



# Face and content validity of a biological papilla designed for the Boškoski-Costamagna ERCP simulator

Sara Teles de Campos, MD,<sup>1,2</sup> Ivo Boskoski, MD, PhD,<sup>4</sup> Theodor Voiosu, MD, PhD,<sup>5</sup>  
Marianna Arvanitakis, MD, PhD,<sup>2,3</sup> Guido Costamagna, MD, PhD,<sup>4</sup> Jacques Devière, MD, PhD<sup>1,2,3</sup>

Lisbon, Portugal; Brussels, Belgium; Rome, Italy; Bucharest, Romania

**Background and Aims:** A biological papilla made of chicken heart tissue, incorporated into the Boškoski-Costamagna ERCP Trainer simulator, was recently designed to allow training in sphincterotomy. This study aimed to evaluate the face and content validity of this tool.

**Method:** Participants from 2 groups (nonexperienced and experienced [ $<600$  or  $>600$  lifetime ERCPs, respectively]) were invited to perform standardized assignments on the model: sphincterotomy and precut for both groups and papillectomy for the experienced group. Following these assignments, all participants filled out a questionnaire to rate their appreciation of the realism of the model, and experienced endoscopists were also asked to evaluate its didactic value using a 5-point Likert scale.

**Results:** A total of 19 participants were included (nonexperienced,  $n = 10$ ; experienced,  $n = 9$ ). Parameters regarding the realism of the tool in terms of general appearance, sphincterotomy, precut, and papillectomy were overall considered realistic (4 of 5), with good agreement rates in terms of overall realism between groups. Experienced operators reported the highest realism for “positioning the scope and needle-knife in the field of view” and “during precut,” “cutting in small increments during precut,” and “controlling the scope during papillectomy,” and they highly agreed that this papilla should be included for training novice and intermediate trainees in sphincterotomy, precut, and papillectomy.

**Conclusions:** Our results show good face validity and excellent content validity of this biological papilla combined with the Boškoski-Costamagna ERCP Trainer. This new tool provides a useful, inexpensive, versatile, and easy tool for training regarding sphincterotomy, precut, and papillectomy. Future studies should explore whether including this model in real-life training improves the learning curve of endoscopy trainees. (Gastrointest Endosc 2023;98:822-9.)

ERCP is one of the most challenging and complex endoscopic procedures, with a steep learning curve.<sup>1</sup> Proper training is therefore essential to achieve competence and to accomplish these procedures safely and with efficacy. To limit the exposure of patients to performer-related risk factors such as operator experience, simulator-based endoscopy education has been increasingly advocated as a potential solution to accelerate trainee learning curves.

Several training models have been developed thus far, including in vivo and ex vivo models, mechanical simulators, and virtual reality simulators.<sup>2</sup> The Boškoski-Costamagna ERCP Trainer is one of the most highly valued simulation prototypes for ERCP training in ductal cannulation, stent placement, and stone extraction. It has already been shown to have good face and construct validity,<sup>3</sup> and it is currently being evaluated for its predictive validity

Abbreviation: ICC, intraclass correlation coefficient.

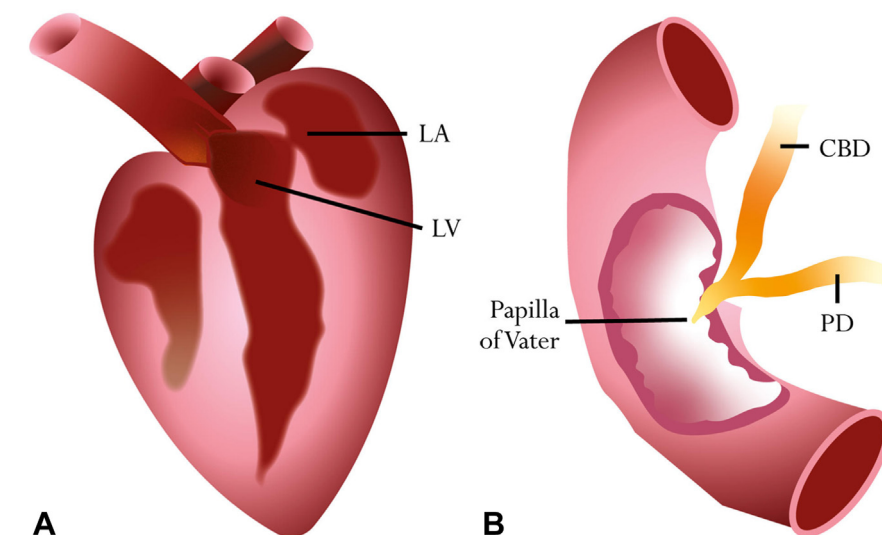
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Current affiliations: Gastroenterology Department, Digestive Unit, Champalimaud Foundation, Lisbon, Portugal (1); Université Libre de Bruxelles, Brussels, Belgium (2); Gastroenterology, Hepatopancreatology and Digestive Oncology, Erasmus University Hospital, Brussels, Belgium (3); Gastroenterology and Digestive Endoscopy, Fondazione Policlinico Gemelli, Rome, Italy (4); Gastroenterology Department, Colentina Clinical Hospital, Carol Davila Faculty of Medicine, Bucharest, Romania (5).

Reprint requests: Sara Campos, MD. E-mail: [saratcampos@gmail.com](mailto:saratcampos@gmail.com).



**Figure 1.** Schematic figure of anatomical representation. **A**, Chicken heart. **B**, Papilla of Vater. *LA*, Left atrium; *LV*, Left ventricle; *CBD*, common bile duct; *PD*, pancreatic duct.

in a randomized prospective study ([ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT05533944) identifier: NCT05533944).

The Boškoski-Costamagna ERCP Trainer has been optimized over time. The original version of the simulator was equipped with a papilla composed of latex, and sphincterotomy on this iteration of the model was not possible. However, endoscopic sphincterotomy constitutes a key therapeutic step of ERCP,<sup>4</sup> and it is also considered to be one of the high-risk components of this procedure that is associated with the endoscopist's experience.<sup>5</sup> As such, it became crucial to develop a tool to ensure training on this aspect. To accomplish this goal, a single-use synthetic papilla was developed by Cook Medical (Limerick, Ireland) for the Boškoski-Costamagna ERCP Trainer and later evaluated for its face validity.<sup>6</sup> Although the Cook Medical synthetic papilla was found to be satisfactory in terms of overall realism for performing a sphincterotomy, the level of haptic feedback was limited by the cutting effect, which was "not perceived as expected."<sup>6</sup> To overcome the limitations inherent to a synthetic tissue, a biological papilla, made of chicken heart tissue, has been recently created, with the aim of enabling a more realistic training experience.

There are different levels of assessment used to test the validity of a simulator, with the initial steps being the face validity and the content validity. Face validity is defined as the extent to which a simulator's content is representative of the skills that are learned in the real environment, which, in this case, addresses the question of how realistic the simulator is considered.<sup>7-9</sup> Content validity answers the question of how useful the simulator is for learning relevant skills, which, in the context of the biological papilla, refers to the assessment of its suitability as a learning tool for both achieving ductal access and performing sphincterotomy. The aim of the current study was to evaluate

the realism (face validity) and didactic value (content validity) of this biological papilla.

## METHODS

### Biological papilla

The biological papilla is a newly developed insertable component in the previously described mechanical Boškoski-Costamagna ERCP Trainer that can be used to simulate the selective ductal cannulation process and the techniques of ductal access, namely sphincterotomy.

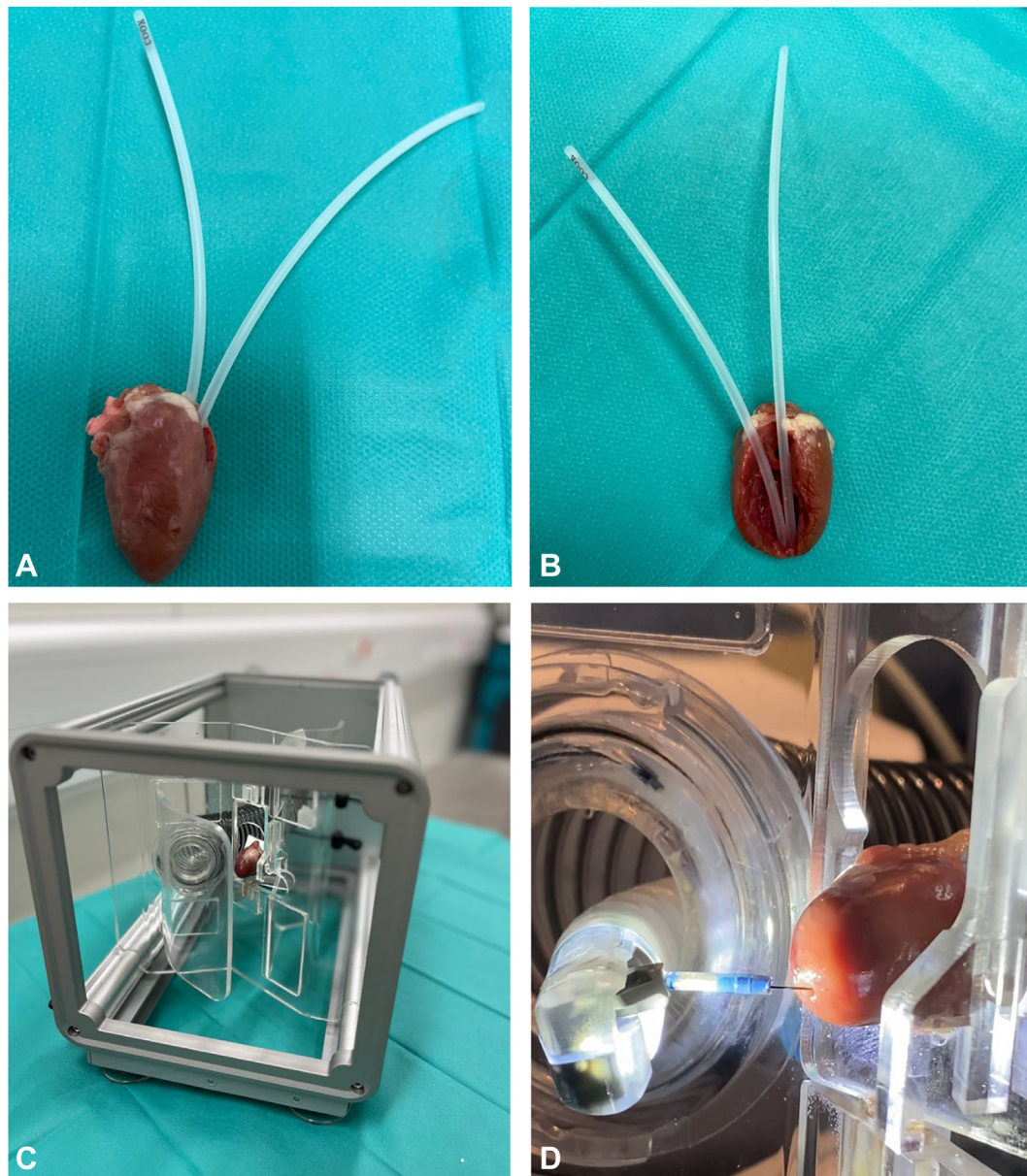
The use of chicken heart tissue in ERCP simulators has been previously reported,<sup>10-12</sup> and it was selected because it resembles a real major papilla in terms of size, shape, and color (Figs. 1, 2A and B). The chicken heart tissue papilla can be easily manually inserted into the ERCP trainer (Fig. 2C), and rapidly exchanged. A millimeter-sized hole is artificially created at the apical wall of the left ventricle to allow ductal cannulation through one of the chambers (Fig. 2D). The biological papilla is a disposable tool that allows for electrical conduction and cutting of the material with all commercially available sphincterotomes and needle knives.

### Ethics committee approval

Because the study involved no human or live animal subjects, it was exempt from review by the institutional review board.

### Participants

Participants were divided into 2 study groups based on their self-reported lifetime ERCP experience: nonexperienced (up to 600 lifetime ERCPs performed) and experienced (>600



**Figure 2.** **A**, Frontal view of the chicken heart specimen. **B**, Chicken heart with the plastic tubes inserted into the chambers to resemble biliary and pancreatic ducts to allow cannulation. **C**, Frontal view of the chicken heart papilla attached to the model. **D**, Lateral view of the chicken heart papilla attached to the model.

lifetime ERCPs performed). Because there is no formal definition of an “experienced” ERCP endoscopist, we adopted the same definition as has been previously reported in the literature for the same purposes.<sup>3,6</sup>

### Simulation setting

Simulator sessions were organized at the participating institutions (Fondazione Policlinico Gemelli, Rome, Italy; Erasmus Medical Center, Rotterdam, the Netherlands; and Institute de Recherche contre les Cancers de l’Appareil Digestif, Strasbourg, France) either to perform general ERCP simulation-training using the Boškosi-Costamagna ERCP

Trainer simulator (for the nonexperienced group) or to specifically target the aim of this study (for the experienced group). All participants were invited to perform up to 3 standardized assignments: sphincterotomy and precut for both groups, and papillectomy for the experienced group. A DASH Sphincterotome DASH-35-48 (Cook Medical) and a guidewire Acrobat2 (Cook Medical) were used to perform sphincterotomy; a Huibregtse Precut Knife HPC-2 (Cook Medical) was used for precut; and an ACU Snare AS-1-S (Cook Medical) was used for papillectomy. An ERBE VIO 200D (Erbe Elektromedizin GmbH, Tübingen, Germany) electrosurgical system was used, with the

**TABLE 1. Baseline characteristics of participants**

Characteristic	Nonexperienced (n = 10)	Experienced (n = 9)
Sex, male	8 (80%)	9 (100%)
Age, median (IQR), y	31 (7)	49 (8)
No. of nationalities	7	4
Medical background		
GE resident	6 (60%)	0
GE specialist	4 (40%)	9 (100%)
Workplace		
Academic hospital	8 (80%)	9 (100%)
Regional hospital	2 (20%)	0
ERCP experience, median (IQR), y	2 (3)	14 (14)
Previous simulator experience	5 (50%)	6 (66.7%)

IQR, Interquartile range; GE, gastroenterology.

following settings: ENDO CUT I, effect 2 for sphincterotomy and precut; and ENDO CUT Q, effect 2 for papillectomy. The cutting length of the sphincterotomy was considered optimal when the cutting reached the rubber edge of the simulator.

Following these assignments, the participants were invited to fill out a questionnaire on demographic characteristics, endoscopy experience, and previous simulator training experience. They were also asked to rate their appreciation of the realism of the cutting papilla. Appreciation was expressed on a 5-point Likert scale, varying from very unrealistic (1) to very realistic (5). Questions included the realism of anatomical representation, simulator setup, endoscopic/device control, the actual cutting, and the achieved cutting result and haptic feedback. Furthermore, the experienced group was also asked to evaluate the didactic value of the cutting papilla on a 5-point Likert scale, varying from strongly disagree (1) to strongly agree (5). The questionnaire is further detailed as [Supplementary Material](#).

### Data analysis

Statistical analyses were performed by using SPSS version 28 (IBM SPSS Statistics, IBM Corporation, Armonk, NY, USA). Face validity was stratified according to nonexperienced and experienced groups, whereas content validity data were only collected in the experienced group. Data were tested for normality by using the Shapiro-Wilk test and are expressed as median and interquartile range (IQR). In addition, differences between nonexperienced and experienced ratings for each face validity statement were analyzed with the Mann-Whitney *U* test, with a *P* value  $\leq .05$  indicating significance. Inter-rater agreement and reliability were evaluated by computing the intraclass correlation coefficient (ICC) in a 2-way mixed model.

## RESULTS

### Demographic characteristics

A total of 19 participants (17 male subjects [89.5%]) from 9 different countries and with different levels of ERCP expertise agreed to participate in this study. Based on the lifetime number of ERCPs performed, 10 were included in the nonexperienced group and 9 in the experienced group. Participants' baseline characteristics are presented in [Table 1](#).

### Face validity

Participants rated the biological papilla according to several parameters of face validity (Question 1-Question 25), which are described in [Table 2](#). Practically all of the parameters were rated as "realistic," with a few exceptions for "positioning of the sphincterotome during cannulation" and "controlling the direction of the sphincterotome during cutting" for the nonexperienced group; "cutting slowly with small increments during precut" and "controlling the scope during papillectomy" for the experienced group; and "positioning of the needle-knife in the field of view" and "during cutting" for both groups, which achieved the highest scores ("very realistic"). There were no significant differences in ratings between groups.

For validity content, the ICC displayed a good agreement rate and reliability between both groups concerning the overall realism of the tool (ICC = .743; 95% confidence interval, .237-.969).

### Content validity

Median scores of statements from the experienced participants regarding chicken heart papilla as a learning tool (Question 26-Question 31) are shown in [Table 3](#).

For content validity, the ICC displayed a high overall agreement and reliability between experienced participants (ICC = .858; 95% CI, .555-.977), indicating that the "expertise gained with this papilla can be transferrable into clinical setting" and that it is a useful tool to be included "in an ERCP training curriculum" for "novice and intermediate endoscopists," despite having a limited role for "training of experienced endoscopists" or "(re)certification in ERCP."

## DISCUSSION

Our results show good face and content validity of this hybrid model, consisting of a new biological papilla adapted to the mechanical Boškoski-Costamagna ERCP Trainer simulator, for endoscopic sphincterotomy, precut, and papillectomy training. The latter 2 situations are those in which clinical training is particularly difficult to obtain during ERCP fellowships, either because it comes late after starting the ERCP procedure or because it is potentially associated with severe adverse events. All experienced

**TABLE 2. Items used to determine face validity, rated by the participants with different levels of ERCP expertise, on a 5-point Likert scale**

Face validity parameters	Median (IQR) score according to level of ERCP expertise			P value
	Total	Nonexperienced opinion	Experienced opinion	
General appearance				
Q1. Resemblance to the real papilla	4 (0)	4 (0)	4 (1)	NS
Q2. Positioning in front of the papilla	4 (0)	4 (1)	4 (0)	NS
Sphincterotomy				
Q3. Positioning of the sphincterotome during cannulation	4 (1)	5 (1)	4 (1)	NS
Q4. Controlling the direction of the sphincterotome during cutting	4 (1)	5 (1)	4 (1)	NS
Q5. Controlled cutting in small increments	4 (1)	4 (1)	4 (1)	NS
Q6. Cutting/coagulation effects	4 (1)	4 (1)	4 (1)	NS
Q7. Controlling guidewire introduction	4 (0)	4 (1)	4 (0)	NS
Q8. Controlling the scope during procedure	4 (1)	4 (1)	4 (1)	NS
Q9. Overall appreciation in comparison to real situation	4 (1)	4 (1)	4 (1)	NS
Precut				
Q10. Positioning of the needle-knife in the field of view	5 (1)	5 (1)	5 (1)	NS
Q11. Positioning of the needle-knife during cutting	5 (1)	5 (1)	5 (1)	NS
Q12. Cutting slowly with small increments	4 (1)	4 (1)	5 (1)	NS
Q13. Cutting control "layer-by-layer," exposing deeper layers	4 (1)	4 (0)	4 (1)	NS
Q14. Cutting/coagulation effects	4 (1)	4 (1)	4 (1)	NS
Q15. Controlling guidewire introduction	4 (1)	4 (1)	4 (0)	NS
Q16. Controlling the scope during procedure	4 (1)	4 (2)	4 (1)	NS
Q17. Overall appreciation in comparison to real situation	4 (1)	4 (1)	4 (1)	NS
Papillectomy				
Q18. Positioning of the snare in the field of view	4 (1)	–	4 (1)	NS
Q19. Controlling the scope during the procedure	5 (1)	–	5 (1)	NS
Q20. Overall appreciation in comparison to real situation	4 (0)	–	4 (1)	NS
Overall realism				
Q21. Anatomical representation	4 (0)	4 (1)	4 (0)	NS
Q22. Simulator setup	4 (1)	4 (1)	4 (0)	NS
Q23. Endoscopic and devices control	4 (1)	4 (1)	4 (1)	NS
Q24. Haptic feedback	4 (1)	4 (1)	4 (1)	NS
Q25. Difficulty	4 (1)	4 (0)	4 (1)	NS

IQR, Interquartile range; Q, question; NS, not significant.

**TABLE 3. Items used to determine content validity, rated by the experienced participants, on a 5-point Likert scale**

Content validity parameter	Experienced opinion
Q26. Expertise gained with this papilla is transferrable into clinical setting	5 (0)
Q27. Useful tool to be included in an ERCP training curriculum	5 (0)
Q28. Useful tool to be included in the training of novice endoscopists (<50 lifetime ERCPs)	5 (0)
Q29. Useful tool to be included in the training of intermediate endoscopists (50-600 lifetime ERCPs)	5 (1)
Q30. Useful tool to be included in the training of experienced endoscopists (600-2500 lifetime ERCPs)	3 (1)
Q31. Useful tool for (re) certification in ERCP	3 (2)

Values are median (interquartile range).

Q, Question.

ERCP operators strongly agreed on the didactic value of this tool, which goes beyond the novice trainees and extends to intermediate ERCP operators, and on its incorpo-

ration into the ERCP training curriculum. The Boškoski-Costamagna ERCP Trainer, a mechanical simulator that has been proven to have good face and construct validity

for basic ERCP training,<sup>3</sup> offers better therapeutic training capabilities with this biological model, even compared with the synthetic papilla that was available previously.<sup>6</sup>

Teaching endoscopic sphincterotomy traditionally involves supervised hands-on clinical practice in a master/apprentice model. However, sphincterotomy and precut techniques are high-risk components of ERCP because they can be associated with several adverse events, including perforation, pancreatitis, and bleeding.<sup>5</sup> Proper positioning of the scope (to allow a correct orientation toward the papilla) and appropriate cutting along the correct axis, while adjusting and controlling the cutting devices, the scope, its wheels, and elevator,<sup>15</sup> are crucial to reducing adverse events and optimizing results. Because most adverse events have been systematically associated with endoscopist experience,<sup>14</sup> training for this step in real-life situations can be limited. In addition, because it is recommended that training be performed in tertiary high-volume centers,<sup>15</sup> the training opportunities for novice ERCP endoscopists can be limited.<sup>16,17</sup> At referral centers, the number of complex procedures tends to be high, and the number of naïve papillae to be relatively low, as previously reported,<sup>18</sup> resulting in a reduced exposure of trainees to potential cases of native papilla anatomy. This is even more clear for the indications related to precut, which is often decided at a time when the master has already taken over or for the rare indication of papillectomy. Taking all these aspects into account, the development of alternatives for complementing traditional ERCP training programs is urgently needed. The possibility of using simulators to provide training in an optimal risk-free environment with supervisor feedback is therefore highly appealing.

This biological papilla design incorporated into the ERCP trainer has multiple advantages. Chicken hearts are inexpensive (the price of a pack of 25 chicken hearts is \$2.56, compared with a synthetic papilla that costs \$.80 per unit) and available in local grocery stores and can be easily prepared and attached to the simulator. This results in a versatile cutting model because it can be rotated manually to allow further cuts along different axes, before exchanging it for a new papilla (an average of 2 to 3 attempts in each papilla can be performed to train sphincterotomy/precut). To train ductal access, the traditional plastic tubes used in this mechanical simulator can be easily mounted on this tissue (Figs. 2A and B), and both the common bile duct and pancreatic ducts can be cannulated, separately or simultaneously. Apart from enabling training of conventional sphincterotomy using a pull-type sphincterotome and precutting by using a needle-knife, this tool also allows teaching of endoscopic papillectomy with diathermy snares, a seldomly available feature in comparisons versus other simulators. As a result, this new tool incorporated in the Boškoski-Costamagna ERCP Trainer now makes it feasible to perform all ERCP interventions with this simulator. In fact, apart from enabling the scope to freely move in the duodenum and be correctly positioned, while also enabling handling the

wheels and the elevator, targeting the papilla with different grades of complexity (due to different levels of patient position and papilla orientation) and attaining the proper axis to selectively cannulate the biliary and pancreatic ducts, extract stones, and place plastic and metal stents,<sup>3,19</sup> it is now possible to perform sphincterotomy, precut, and papillectomy in a very simple and realistic way.

For face validity, parameters regarding the realism for general appearance, sphincterotomy, precut, and papillectomy were overall rated as “realistic” (median score, 4 of 5), with good agreement rates between all participants for the overall realism of the tool. The minor differences in realism compared with human papilla tissue may be accounted for by the lack of clear papillary complex landmarks, the lack of respiratory variation and bowel wall peristalsis, and the lack of intraprocedural bleeding, as reported in the individual comments from the experienced group.

Agreement rates regarding content validity were high for using this tool “in the ERCP training curriculum” and for “training novice and intermediate endoscopists” as the “expertise gained with this papilla can be transferrable into clinical setting.” Nonetheless, its role for “training of experienced endoscopists” or “(re)certification in ERCP” is limited.

Although the goal of the current study was validation of this biological model, without comparison versus other teaching models, it offers obvious advantages over its former synthetic version constructed of rubber. The major advantage is the cutting effect itself, which seems to be more realistic than the previous version for which the “cutting process” was only rated as 6 on a 10-point Likert scale.<sup>6</sup> In fact, the cutting settings on the electrosurgical generator are the same as the ones used in real-life situations. In addition, compared with the synthetic papilla, this new version enables the performance of other ERCP procedures, namely papillectomy, the performance of which requires specific procedures to ensure en bloc nonsuperficial resection. The complexity associated with papillectomy, a grade 4 procedure according to the Schutz classification,<sup>20</sup> is partially due to its associated risks.<sup>5</sup> As such, all training opportunities in ex vivo models should be explored before attempting such procedures in real-life patients.

Several other ERCP simulators are currently available.<sup>2</sup> Mechanical simulators, such as the X-Vision ERCP Training System<sup>21</sup> and the ERCP Mechanical Simulator,<sup>22</sup> use nonbiological casted organic rubber and foamy soaked conducting gel, respectively, to train endoscopic sphincterotomy, with its inherent limitations mentioned earlier. Live anesthetized pig models, although shown to be adaptable to all procedural aspects of ERCP, are currently underused due to high costs, logistical demands (specialized personnel), and the need for bioethics committee approval. Furthermore, anatomical differences between porcine and human anatomy, including the unusual location of the major papilla (rather difficult to localize because of its more proximal location compared with human papilla), tight angulation of the

bile duct, and the lack of the pancreatic duct adjacent to the bile duct orifice and sphincter render this model impractical for standard training programs. Itoi et al<sup>23</sup> reported an in vivo and ex vivo model using a porcine stomach and rectum using a simulated papilla, by submucosal injection of hyaluronate solution into the porcine mucosa to make it swell and allow endoscopic sphincterotomy and papillectomy. This model requires the preparation of a porcine stomach, is limited by the maneuverability of the scope, and does not allow the cannulation and placement of a guidewire to perform sphincterotomy. Ex vivo porcine simulators offer the same advantages as a live animal and are easier to use, less costly, and eliminate ethical concerns, but the issue regarding the anatomy of a porcine papilla remains. As such, alternatives have been developed to overcome this limitation, and chicken heart explants have been used. The artificial neo-papilla model by Matthes and Cohen<sup>10</sup> uses a modified chicken heart, which is more visible because of its increased prominence, and is attached to an porcine ex vivo model such as the Erlanger Active Simulator for Interventional Endoscopy. However, the protocol for preparation and attachment of this tissue to a porcine duodenum is rather cumbersome and time-consuming (preparation time, 75 minutes).

More recently, another version has been developed<sup>11</sup> with 2 main advantages over the Matthes-Cohen model: the formation of a duodenal sweep by using the pig stomach, which overcomes the complex and different pig stomach anatomy and allows for focused training in sphincterotomy and biliary cannulation; and the development of an easily exchanged neo-papilla, made from chicken heart and trachea tissue that is more easily obtained than previously reported neo-papillae. Similar to the other ex vivo porcine simulators, including that of Artifon et al,<sup>12</sup> the protocol for preparing the model is rather complex. A Japanese dry model, specific for sphincterotomy and needle knife precut, was designed by Katanuma et al<sup>24</sup> using a piece of rolled uncured ham mimicking the ampulla of Vater. Although easy to prepare and use, the duodenum simulator is rather expensive, and the reproduction of scope operability is rather poor. Virtual reality simulators, such as GI Mentor II (Simbionix Ltd., Airport City, Israel), have the possibility of treating adverse events such as bleeding or perforation; however, they have a high start-up cost and a low perceived realism due to lack of tactile feedback and control of handling real equipment,<sup>25</sup> and thus they are not frequently used in this manner.

In conclusion, this pilot study showed the good face and content validity of a real-tissue papilla combined with a mechanical simulator. It provides a useful, inexpensive, versatile, and easy tool for endoscopic sphincterotomy, precut, and papillectomy training. Experienced operators strongly agreed that this tool should be included in ERCP training programs for novice and intermediate trainees. Although a prospective randomized study is underway to clinically validate the usefulness of this new simulator tool for teach-

ing ERCP, and a comparative evaluation with other simulators should be performed in the near future, this initial assessment of our biological papilla shows promise for training all ERCP steps in a simple and realistic manner.

## DISCLOSURE

The following authors disclosed financial relationships: I. Boskoski: Consultant for Apollo Endosurgery, Boston Scientific, Cook Medical, Pentax, Nitinotes, EndoTools; Research grants from Apollo Endosurgery, Erbe Elektromedizin, EndoTools; Sponsored lectures for Cook Medical, Boston Scientific, Apollo Endosurgery, Microtech, Olympus; Patents for USA No: US D740,361 S (Endoscopy Training Apparatus) Oct. 6, 2015; Stent for electrothermal treatment, Patent No: 0001426680, Class A61B1814 – Feb. 7, 2017. G. Costamagna: Cook Medical. T. Voiosu: Honoraria for educational events and travel grant from Cook Medical; honoraria for educational events from Boston Scientific. All other authors disclosed no financial relationships.

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**SUPPLEMENTARY MATERIAL - QUESTIONNAIRE:**

We kindly invite you to provide us your feedback on your experience regarding the new biological papilla of the Boškoski-Costamagna ERCP Trainer. Please fill out the short questionnaire below and help us validating the ERCP Trainer.

**1. Demographics**

- a. Gender:
- b. Age:
- c. Country:
- d. Medical background (GE specialist, GE resident – year, other):
- e. Working place (academic hospital, regional hospital, other):

**2. Exposure to endoscopic interventions and learning methods in endoscopy**

- a. Number of years of ERCP experience:
- b. Average number of ERCPs performed per year:
- c. Estimated lifetime number of ERCPs performed:
- d. Previous experience in other medical simulators (no, yes):
- e. If simulator familiarity:
  - a. Please state how many times (0-5, 6-10, > 10 times):
  - b. Please state which simulator(s):

**3. Adequacy and realism of the novel biological papilla (5-point Likert scale; varying from very unrealistic (1) to very realistic (5)) Realism of the novel biological papilla compared to patient-based ERCP.****3.1. General appearance - opinion regarding the level of realism:**

- Q1. Resemblance to the real papilla:
- Q2. Positioning in front of the papilla:

**3.2. Sphincterotomy - opinion regarding the level of realism:**

- Q3. Positioning of the sphincterotome (tip control and wire deflection and angulation into intended position) during cannulation:
- Q4. Controlling the direction of the sphincterotome (tip control and wire deflection and angulation into intended position) during cutting:
- Q5. Controlled cutting in small increments:
- Q6. Cutting/coagulation effects:
- Q7. Controlling guidewire introduction:
- Q8. Controlling the scope during procedure (considering the several known dimensions for movement control):
- Q9. Overall appreciation in comparison to real situation:

**3.3. Precut - opinion regarding the level of realism:**

- Q10. Positioning of the needle-knife in the field of view:

Q11. Positioning of the needle-knife (tip control, deflection, and angulation into intended position) during cutting:

Q12. Controlled cutting in small increments:

Q13. Cutting control “layer-by-layer”, exposing deeper layers:

Q14. Cutting/coagulation effects:

Q15. Controlling guidewire introduction:

Q16. Controlling the scope during procedure:

Q17. Overall appreciation in comparison to real situation:

**3.4. Papillectomy - opinion regarding the level of realism:**

Q18. Positioning of the snare in the field of view:

Q19. Controlling the scope during the procedure:

Q20. Overall appreciation in comparison to real situation:

**3.5. Overall realism:**

Q21. Anatomical representation:

Q22. Simulator setup:

Q23. Endoscopic and devices control:

Q24. Haptic feedback:

Q25. Difficulty:

**4. Appreciation of the novel biological papilla as a learning tool (5-point Likert scale; varying from strongly disagree (1) to strongly agree (5)).****4.1. Your opinion about using novel biological papilla as a learning tool:**

- Q26. Expertise gained with this papilla is transferable into clinical setting?
- Q27. Useful tool to be included in an ERCP training curriculum?
- Q28. Useful tool to be included in the training of novice endoscopists (< 50 ERCPs lifetime)?
- Q29. Useful tool to be included in the training of intermediate endoscopists (50-600 ERCPs lifetime)?
- Q30. Useful tool to be included in the training of experienced endoscopists (600-2500 ERCPs lifetime)?
- Q31. Useful tool for (re) certification in ERCP?

**5. Are there any other potential benefits of this teaching tool?**

*In case of publication of the results of this study, we would like to acknowledge those who contributed to the results. Please let us know if you have any objections against stating your name in the acknowledgements.*

I have no objection.

I rather not have my name stated in the acknowledgements.

**Thank you for your collaboration.**