. Future research should demonstrate its educational efficacy and validity.

Keywords: bile ducts; simulation training; anastomosis, surgical; simulation, surgical

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1. Introduction

Simulation-based medical education plays a crucial role in developing surgeons' skills, allowing them to improve their technical skills in a safe and risk-free environment. In this way, the surgeon in training has the opportunity to make mistakes, learn from them and perfect their skills without endangering patient safety(1). There are various models and devices that use simulation as a method for surgical training(2). In general terms, surgical simulators can be classified as organic and inorganic(3). While organic simulators, whether *in-vivo* in animals or cadaveric, have high fidelity and realism, inorganic models tend to be less faithful, being expensive and not fully adapted to the needs of the student4. 3D printing has emerged in simulation-based medical education as a low-cost alternative for learning technical skills(4). The repetitive execution of simulated surgical acts can improve the safety, speed and technical fluency of the surgeon in training compared to traditional learning methods1. Since we have a post-basic residency in hepatopancreatobiliary (HPB) surgery and liver transplantation, we set out to develop a surgical simulator for end-to-end biliary anastomosis. This 3-year post-basic training program progressively exposes residents to increasingly complex procedures. This reconstruction technique is widely used in liver transplants and in the repair of surgical injuries to the biliary tract detected during surgery(5). Our residents begin performing this technique at the end of their first year of training and throughout their second year.

The main objective of this work was to describe the creation and development of an end-to-end biliary anastomosis simulator by implementing additive manufacturing technologies, as well as to provide an initial evaluation of it by surgeons at different stages of training.

2. Methods

This was a retrospective, descriptive, observational study created using non-probability convenience sampling. The simulator was designed to train HPB surgery and liver transplant residents. It was created in early December 2023 with the collaboration of two groups: the team from the Biomedical Modeling Area of the institution and surgeons from the HPB surgery and liver transplant service. After the development and production of the simulator, its evaluation was carried out between January and April 2024 at the Simulation Center by specialist surgeons, residents, and rotating surgeons (usually general surgery residents) of the service to determine its fidelity, functionality, and teaching quality.

The simulator was created using additive manufacturing techniques through 3D printing and liquid silicone molding. The following programs were used for its design: Autodesk Fusion 360® and its Meshmixer® application for 3D modeling (*Autodesk Inc, Mill Valley, California, United States*) and the Simplify3D® printing software (*Simplify3D Soft, Cincinnati, Ohio, United States*). The materials used to build the simulator were:

- For the negative mold or the 3D printed structure: 1.75 mm polylactic acid (PLA) filament in SILK® blue color was used (*Grilon3, Chivilcoy, Buenos Aires, Argentina*).
- For the positive mold or simulator itself: 10A 00-20 FAST® platinum-based addition-cure liquid silicone (*Smooth-On Inc, Macungie, Pennsylvania, USA*) was used. This silicone, characterized by its translucency, has a viscosity of 7000-9000 centipoise (cps), a Shore hardness of 0010, a tensile strength of 300 Psi, a tear strength of 80 Pli, an elongation of 600%, and a shrinkage of 0.1%.

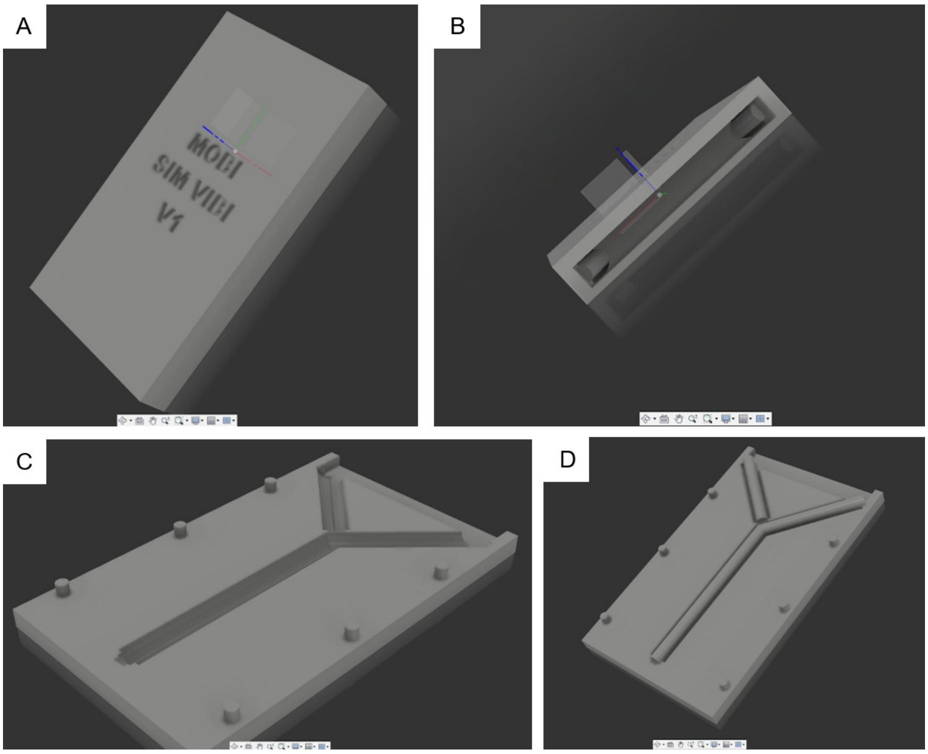

Figure 1. 3D rendering of the model mold in Autodesk Fusion 360®. (A) General, external view. (B) Top end where the silicone is poured. (C) Top half with the pouring channel. (D) Bottom half with the rods in position.

The simulator is made up of a 3D printed mould, which acts as a negative for pouring the silicone. The design of the simulator mould (Figure 1) was conceived to reproduce the fundamental structure of the main bile duct, representing the common bile duct/common hepatic duct and its respective bifurcation into the right and left hepatic ducts. In this way, a uniform hollow cylindrical structure of 10 mm in diameter is obtained, with 2 mm thick walls and an internal lumen of 6 mm. After demoulding and final trimming, a 130 mm long model is obtained. The design consists of two halves that are joined and compressed using screws and wing nuts, thus creating the tunnel necessary for pouring the silicone. Two 6 mm diameter rods were designed to fit into this tunnel and ensure that the bile duct is hollow.

To make the simulator, it was necessary to properly assemble the mold to allow the silicone to be poured directly into it (Figure 2). First, all the 3D printed components were properly positioned. It is important to note that three notches were incorporated at the ends of the model to ensure proper placement of the rods during pouring, as well as a receptacle on top to prevent possible spills. This commercial silicone consists of 2 compounds: a reagent A and a reactant B that must be mixed well in equal parts before pouring, allowing a working time of 30 minutes before it begins to harden. The model is completely filled with 15 cc of the final compound. This must dry for a period of 4 to 6 hours, depending on the ambient humidity conditions (23°C, according to the manufacturer's instructions).

Figure 2. Printed and finished mold, ready for the pouring process. (A) External, front view and (B) side view with four thumbscrews that ensure the mold is watertight. (C) Internal detail of the components.

To minimize the presence of air bubbles, the combined silicone mixture was poured gradually, and the mold was gently tapped on the sides and on the table. This procedure facilitated the displacement of the silicone along the tunnels and allowed the air bubbles to be released. The removal process involved separating the two outer halves of the mold. No release agent was necessary to facilitate removal. The rods were pushed out of the silicone, and the excess material was cut away to shape the bile duct. The properties of the material allow it to be fixed to various surfaces to ensure that it can be easily sutured by users. The completed simulator is shown in Figure 3.

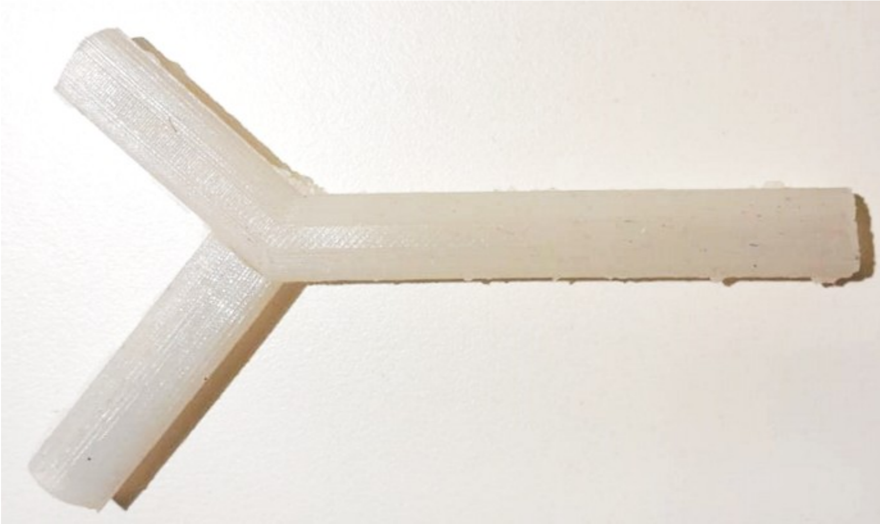

Figure 3. Finalized model after the curing process, ready to perform the anastomosis.

The end-to-end anastomosis technique used is the standard one for biliary reconstruction of liver transplants in adults with cadaveric donors in our center. The material used was: Castroviejo needle holder (17 cm), DeBakey atraumatic forceps (16 cm), curved Metzembaum scissors (14 cm), 6-0 PROLENE ® polypropylene suture as needed (*Ethicon Inc, Cincinnati, Ohio, United States* ; double needle 13 mm, ⅜ circumference, 75 cm) and straight or curved Mosquito forceps protected with a silicone sheath to pull the repair threads. The technique is summarized in the following steps: the user, located to the right of the model, cuts the main duct at the desired height to obtain two ends to anastomose, then begins by placing a stitch at the proximal end of the distal end (hour three) of the ends to anastomose, using a thread with two needles, following the direction "from outside to inside and from inside to outside" (Fig. 4-A). After tying and repairing one of the ends with a protected Mosquito clamp, the lumen is entered through the distal end of the proximal end and the posterior surget (continuous suture) is started, trying to take the entire thickness of the bile duct and maintaining symmetry as much as possible. When finished, the patient exits again to the exterior through the caudal end and the thread is repaired (hour 9, Fig. 4-B). To fix the posterior surget, a simple stitch is made at hour 9, which is first tied to itself extraluminally, and then to the surget thread. At the end of this plane, all sutures are repaired (Fig. 4-C). The anterior plane is made using simple sutures with threads of the same material, following the same principles as the posterior surget. Medial and lateral sutures are made in an alternating fashion (Fig. 4-D and Fig. 4-E, respectively) until reaching the middle of the plane, at which point they are deferred to adequately capture the walls and not compromise the posterior plane (Figure 4-F). After the last sutures are tied, all sutures are cut, thus completing the anastomosis (anterior plane Fig. 4-G, posterior plane Fig. 4-H). Each participant was assisted by the first author and used magnification with 2.5X Galilean surgical loupes.

The model was evaluated through a survey following a modified version of the *Michigan Standard Simulation Experience Scale* (MiSSES) (6) template to assess the simulator's fidelity, functionality, and teaching quality. All participants gave informed consent and approval to participate in the survey. Personal data have been treated in accordance with data protection laws. This survey consists of four sections:

1. General demographics,
2. Self-efficacy: the degree to which the simulator improves the learner's perception of his or her ability or comfort in completing the task,

3. Fidelity: Evaluation of general or specific attributes of the simulator, such as realism or fidelity as a whole or of its components,
4. Overall rating: overall evaluation of the educational experience.

Likert -type questions with five levels of mandatory response were included , detailed in Table 1. The survey was created and completed in Google Forms® at the end of the practice. The total cost of the simulator materials was calculated in Argentine pesos (ARS) and expressed in US dollars (USD, official exchange rate) at the time of the practice. Both the 3D printed negative mold and the final silicone product were included. The survey variables were considered ordinal data (7-8) and were presented using descriptive statistics, both as distribution frequencies for each question and as average and standard deviation (SD). The data were loaded and analyzed in Microsoft Excel® 16 (*Microsoft Corp, Redmond, United States*).

Table 1. Survey conducted with study participants at the end of the procedure. The value "one" represents the lowest score or totally disagree with the statement; on the other hand, the value "five" represents the highest score or totally agree with the statement.

No.	Sections and variables
	General demographics
1	Last name and first name
2	Age
3	Do you have previous experience with inorganic simulators? (Yes/No)
4	Do you have previous experience in biliary anastomoses? (Yes/No)
5	Years of surgical exposure
	Self-efficacy (scale 1 to 5)
6	This model helped improve my knowledge about the procedure.
7	This model helped improve my confidence in performing the procedure.
8	This model helped improve my ability to perform the procedure.
	Fidelity (scale from 1 to 5)
9	The simulator used has anatomically accurate features.
10	How accurate did the bile duct feel?
11	How well were you able to suture the bile duct?
12	How durable do you think the simulator is?
13	How difficult was it to use the model?
14	It is a useful training tool for the procedure in question.
15	Share comments/suggestions to improve the simulator
16	Overall evaluation of the model (scale from 1 to 5)

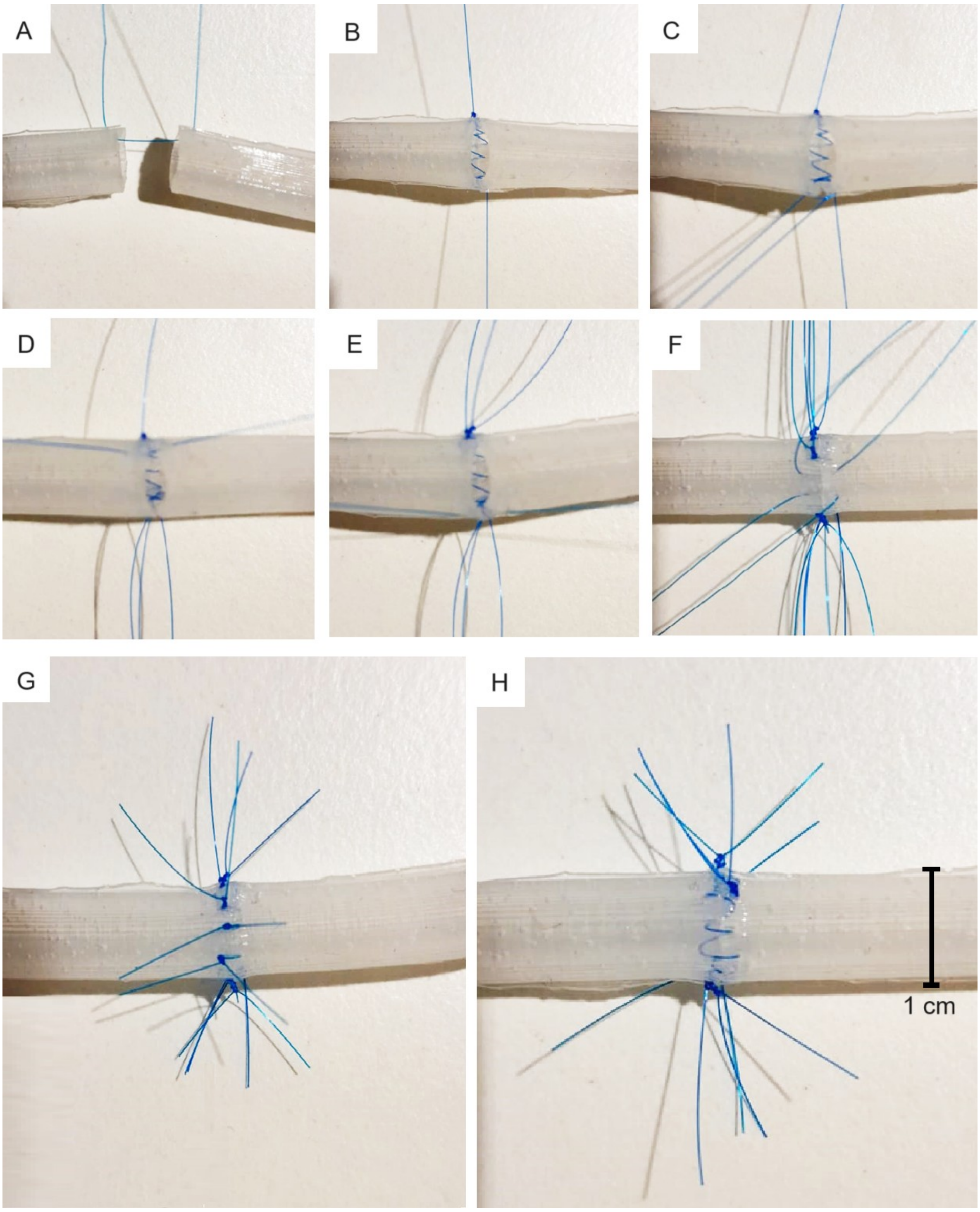

Figure 4. Technical detail of the anastomosis performed.

3. Results

In total, 12 subjects tested and evaluated the simulator. This sample consisted of 3 HPB surgeons, 4 HPB surgery residents, and 5 service rotators (4 4th-year residents and 1 general surgeon). The mean age was 35.33 ± 11.02 years (range 29–67). Three-quarters of the participants had experience using inorganic simulators (n = 9; 75%). Half of the participants had experience performing biliary anastomoses (n = 6; 50%). The mean number of years of surgical exposure since the beginning of surgical training was 9.75 ± 11.01 years (range 4–43). The scores obtained by the survey in each section are detailed in Table 2.

The weakest points of the simulator were anatomical accuracy (2.58/5; SD = 0.79) and level of similarity to the bile duct (2.67/5; SD = 0.98). The functionality of the simulator seemed to be a highlight, with an average response of 3.83/5 (SD = 1.4) on how well users were able to suture the wall, while durability was rated 4.83/5 (SD = 0.39). Looking at the comments and recommendations on the functioning of the simulator in Table 4, we found that many suggestions to improve fidelity included making the bile ducts thinner and coloring them, mostly green or dark green. Although the simulator was highly rated for its durability, user feedback suggests that the strength and hardness of the model make it less accurate.

Another notable result is the educational quality of the simulator, which was rated 4.67/5 (SD = 0.65) for its use as a training tool. The self-efficacy section received lower scores overall than the fidelity section (3.5/5 vs. 3.72/5 respectively). There was wide variability in responses, according to experience and previous exposure to the procedure, regarding the usefulness of the model in improving knowledge, confidence and ability. Although stratified analysis according to surgical exposure and experience was not considered, we were able to observe that the overall self-efficacy rating for experienced HPB surgeons was 1.11/5 (SD = 0.33), for residents it was 3.42/5 (SD = 1.78) and for rotating surgeons it was 5/5 (SD = 0). The overall evaluation of the model yielded a score of 4.5/5 (SD = 0.52), considering it, especially by the most experienced, as a useful tool to systematize the execution of the procedure and generate skill when performing it on patients.

Table 2. Score obtained from the evaluation of the model by the participants.

No.	Sections and variables	
	Self-efficacy (scale from 1 to 5)	Mean ± SD
1	This model helped improve my knowledge about the procedure.	3.33 ± 2.06
2	This model helped improve my confidence in performing the procedure.	3.5 ± 1.93
3	This model helped improve my ability to perform the procedure.	3.67 ± 1.72
	Fidelity (scale from 1 to 5)	3.72 ± 1.3
4	The simulator used has anatomically accurate features.	2.58 ± 0.79
5	How accurate did the bile duct feel?	2.67 ± 0.98
6	How well were you able to suture the bile duct?	3.83 ± 1.4
7	How durable do you think the simulator is?	4.83 ± 0.39
8	How difficult was it to use the model?	3.75 ± 1.36
9	It is a useful training tool for the procedure in question.	4.67 ± 0.65
10	Overall evaluation of the model (scale from 1 to 5)	4.5 ± 0.52

The cost of acquisition of materials, calculated in December 2023, was as follows:

• 1 kg of platinum-based addition-curing liquid silicone 10A 00-20 FAST® (Smooth-On Inc, Macungie, Pennsylvania, United States) at a cost of AR$ 13,570 or USD 15.39;

• 500 g of 1.75 mm PLA filament in SILK® blue (Grilon3, Chivilcoy, Buenos Aires, Argentina) at a price of AR$ 7,699 or U$D 8.73.

The total price was AR$ 21,269 (US$ 24.01). Considering that 166 g of PLA were used for printing the mold (AR$ 2,556) and 15 g of silicone for pouring the model (AR$ 203.55), the cost for each one was AR$ 2,759.55 or US$ 3.13. With each purchase, 3 PLA molds and 66 bile duct models could be made.

Table 3. Participants' comments and suggestions to improve the model.

No.	Input
1	It would be helpful to elevate the model off the work surface and secure some form of fixation to help keep the ends to be anastomosed separated.
2	Improve the fixing system of both the model and the base.
3	Make the walls thinner to give it more flexibility. It would also be a good idea to color it to make it easier to see the edges.
4	Wall thickness. The wall is very elastic. Lacks malleability, does not collapse like a real bile duct. Consider the possibility of coloring the model to better distinguish the walls.
5	The model is very useful for systematizing the procedure and learning how to use suture material. Although it does not optimally reflect reality, it helps to develop surgical habits.

4. Discussion

Surgical training programs are giving increasing importance to simulation-based training in response to the need for greater efficiency in the use of time in the operating room and to ensure patient safety. Surgical simulation allows residents to be trained in a more complete and safe manner, providing them with a set of fundamental skills before performing a procedure on the patient [9] . Importantly, it also allows residents from lower-volume centers or centers not specialized in a particular surgical area to be exposed to different procedures (9). The acquisition of surgical skills requires constant deliberate practice, and many of them can be learned outside the operating room (10). It has been shown that training in a simulated model has improved the overall performance of the resident, with greater efficiency in the use of time and movement, fewer errors, and less discomfort when applying their surgical skills in real patient care (10).

Currently, surgical simulators are divided into two categories: organic and inorganic. Organic models, ranging from live animals to fresh human cadavers, are largely considered high fidelity. However, this modality poses a series of challenges, both economic and ethical-legal (11). This problem has driven the search for other alternatives focused on simulation with inorganic materials. Thus, the initial trigger for creating the model was to acquire operational skills that guarantee safety, absence of risk for the patient, are economically accessible, easy to reproduce and portable to allow continuous training outside the operating room.

Although the model was well received by the evaluators, highlighting mainly its ease of use, durability and resistance, some critical aspects were identified that require analysis. One of the problematic points was the lack of anatomical precision, particularly evident in the diameter and thickness of the walls, which significantly influenced the negative evaluations. On the other hand, it was observed that the silicone exhibited a notable resistance to tearing and traction, which facilitated the manipulation and knotting of the stitches, although this deviated from the real behavior of the tissue. By incorporating the biliary confluence into the three-dimensional model, we wanted to provide the simulator with greater realism. However, this aspect did not ultimately influence the execution of the task. It will surely be useful if one were to simulate a bi-hepaticojejunostomy or hepaticojejunostomy at the level of the confluence, imitating other types of clinical situations.

A similar model created by the University of Montreal(12) obtained similar results to ours regarding material durability and ease of handling of the model. The participants also criticized the lack of realism. As notable differences, they used a 3D mold that could produce 4 simulators at a time and colored the model dark green from the beginning. Paradoxically, the users of that model suggested that it be made lighter or more transparent to facilitate the visualization of the points. The study conducted by Thomas et al.(13) demonstrated the possibility of making realistic 3D prints of extrahepatic bile ducts using elastic polymers, obtaining mechanical properties similar to real tissue. Unlike our experience, this model was used to practice endoscopic biliary stenting.

Researchers from the Autonomous University of Nuevo Leon (14), in Mexico, used 3D modeling and printing techniques with acrylonitrile butadiene styrene, a highly resistant type of plastic, to manufacture videolaparoscopic cholecystectomy models with different variants of the cystic duct outlet. In their research, once the negative mold was created, they poured silicone rubber, a more rigid and manipulable material, to make the final model. They achieved a high acceptance rate among the 30 study participants and maintained a low production cost (US$ 20.5 per reusable model).

Other working groups have explored the applications of synthetic materials to simulate tissues in hepatobiliary-pancreatic procedures. For example, Yoshioka et al.(15) used a commercial model of the pancreas and jejunum made of polyvinyl alcohol to simulate a conventional pancreaticojejunostomy. This study focused on improving technical performance and reducing the time required to complete the task, but did not address cost issues or global acceptance of the model. Similarly, Oshiro et al.(16) used a model printed in the same material with the addition of “fibers” (no further details provided) to reduce the tear rate during suturing. On the other hand, Fangqiang et al.(17) combined commercially available materials with 3D-designed and silicone-printed materials to simulate the same procedure, using the robotic approach in three different scenarios according to Wirsung duct diameter and gland atrophy. Despite high acceptance rates among the three surgeons who performed the procedure, it was acknowledged that the sample size was too small to draw definitive conclusions.

Researchers from the Department of Radiology at George Washington University(18) have pushed the applications and potential of 3D printing to the maximum by creating a complete liver, with its corresponding vascular and biliary segmentation, in polyamide and different types of resin. This model allowed the practice of taking biopsies of liver lesions, simulating transarterial chemoembolization procedures, placing percutaneous drains to drain abscesses and placing a TIPS (*transjugular intrahepatic portosystemic shunt*) device.

Other notable uses of 3D design and printing are preoperative planning and development of approach strategies in perihilar cholangiocarcinomas(19), liver metastases from colorectal cancer and hepatocellular carcinomas(20).

The present study had several limitations. Due to the exploratory nature of the research, formative assessment scales such as the OSATS(21) (*Objective Structured Assessment of Technical Skills*) were not used, and a repeated and longitudinal follow-up of the sample was not performed. Therefore, we were unable to determine whether the model influenced the improvement of long-term surgical skills that could be directly related to real intraoperative situations. In addition to being small, our sample was very heterogeneous, as it included participants at various stages of training, from residents in general surgery to specialist surgeons with more than 40 years of experience. Therefore, the evaluation and final critique of the model were very varied. These factors could make the interpretation of the results difficult and have incurred in a selection bias, preventing the extrapolation of the findings. However, the results of the present study could certainly encourage surgeons to create such devices and/or implement simulation-based training programs in their institutions.

In addition to the shortcomings pointed out by the participants, this model simulated an anastomosis with a 1:1 ratio between the donor and recipient bile ducts. In practice, there is often an incongruity between the two ends, which requires various technical variants of reconstruction, such as the longitudinal opening of the anterior face of the bile duct to increase its diameter, the performance of end-to-side anastomoses or, ultimately, a Roux-en-Y hepaticojejunostomy. A step not considered in the literature, but which could potentially be incorporated into its use, is the evaluation of the patency and tightness of the anastomosis. Some proposals in this regard are the continuous infusion at low flow of dyed water to simulate bile production after hepatic reperfusion, or the direct instillation through syringes with distal closure of the model to evaluate leaks.

Although the initial investment is not negligible, the ability to adapt the model to the educational needs of the learners, the reuse of the same mold and the low amount of silicone needed for its creation make it a reasonable option in terms of cost-benefit. As an experience and as a corollary of this research, taking into account the suggestions and comments of the users, we 3D printed a smaller and more delicate version, with 1 mm walls, 6 mm lumen giving a total diameter of 8 mm, dyed dark green with tempera paint (figure 5). We are still waiting for its testing and evaluation. Although a frequent suggestion from the interviewees was the difficulty that the transparent wall presents for suturing as it does not cast a shadow and alters the perception of depth, we believe that it was positive for evaluating the path and symmetry of the stitch throughout its entire path, being able to give more appropriate feedback to the learner.

We believe that as these models become more widely used, production costs and processing times will decrease even further, allowing them to compete with commercial models available on the market, which are generally more expensive. In addition, this type of activity encourages multidisciplinary work by involving various actors from different departments, such as engineers, technicians, graduates in education or pedagogy, and surgical instrument technicians. As with all clinical and surgical simulation activities, this one was developed in a space of learning and recreation for all participants, allowing them to share experiences in a relaxed and pressure-free environment and fostering camaraderie (Figure 6). The focus of our research was on the preparation of the technical report to develop the simulator and carry out the initial evaluation of the operators. Therefore, the analysis of its validity is beyond the scope of this study.

Further studies are needed with larger and more homogeneous samples, or with groups stratified according to educational levels, where validated evaluation scales are applied to demonstrate the effectiveness of this type of model.

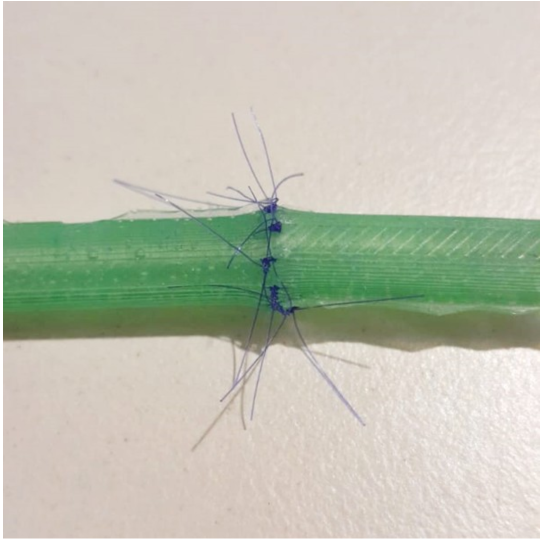

Figure 5. Mold tinted green with tempera paint.

Figure 6. 1st year HPB surgery and liver transplant resident performing the model evaluation.

5. Conclusions

- Our study demonstrated the feasibility of designing and manufacturing a 3D simulator for performing end-to-end biliary anastomosis using additive manufacturing and silicone molding techniques. This model offers an accessible and easily implemented platform for surgical residents to acquire skills in this surgical technique.
- With some adjustments, such as reducing the diameter and firmness of the simulated bile ducts and improving the colors to achieve a more realistic appearance, this simulator has the potential to become an excellent tool for surgical training.
- Future research will be necessary to demonstrate its educational efficacy, validity and transferability of these skills to the operating room.

Supplementary material: indicate the name of the file and what it contains.

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Author contributions : Rodrigo Antonio Gasque (RAG) conceptualized and designed the study. RAG, Noelia Zaietta (NZ), and Lourdes Mollard (LM) participated in data collection and writing the manuscript. José Gabriel Cervantes (JGC) and Magalí Chahdi Beltrame (MCB) collaborated in data analysis and critical revision of the manuscript. Marcelo Enrique Lenz Virreira (MELV) provided technical supervision and made methodological corrections. Emilio Gastón Quiñonez (EGQ) and Francisco Juan Mattera (FJM) participated in the general supervision of the study and in the final revision of the manuscript. All authors read and approved the final version of the manuscript.

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