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Preliminary assessment of two novel mechanical colonoscopic polypectomy simulators: Description, evaluation and validation

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ABSTRACT

Background and study aims Colonoscopic polypectomy is an essential endoscopic skill. The simulators available for training are limited and based on raw porcine colons. Animal intestines are inconvenient and offer limited advantages for polypectomy training. These limitations are avoided by two novel mechanical simulators – the magnetic system based simulator (MSPS) and the simulator for polypectomy with high frequency current (HFPS) – described here. They are equipped to demonstrate self-repair of polyps after making a cut and hybrid polyps. The aim of this study was to describe and establish face, content, and construct validity of the two simulators and to assess their perceived utility as training and assessment tools.

Methods Ten novice, seven intermediate, and 10 advanced endoscopists participated in this study. Each one performed two polypectomies in MSPS and then one polypectomy and polyp retrieval in HFPS. The median times were compared among the three groups to preliminarily assess construct validity as a primary outcome. To establish face validity, the novices and intermediates completed a questionnaire about the credibility of each simulator after finishing the tasks. For content validity, the experts completed a questionnaire grading different aspects of the simulators' realism and their usefulness for training.

Results All 27 participants completed the modules. Median times needed to complete the tasks in both simulators differed significantly between the participants with different levels of experience ($P<0.05$). Both MSPS and HFPS received favorable scores regarding face and content validity. No technical problems were encountered.

Conclusion This study provides preliminary validation for MSPS and HFPS as useful training tools in a preclinical setting as well as during colonoscopy training. Moreover, we demonstrated the construct validity of both simulators, which confirms their use as a skill assessment tool during a colonoscopy training program.

Introduction

Colonoscopic polypectomy (CP) is one of the most important endoscopic interventions as it is associated with a reduction in incidence of colorectal cancer [1, 2]. Low-volume endoscopists have higher rates of complications related to CP [3]. Achievement of technical competence with CP requires a long learning curve and a dedicated training program, and above all, appropriate simulators for training [4–6]. However, the number of training simulators available for colonoscopic polypectomy is

▶ **Fig. 1** **a** The housing of the simulator (below) consists of a cylindrical part and the base module to which it is screwed on. The simulator is fixed to an Olympus trolley with a custom-made mount. The endoscope is inserted through the intubation tube. The endoscopic image shows the colon for MSPS equipped with a pedunculated polyp. The arrangement of the simulator and endoscopy trolley makes a perfectly ergonomic training station. **b** The cylindrical part of its housing has been screwed off, exposing the interior of the base module. The base module consists of the white lid of the housing, reinforced with two round, green metal plates and the cylindrical white holder for the colon module. The colon module consists of the rubber colon inserted into its Plexiglas sleeve, which is pushed onto the holder. The base module shown is the one used for the HFPS. The wiring connects the polyp sockets, which can be seen sticking out of the colon wall. **c** Inner and outer aspects of the HFPS base module (green, in the foreground). In the background are the three different colon modules.
Left: HFPS colon module with the wiring for the polyps. The black plug fits into the inner part of the main socket (left base module). The outer part (right base module) of the main socket serves the connection to the electrosurgical unit needed for HF polypectomy.
Middle: MSPS colon module for pedunculated polyps. The visible stalk belongs to one of the stalked polyps inside.
Right: MSPS colon module for sessile polyps. The two magnets fixed to the outside of the colon keep the two sessile polyps inside the colon in position.
All the colon modules are easily interchangeable in the same simulator.

small [6–9]. Their functional parts are made from raw pig intestine. This material offers limited advantages for polypectomy such as submucosal injection [10]. Moreover, to use these ex vivo animal platforms, special animal use endoscopes, organ preparation, extensive setup, and disposal processes are required. Because of the quickly degrading material, a continuous cool chain is required [10]. Finally, the training possibilities in ex vivo simulators can be considered limited.

To improve endoscopy training during courses, we developed two novel simulators to allow for training of colonoscopic polypectomy, the magnetic system-based simulator (MSPS) and the simulator for polypectomy with high frequency current (HFPS). They offer sessile and pedunculated polyps, and perfect ergonomic training stations in combination with endoscopy towers.

This study aimed to describe and establish face, content, and preliminary assessment of construct validity for these two novel mechanical simulators and to assess their perceived utility as training and assessment tools.

Methods

Simulators

The MSPS and HFPS presented, including the polyps, were developed and custom-made by one of the authors (EF). The size of the simulators is 24 cm x 13 cm, excluding the detachable intubation tube. The weight of the individual simulators, including the colon modules, is 560 g. The housing consists of a cylindrical part, which can be screwed off, and a base module (▶ **Fig. 1a**, ▶ **Fig. 1b**, ▶ **Fig. 1c**).

The base module is composed of the lid of the cylindrical part, which is reinforced with aluminum discs, a cylindrical holder for the colon module, and the intubation tube. The colon module consists of a custom-made cylindrical rubber colon, measuring 198 x 53 mm, which is inserted into a sleeve made of Plexiglas (▶ **Fig. 1b**, ▶ **Fig. 1c**). The colon is provided in two versions, with (▶ **Video 1**,“02:16”) and without (▶ **Video 1**,”00:22”) haustration, and has holes for fixing the polyps.

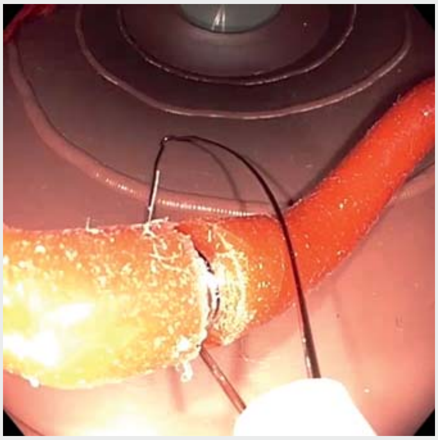
The colon module containing the polyps can be easily exchanged after unscrewing the cylindrical housing (▶ **Fig. 1b**).

The simulators can be mounted onto endoscopy towers (▶ **Fig. 1a**) with custom-made holders, compatible with various endoscopy trolleys. They allow for fixation of the simulators at the appropriate height, and an easy 360-degree rotation for changing the position of the polyps (▶ **Video 1**).

Specially designed transport cases have been made to facilitate packaging and shipping of the simulators to training course locations (▶ **Fig. 2**). They measure 67 x 46 x 30 cm, accommodating up to three simulators each, including the accessories needed.

Specific features of the MSPS

The MSPS colon module can be equipped with pedunculated and sessile rubber polyps of various shapes and sizes (▶ **Fig. 3**), not all of which are lifelike. The small spherical heads of the pedunculated polyps have a diameter of 12 mm and 14.5 mm. The large head of the cylindrical spiky polyp is 26 x 36 mm. The stalk of the polyps has a diameter of 4 mm, and is up to 60 mm long. The width of the spiky worm polyp is 16 mm and its working length is 12 cm. The stalk of the polyps is divided into



▶ **Video 1** (00:00–00:22) MSPS mounted on the trolley. Rotation of the simulator, outside and inside view. (00:22–03:50) Polypectomy of different-shaped polyps with the principle of self-repair used in MSPS. (03:50–05:39) Polypectomy of pedunculated polyps with HF current.

▶ **Fig. 2** Transport case packed with three simulators, MSPS/HFPS, plus accessories. Please take note the extraordinarily small size of the simulators, which facilitates packaging and transport.

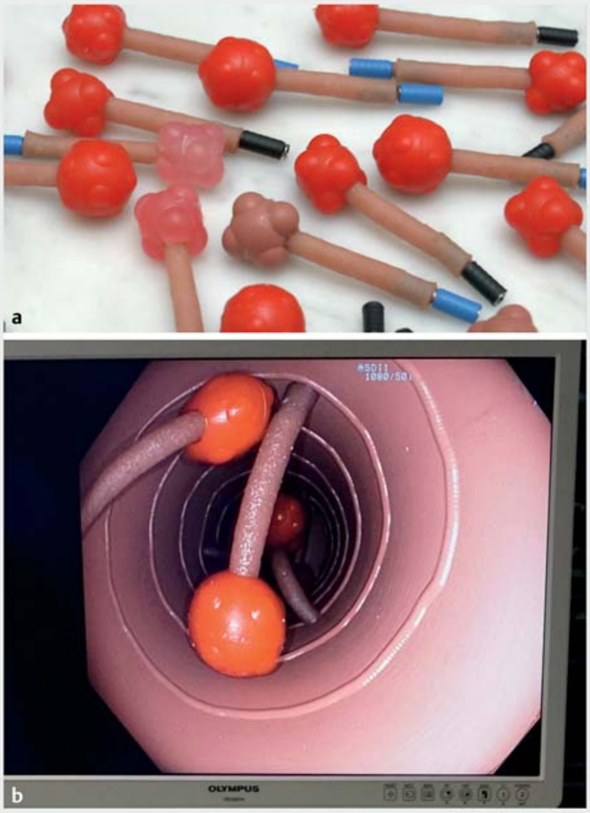
▶ **Fig. 3** Pedunculated and sessile polyps for MSPS. All polyps contain magnets that self-repair after "polypectomy." Some of the polyps are not lifelike, e. g. the large spiky polyp and the spiky worm polyp. They were created to make polypectomy more challenging, and to train extraordinary skills in young colonoscopists. Lifelikeness is not considered as a value of its own.

two parts, each of which contains a magnet that keeps them together. For attaching the polyps to the colon, the stalks of the pedunculated ones are threaded through the holes of the colon from the inside out. The length of the stalks inside the colon can be adjusted, depending on how far the stalks are pulled out. They are held in place by the elasticity of the colon wall, since the diameter of the holes is slightly smaller than the diameter of the stalks. A successful polypectomy is carried out once the snare has been precisely directed to the point where the two magnets meet. Once the snare is closed for the cut, the two magnets are separated by the traversing snare (▶ **Video 1,** "00:22"), which when set free indicates a correct polypectomy. The magnets will snap back instantly, "repairing" the cut stalk (▶ **Video 1,** "00:22–03:49"). If the stalk is pulled apart by incautiously pulling the snare, without having it placed correctly at the gap, it can be endoscopically repositioned by the trainee (▶ **Video 1,** "00:22).

The sessile polyps are fixed to the colon with magnets. One of them is integrated into the center of the polyp and the other one onto the outer surface of the colon wall (▶ **Fig. 1c**). The diameters of the polyps vary between 7 mm and 24 mm and the circumferences are smooth or star-like. Large star-like polyps are more difficult to grasp in one piece. Cutting is achieved by closing the snare, which then slides through the gap between the polyp and colon wall, setting the snare free and indicating a successful polypectomy (▶ **Video 1,**"03:07"). The two magnets keep the polyp in its original position, both during and after the cut.

Specific features of the HFPS

This simulator is only equipped with pedunculated polyps (▶ **Fig. 4a**), which can be cut by HF-current. They are a hybrid of two different materials. The reusable rubber heads of the polyps are identical to the ones used in the MSPS described above. The stalk is made of material called DCM, which is made from an innocuous material, developed specially for this simulator, from processed animal material available in regular commercial stores. Less than 1 g of this material is needed per polyp. The polypectomy carried out on the DCM material with HF current is quite realistic. The lightened coagulation area and smoke obscuring the view during the cut (▶ **Video 1,**"03:50") closely resemble the polypectomy in patients. DCM is a convenient alternative to slaughterhouse material used for ex vivo simulators, as it does not require an uninterrupted cool chain. It is stable up to 2 to 3 days at room temperature. The stalk has a usable cutting length of up to 35 mm, and a

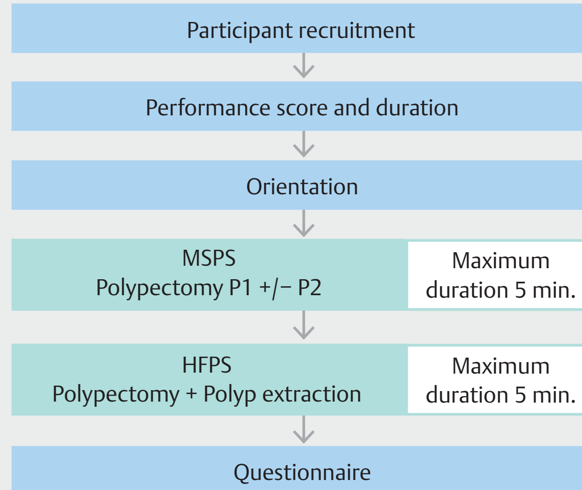


▶ **Fig. 4** **a** Pedunculated hybrid polyps for the HFPS. The reusable heads made of rubber are fixed onto the DCM stalks, a new material which can be cut with HF-current. At the ends of the polyps, sockets are integrated for the connection to the surgical HF generator. The wiring of the polyps for connection to the HF electrosurgical generator is shown in Fig. 1b and Fig. 1c. **b** For training courses, the readily exchangeable colon modules can be equipped with six (or even more) polyps.

diameter of 4.5 mm. A socket is integrated at the free end of the stalk for connecting the polyp to the surgical HF generator (▶ **Fig. 4a**, ▶ **Fig. 1b**). For training courses, the colon modules are preloaded with the needed polyps (up to six per module) (▶ **Fig. 4b**). More polyps can be installed as well, reducing the distance between the polyps. During the courses, the modules are kept in airtight bags prior to their use to prevent the polyp stalks from drying out. When the cylindrical enclosure of the simulator has been unscrewed, the modules with the cut polyps can be replaced with fresh ones (▶ **Video 1**,"05:02").

Endoscopic equipment

A standard colonoscope (CF-H180, Olympus Germany, Hamburg, Germany) was used. In MSPS, polypectomy was done using a monofilament oval polypectomy snare (SD-990-25, Olympus Germany, Hamburg, Germany). In HFPS model, polypectomy was done with a braided electrosurgical polypectomy snare (SD-210U-25, Olympus Germany, Hamburg, Germany) and with the use of a electrosurgical generator (VIO 300 D, Erbe Elektromedizin, Tübingen, Germany).



▶ **Fig. 5** Study design.

Set-up for evaluation

Two pedunculated polyps were fixed in the MSPS model. The first proximal polyp (P1) had a smooth surface and a diameter of 12 mm, the second distal polyp (P2) had a spiky one and the diameter of the head was 26 x 36 mm. In the HFPS model, one polyp was fixed distally.

Study design

A total of 27 participants were recruited for this study. There were 10 novices, seven intermediate-level, and 10 advanced endoscopists. No participant had used the MSPS or the HFPS simulators before the study. Participant demographic information, including the endoscopic experience and the number of colonoscopic and polypectomy procedures, were collected. Each participant received an orientation including explanation and inspection of the simulators. Moreover, they were informed about the endpoint of the study, which was defined as the time needed for completion of each task. Afterwards, each participant received an individual brief demonstration of the simulators and operation of the colonoscope and the endoscopic instruments. Finally, each participant was asked to complete the two simulation models, starting with MSPS with which the participant was asked to perform two polypectomies for the two fixed polyps starting with the first polyp (P1) and then continuing with the second polyp (P2). The time needed for each polypectomy was recorded. Afterwards, the participant moved to the HFPS and asked to perform a polypectomy using high-frequency current and then to retrieve the polyp outside the simulator. The time needed for polypectomy and the polyp retrieval was recorded. Five minutes were allowed at maximum to complete the tasks in each simulator (▶ **Fig. 5**).

Outcome variables and data collection

The primary outcome of this study was to establish construct validity by investigating whether MPSP and HFPS simulators can distinguish between novices, intermediates, and experts. The preliminary assessment of construct validity was based on the median time needed to complete the tasks. This concept has been used in previous pilot studies [11].

Secondary endpoints included establishment of face and content validity. To assess the face validity, the non-expert (novice and intermediate) and expert participants filled out an evaluation questionnaire regarding credibility of each simulator as an adjunct to colonoscopy training after completing the previously described tasks. To assess content validity the expert participants completed a questionnaire grading different aspects of the simulators' realism and their usefulness for training after completing the previously described tasks. The questionnaires were adapted from previous published studies and the following criteria were scored using a 7-point Likert scale (1 = poor, 7 = excellent) [12–14].

Face validity questionnaire: (1) Practicing with this simulator improved my specific skills; (2) I would like to continue exercising with this simulator in my further training; (3) training with this simulator reduces the risks for patients in my opinion; and (4) I would recommend this simulator.

Content validity questionnaire: Realism: (1) The models are easy to handle (preparation, down time, complexity during the course); (2) Practicing with the model is advantageous during a training program; (3) Models can be easily integrated into a training program; (4) Models display enough realism for the practiced procedure; and (5) Training with the models leads to a direct improvement of the trainee.

Participants

Novices were medical students (n = 8) and medical residents (n = 2) who didn't have any flexible endoscopy experience before the study.

Intermediates were gastroenterology (n = 6) and surgical (n = 1) residents or fellows who performed more than 50, but less than 200 colonoscopies.

Experts were gastroenterology (n = 7) and surgical (n = 3) staff endoscopists who had performed more than 200 colonoscopies.

Data analysis

All analyses were performed using SPSS, Version 23. Results of Likert scaled questions were summarized as median and range. Distributions of duration times stratified for participants' experience are illustrated by boxplots. To test for differences across the study groups, Kruskal-Wallis tests were performed in a first step. If the null hypothesis could be rejected, Mann-Whitney U tests for pairwise group comparisons were conducted afterwards. A level of significance of 5 % was used for each test.

Results

A total of 27 / 27 participants completed the task on the two simulators.

Primary outcome (construct validity)

Median time needed by the experts to complete the MSPS was 60 seconds (range, 30–150), which was significantly faster than the intermediate subjects' time (98 seconds (range, 81–195), $P = 0.005$. The median time needed by the novice participants to complete the MSPS was significantly slower than the intermediate and expert groups (217 seconds (range, 105–300), $P = 0.007$ and $P < 0.001$ respectively).

Median time needed by the experts to complete the HFPS was 46 seconds (range, 31–105), which was significantly faster than the intermediate subjects' time of 78 seconds (range, 50–140), $P = 0.012$). The median time needed by the novice participants to complete the HFPS was significantly slower than the intermediate and expert groups (123 seconds [range, 100–280], $P = 0.008$ and $P < 0.001$ respectively). (▶ **Fig. 6**, ▶ **Fig. 7**).

Secondary outcome

Face validity

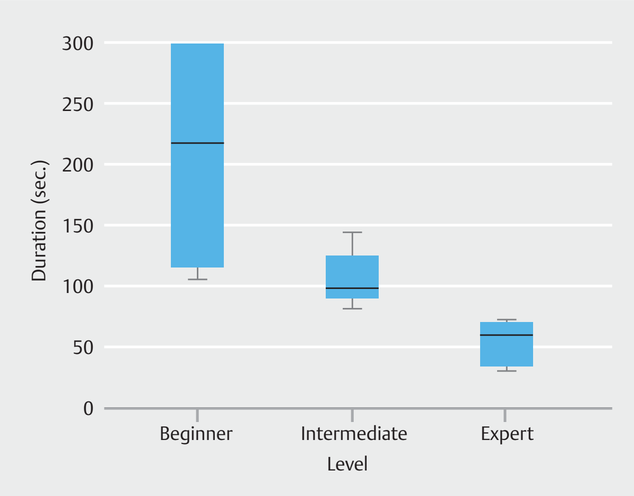
All participants (10 novice, 7 intermediate, and 10 experts) filled out the first questionnaire after completing each simulator. Median scores of face validity are detailed in ▶ **Table 1**. Skills improvement, willingness to continue to use in training, risk reduction for patients and finding the simulator recommendable were overall scored median values of 6 (4–7), 5 (3–7), 6 (4–7), 6 (3–7) regarding MSPS and 6 (3–7), 6 (4–7), 6 (3–7), 7 (4–7) regarding HFPS. The first two statements were rated significantly higher by non-experts in comparison to experts.

Content validity

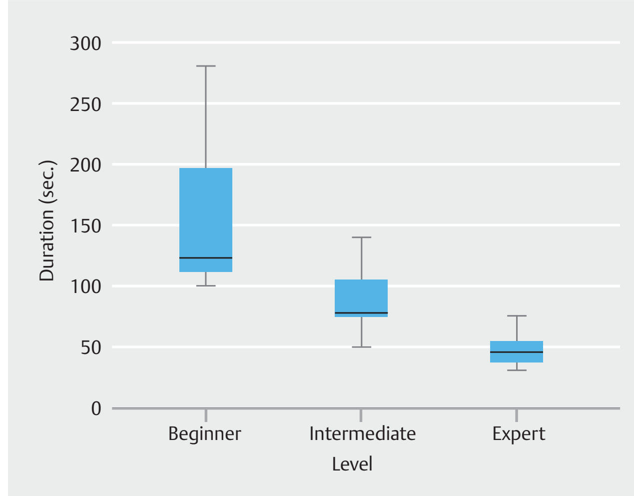
All 10 experts filled out the second questionnaire after completing each simulator. Ease of use, utility as a training modality, ease of integration, realism and learning success of the trainee were scored median values of 6 (4–7), 6 (5–7), 6 (5–7), 6 (5–7) and 6 (5–7) regarding MSPS and 6 (5–7), 6 (5–7), 6 (5–7), 6 (5–7) and 6 (4–7) regarding HFPS (▶ **Table 2**).

Discussion

Achieving competence with CP and objective assessment of this technique pose a significant challenge [15]. Traditionally, procedure numbers are used to measure the level of technical competency. However, the number of procedures varies between different training programs and does not correlate with the quality of performance [16, 17]. For that purpose, some CP simulators have been developed. However, very few of these simulators have been independently validated as training or assessment tools [6, 16]. Moreover, most of these simulators are available as ex vivo versions, which combine fresh animal parts with housings made from metal and/or plastic [6–9]. Ex vivo organs are praised for their lifelike properties and for being realistic. However, it is doubtful whether this assessment is justified,



▶ **Fig. 6** Box lot showing the minimum, maximum, interquartile range and median duration of performed polypectomy using MSPS by three different levels of participants.



▶ **Fig. 7** Box plot showing the minimum, maximum, interquartile range and median duration of performed polypectomy using HFPS by three different levels of participants.

and whether it is a relevant criterion at all. Cadaver colons are limp, as they lack tone and any haustration. Moreover, their original anatomy is not accurately represented because they are detached from their specific intraabdominal fixation, and are instead housed in metal spirals [9] or exhaust pipings [6]. An unequivocal lifelike feature present in the decomposing ex vivo materials is the smell.

This study describes and demonstrates the preliminary assessment construct validity in addition to face and content validity of the two novel CP mechanical simulators, namely MSPS and HFPS.

The MSPS can be equipped with various artificial rubber polyps. All of them are self-repairing after the cut, and therefore, they do not need to be restored or replaced during the training. Although some of the polyps have unrealistic shapes (e. g. spiky head polyp and spiky worm polyp), they were purposefully created to elicit and train ultimate skills of the trainee like passing a snare over difficult spiky structures (representing strongly lobulated large polyp heads) or to free a snare caught in the middle of those spikes (▶ **Fig. 3**, ▶ **Video 1** "01:23–03:08"). This needs to be done carefully, otherwise the magnets holding together the stalk will separate, representing a fragile thin stalk in a patient. The snare then needs to be passed to a tiny specific point, exactly to the gap between the magnets and only then can the cut be carried out (▶ **Video 1**,"00:22–03:50"). Trying to overcome these challenges is an ideal preparation for a real-life polypectomy.

After physical snaring, electrophysical polypectomy techniques can be practiced with the HFPS, which is equipped with pedunculated hybrid polyps suitable for diathermic HF-polypectomy training. The reusable rubber heads of the polyps, which are used in MSPS as well, offer a variety of polyp shapes,

▶ **Table 1** Face validity: median score ratings between non-experts and experts (n = 27) regarding the MPSP and HFPS simulators.

Face Validity Questionnaire	MPSP				HFPS			
	Median score (range)				Median score (range)			
	Non-experts (n = 17)	Experts (n = 10)	Overall	*P* Value	Non-experts (n = 17)	Experts (n = 10)	Overall	*P* Value
Practicing with this simulator improved my specific skills	6 (4–7)	5 (4–6)	6 (4–7)	0.020	6 (3–7)	5 (3–6)	6 (3–7)	0.015
I would like to continue exercising with this simulator in my further training	6 (4–7)	5 (3–7)	5 (3–7)	0.021	6 (4–7)	5 (4–6)	6 (4–7)	0.016
training with this simulator reduces the risks for patients	7 (4–7)	6 (4–7)	6 (4–7)	0.541	6 (3–7)	5.5 (3–7)	6 (3–7)	0.230
I would recommend this simulator	7 (3–7)	6 (4–7)	6 (3–7)	0.667	7 (4–7)	6 (4–7)	7 (4–7)	0.425

Median scores and range on a 7-point Likert scale (1, complete disagreement; 7 complete agreement).

▶ **Table 2** Content validity: experts' evaluation scores (n = 10) of the MSPS and HFPS simulators.

Evaluation item	MSPS	HFPS
Ease of use	6 (4–7)	6 (5–7)
Utility as a training modality	6 (5–7)	6 (5–7)
Ease of integration	6 (5–7)	6 (5–7)
Realism	6 (5–7)	6 (5–7)
Learning success of the trainee	6 (5–7)	6 (4–7)

Median scores and range on a 7-point Likert scale (1, complete disagreement; 7 complete agreement).

which is not feasible with polyps made from pig colons [6]. The DCM stalk, the second material used for the hybrid polyps, has a socket at one end for an easy connection to the HF electrosurgical generator (▶ **Fig. 1b**, ▶ **Fig. 1c**, ▶ **Fig. 4a**). DCM is a convenient material that does not require a steady cool chain, unlike fresh pig colons, and is stable for 2 to 3 days at room temperature. This makes the shipping of the material to the training courses less complicated. The stalks are adjusted to be soft enough so that, if the snare is negligently closed too fast, it causes an inadvertent cut. The consequence of this mechanical "cold" cut, which happens inadvertently in patients as well, would be bleeding from the stalk. DCM is firm enough to allow careful and snug grasping of the stalk with the electrosurgical snare, before transmitting HF current for coagulation. During proper application of the current, the DCM-stalk produces the same effects as diathermic cutting in patients: smoke emanating from the coagulation area obscuring the view of the cutting site and a lightened area of coagulation. After polypectomy, the polyps can be caught and retrieved. (▶ **Video 1**,"03:50")

The artificial colons used in MSPS and HFPS offer additional advantages over the pig colons. They can be made in different forms, including haustra, which are absent in ex vivo colons. Polyps located in haustrated segments add to the difficulties of carrying out polypectomy training (▶ **Video 1**,"01:23–03:08").

There are only two advantageous features of ex vivo polypectomy simulators: Submucosal injection techniques can be trained, and sessile polyps suitable for HF polypectomy can be made from this material. However, the polyps being sutured in, made by ligation of the mucosa, or created by injection of gelatin into the submucosa are not really lifelike [6, 8, 9]. Nevertheless, there is no alternative for HF-current polypectomy of sessile polyps. MSPS for sessile polyps offers only the physical, but not the electrophysical, part of training.

There is no one perfect simulator available for all aspects of polypectomy training courses. Therefore, looking for a suitable polypectomy simulator means always searching for the best compromise. The new MSPS and HFPS offer quite a few favorable features needed for comprehensive training. They avoid the inconveniences that are related to the simulators based on slaughterhouse materials. Notwithstanding their very small size, they offer excellent training possibilities, overall exceeding the currently available simulators. They are part of a system, aimed at facilitating the establishment of high-quality training courses. Due to their extraordinarily small size, they can beeasily packed and shipped to training locations (▶ **Fig. 2**). The uncomplicated set-up of the simulators on the tower through a new fixing system provides an ergonomically perfect working station (▶ **Fig. 1**, ▶ **Video 1**). The trainee can stand in front of the tower, facing the monitor, and have the simulator in the same position as the patient. The easy and quick exchange of the colon modules (▶ **Video 1**,"05:01"), and the self-repairing polyps (▶ **Video 1**,"00:22–03:10"), extend the training time for the trainees. In addition, compared to non-haustrated colons currently available, haustrated ones are offered as well. Effortless and swift rotation of the simulator enables easy repositioning of the polyp, varying the challenge of snaring. It is worth pointing out that the MSPS and HFPS can easily be reduced to one simulator. To achieve this, only the colon module needs to be exchanged (▶ **Fig. 1b**, ▶ **Fig. 1c**). This does not take more than 1 to 2 minutes. The sum of the properties mentioned also makes the new polypectomy simulators a standardized tool for objective assessment of endoscopic skills in all endoscopists, not just novices.

One could criticize the devices presented for not simulating negotiation of the scope through a tortuous colon. However, advancing the scope through a difficult colon requires a different kind of simulator, which we have also developed. These simulators have produced favorable results in training that will be published elsewhere.

We were able to preliminary demonstrate that both simulators have high construct validity as they can discriminate between endoscopists with different levels of experience regarding the time needed to complete different polypectomy tasks. We were also able to show that both simulators have excellent face validity across a range of parameters. The simulators received favorable scores from novice and intermediate participants regarding improving endoscopic skills, risk reduction for the patient, and use for further training, and the majority judged the simulators as recommendable. In addition, both simulators showed high content validity as they received high scores from experienced endoscopists regarding ease of use, utility as a training modality, ease of integration, realism, and learning success of the trainee. These validity tests demonstrated that MSPS and HFPS can be used as training models for CP.

Conclusion

In conclusion, this paper presents and validates two novel simulators for colonoscopic polypectomy, MSPS and HFPS, which are equipped with new self-repairing polyps and hybrid polyps. They avoid the use of fresh animal organs and the inconveniences related to them and offer, at the same time, a combination of training facilities that exceed, by far, the status quo. This is achieved by sacrificing lifelikeness, but that actually enhances the training outcome.

Acknowledgements

Dr. Frimberger is the inventor of the simulator training model. He manufactured it and uses it for training courses.

Competing interests

The authors declare that they have no conflict of interest.

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