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Physical simulator for colonoscopy: a modular design approach and clinical validation

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ABSTRACT Simulators for gastrointestinal (GI) endoscopy offer the opportunity to train and assess clinician skills in a low-risk environment. Physical simulators can enable direct instrument-to-organ interactions not provided by virtual platforms. However, they present scarce visual realism and limited variability in their anatomical conditions. Herein, we present an innovative and low-cost methodology for the design and fabrication of modular silicone colon simulators. The fabrication pipeline envisages parametric customization and development of 3D-printed molds for silicon pouring to obtain colon segments. The size of each colon segment is based on clinical data extracted from CT colonography images. Straight and curved segments are connected through silicone conjuncts to realize a customized and modular monolithic physical simulator. A 130 cm-long colon simulator prototype with assorted magnetically-connected polyps was fabricated and laid on a custom-made sensorized abdominal phantom. Content, face and construct validity of the designed simulator were assessed by 17 GI endoscopists. In summary, this work showed promising results for improving accessibility and flexibility of current colonoscopy physical simulators, paving the way for modular and personalized training programs.

INDEX TERMS Physical simulators, endoscopy, colonoscopy, medical training, modularity.

I. INTRODUCTION

Since its first introduction in 1969, colonoscopy has demonstrated to be a life-saving screening procedure for early cancer detection [1], [2]. However, difficulties and potential drawbacks of colonoscopy are: i) perforation and postprocedural bleeding (low incidence rates but unaltered in the last 15 years [3]); ii) sedation-associated complications (*i.e.*, up to 13% increased risk of complications for patients undergoing anesthesia, including a higher risk of perforation [4]); and iii) patient's discomfort with abdominal pain (*i.e.*, 22.5% and 14.2% of unseated patients reported pain, respectively, during and after colonoscopy on a study involving more than 20,000 patients [5]). In this perspective, skills in performing an efficient and safe procedure are a core element in gastroenterology practice.

Mastering a complex procedure such as colonoscopy requires physicians to show cognitive and technical competencies, *e.g.*, subtle control of the endoscope navigation and high-level visual-motor coordination [6]. As colonoscopy represents a gold standard procedure with a great impact on public healthcare, there is an evident need to reduce its operator-dependence through an extensive training program [7]. Endoscopy-related skills can be achieved through the repetitive and progressive performance of simulated procedures in a lifelike interactive environment with the aid of real-time formative feedback. The historical but still adopted model of the colonoscopy training program, *i.e.*, "see one, do one, teach one", relies on the supervision

TABLE I
FEATURES AND LIMITATIONS OF COMMERCIAL AND RESEARCH ORIENTED SIMULATORS

Feature	**M40 Colonoscope Training Simulator (Kyoto Kagaku Co.)**	**Colonoscopy Simulator Type II (Koken Co.)**	**Mikoto**	**MESA**
				
Material	Soft and hard resins	Silicone rubber	Silicone resin	Ecoflex Series 00-10
Offers different layouts	✓	✗	✗	✗
Patient position changes	✓	✗	✓	✓
Attachable polyps	✗	✓	✓	✗
Anatomical realism	✓	✓	✓	✓
Modularity	✗	✗	✗	✓
Performance feedback	✗	✗	✓	✗
Cost	~$ 3000	~$ 5800	N/A	N/A

3D Colonoscope Training Simulator NKS (Kyoto Kagaku Co.) [6]; Colonoscopy Simulator Type II (Koken Co.) [14]; Mikoto [18]; MESA [20].

and guidance of an experienced mentor during the practice of novices on live patients [8]. Although a master-apprentice model enables the direct supervision and real-time evaluation/correction of the mentor, patient discomfort, associated risks, and increased procedural time are inevitable. Recent guidelines from the American Society for Gastrointestinal Endoscopy (ASGE) encouraged the application of simulators in the training pipeline [9], [10]. In this context, simulation-based education offers a low-risk teaching and assessment tool that provides repetitive and low-stress training in a non-patient care environment [11]. Extensive use of simulators is beneficial not only for the independent and self-confident acquisition of skills but also for the prevention of skills decay, the shortening of the learning curve, and consequently for enhancing patient safety and the quality of health care [12]. Therefore, the goal of effective simulation-based training is to assist the endoscopist in developing, improving, and maintaining the required competencies in a reduced time and controlled domain to support the transfer of the acquired expertise into the clinical setting [6]. Over the past ten years, several simulators have been developed to acquire lower GI endoscopy competencies, varying in affordability and anatomical realism, and targeting different tasks and expertise levels [6], [9]. Focusing on mechanical/physical models, they rely on a passive semi-rigid platform embedded with a soft plastic replica of the colon lumen, rarely including reproductions of pathological tissue such as polyps [13]–[15]. The strengths of this type of simulator are: *i)* the level of immersive interaction they offer to the trainee given their physical consistency, *ii)* their natural integration in the standard clinical layout with the ordinary instrumentation, and iii) the real tactile feedback [6]. Nevertheless, they often lack several features, *e.g.*, i) detailed visual realism, ii) the possibility of selecting different anatomical configurations, and iii) the inclusion of objective feedback on the performance, besides their limited affordability [16]. To this end, recent research-oriented simulators [17], [18] have been developed to offer a wider range of realistic cases and reduce costs. This goal was achieved by using inexpensive materials and exploiting 3D-printing manufacturing, paving the way for adaptable and easy-to-fabricate phantoms. King et al. [19] designed and fabricated a colon simulator by assembling common and inexpensive modules. Although clinical validation highlighted the ability of this platform to distinguish trainees and experts, this solution does not incorporate insufflation nor transmit the true haptic feedback of a realistic endoscope interaction. Formosa et al. [20] proposed the innovative Modular Endoscopy Simulation Apparatus (MESA) that relies on 3D printed molds and open steel piping components designed to be the negative of the colon geometry. Even though the model was scaled to twice the average colon size and silicone selection was guided by the ease of casting and pigmenting, mold-by-mold stacking enables a modular conjunction of shorter sections, offering a simplified fabrication process. Table I reports a schematic overview of the key aspects of the latest and most advanced mechanical simulators.

In this perspective, future mechanical training platforms leading to a wider employment of simulators in training curricula will need to incorporate more complex scenarios and anatomical configurations with improved realism and performance feedback. This article presents an innovative, modular, repeatable, and low-cost workflow for fabricating customized silicone-made colons. Based on the modeling and parametrization of the real colon morphology, the proposed workflow enables the creation of full colon anatomy, or pieces of it, by fabricating and connecting multiple silicon-based colon segments. The design process gives full freedom to the user to customize the colon models in terms of morphology, length and materials used.

The paper is organized as follows: *Section II* presents the modular design concept of the simulator, *i.e.*, (II.A) analysis and parametrization of the real colon morphology, (II.B) design of the molds for silicon pouring to obtain the colon segments and their connections; *Section III* shows the full realization process of a colon simulator following the modular design approach (III.A), including the analysis of different silicon materials to find the one best replicating the properties of the real tissue (III.B), the fabrication steps (III.C), the fabrication of a custom-made sensorized abdominal cavity replica (III.D) and the clinical validation study (III.E). Finally, the results are presented in *Section IV*, followed by a discussion in *Section V*.

II. DESIGN CONCEPT

This work aims to design a methodology to fabricate custom-made physical colon simulators. Due to the extreme variability in configurations, length, and tortuousness of the human colonic tract, a versatile and easy-to-use approach is necessary for a faithful, flexible and affordable replication of its anatomy. A complete colon simulator can be created by combining and assembling modular colonic pieces obtained with 3D printable molds. As the main challenge in designing colonoscopy simulators involves a deep understanding of colorectal morphology and its variability across the population, the first step investigated (*Section II.A*) was the definition and design of a faithful and symmetric model for mimicking the average lumen cross-section. Secondly, two types of modular molds were designed to create i) straight and curved colon segments and ii) connectors to assemble them (*Section II.B*). Therefore, a fully customizable colon anatomy can be fabricated by printing molds and connectors and assembling segments, as shown in *Section III*.

A. DESIGN OF THE COLON MODEL

Patient-related factors, *e.g.*, sex, body mass index and previous colonic resections, play a pivotal role during the endoscopic procedure [21]–[23]. The complexity of the human colon mostly arises from the presence of haustra, semilunar folds, and taenia coli, which may create structural abnormalities and introduce navigational difficulties during endoscopy. Therefore, an exhaustive analysis of the length, diameter, tortuosity, and thickness of the colon is essential to reproduce those anatomical barriers within a colon simulator. Taeniae are described as three outer longitudinal bands of the gut tunica muscularis, creating a three-helix structure of strong cables upon contraction. In contrast, semilunar folds are visible circumferential folds of the mucosa resulting from the circumferential contraction of the inner muscles between stiffened taeniae. Haustra are the wall protrusions of the colon that are delimited by their corresponding semilunar folds [24]. Inspired by the three-fold topology presented by *Langer et al.* in [24], we defined a symmetrical and triadic configuration, *i.e.*, a clover-like section, as the nominal lumen cross-section of the model. *Ad-hoc* measurements were retrieved by real colon models (*i.e.*, eight in total), which were 3D reconstructed from colonography examinations (source: The Cancer Imaging Archive [25]). Three qualitative haustral loops were analyzed for each model using three planes intersecting the lumen section in ascending, descending, and transverse segments to highlight three different geodesics. Incident planes were chosen appropriately to identify clover-like sections and inscribed triangles were sketched to distinguish the three haustral pockets (Fig. 1). Specifically, the width and height of each haustra (the a and b parameters in Fig. 1.c, respectively) were quantified. A dimensionless parameter R, the ratio between height and width, was defined to represent the extent of the fold bulge. A graphical representation of these parameters is shown in Fig. 1.c. Therefore, a total of 24 measurements for both a and b parameters were retrieved. The computed mean value of R was 0.372 ± 0.077, with minimum and maximum values measuring respectively 0.203 and 0.668. To reproduce the oscillatory appearance of the colon haustra along the longitudinal direction, the mean value of R was adopted for sections that are coplanar with the semilunar folds (*i.e.*, terminal), and the maximum R for the in-between sections (*i.e.*, middle), in which the colon lumen shows the typical bumped shape. In terms of average external diameter, the choice relied on *Alazmani et al.* findings [26]:

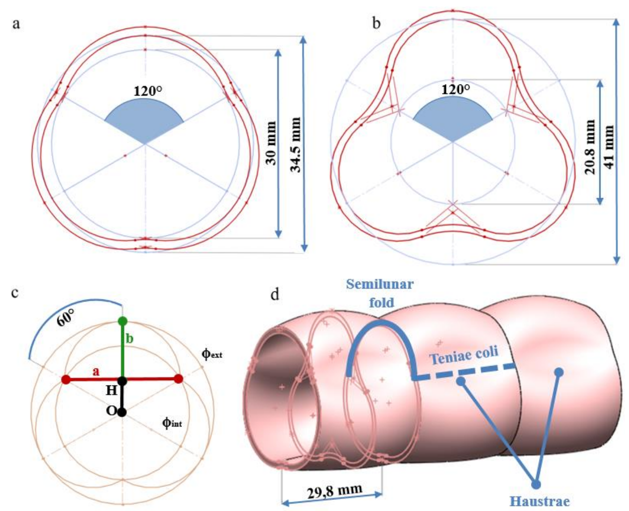

FIGURE 1. **Colon *clover-like model* sized according to the *terminal* (a) and *middle* (b) sections, with main parameters (c); (d) final singular colon module composed of N = 3 colon units.**

- 34.5 mm, *i.e.*, the mean of the average diameter measured on each colonic tract weighted for the tract length, was assigned to the *terminal* sections (Fig. 1.a);
- 41 mm, *i.e.*, the average between the total colonic diameters in the supine and prone positions, was assigned to the *middle* sections (Fig. 1.b).

Given these parameters and assuming that non-inflated colonic wall thickness ranges between 0.2 and 2.5 mm [27], the nominal colonic thickness was taken as the average, *i.e.*, 1.35 mm.

An additional dimension was needed to complete the design of the *clover-like section*, *i.e.*, the internal diameter delimiting the attachments of the taeniae coli. For this reason, simple trigonometric relationships were deployed referring to the triadic model of Fig. 1.c:

$$R = \frac{b}{a} \qquad (1)$$

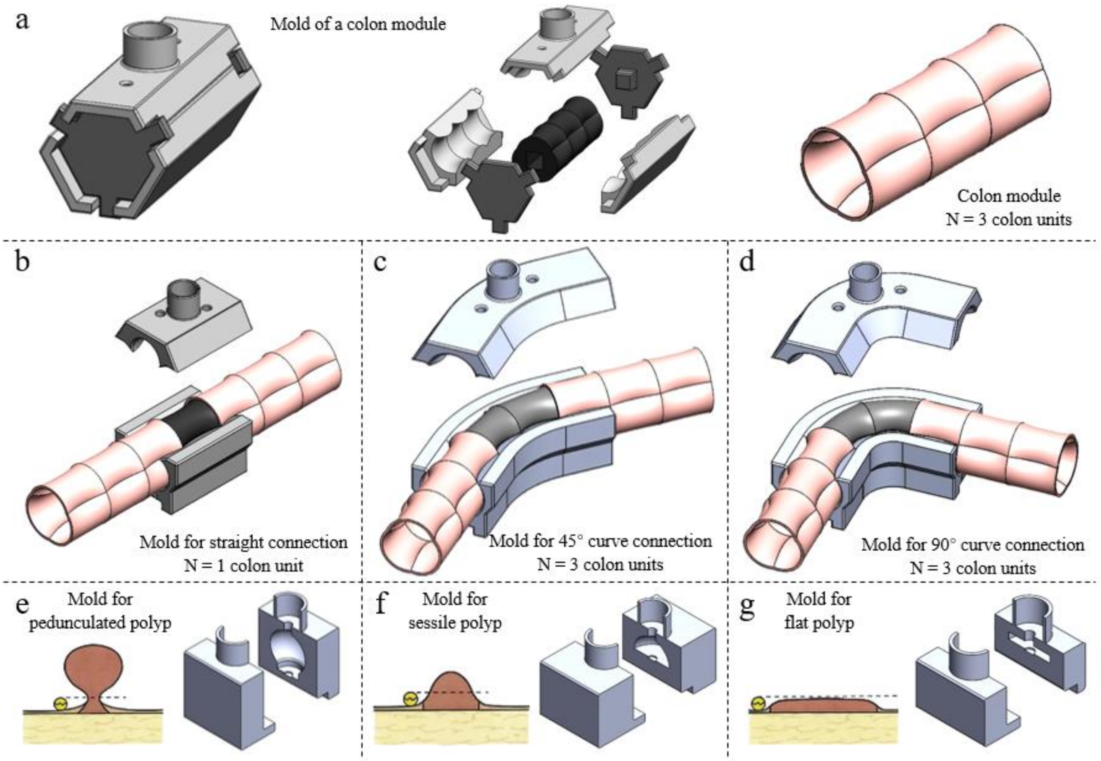

FIGURE 2. **Examples of molds for the fabrication of a colon simulator: (a) the mold of one colon module and the corresponding colon module; the mold set for (b) straight, (c) 45° curve, and (d) 90° curve connections, respectively; the mold of pedunculated (e), sessile (f), and flat (g) polyps.**

$$OH = \frac{\varphi_{int}}{2} \cdot \cos 60° = \frac{\varphi_{int}}{4} \quad (2)$$

$$a = 2 \cdot \frac{\varphi_{int}}{2} \cdot \sin 60° = \varphi_{int} \cdot \frac{\sqrt{3}}{2} \quad (3)$$

$$b + OH = \frac{\varphi_{ext}}{2} \leftrightarrow \varphi_{int} = \frac{\varphi_{ext}}{\sqrt{3}R + \frac{1}{2}} \quad (4)$$

where φ_{ext} and φ_{int} represent the external and internal diameters, respectively. Therefore, the internal diameter was set to 30.00 mm and 20.80 mm for the *terminal* and *middle* sections, respectively. At the same time, the values of width (a) and height (b) were set respectively to 2.61 mm and 0.97 for the *terminal* section and 1.80 and 1.20 for the *middle* section. Finally, following a pilot assessment by expert clinicians (co-authors of the manuscript), 8 mm bevels were applied in correspondence to the three clover "edges" to simulate the presence of the outer taeniae bands.

A modular assembly system design requires selecting the minimum fabrication length according to the "building blocks" concept. Herein, we refer to the *taeniae unit* as the distance in the longitudinal direction of the lumen between each triad of semilunar folds. Taking as reference an average colonic length of 185 cm [26] and the number of haustral loops identified by a team of experienced clinicians on 10 colons [28], the length of the taeniae unit was computed as the mean of the ratios between colon length and the number of extracted loops, *i.e.*, 29.80 mm. At this point, the design of the final colon module results from filling the sequential arrangement of the clover-like sections in parallel at a reciprocal distance of half of the taeniae unit. Therefore, a 1-unit colon comprises two *terminal* sections and one *middle* section in between. The minimum colon module can be further expanded (Fig. 1.d) to envisage longer straight colonic tracts, essentially constituted by the replication of N (*i.e.*, three) identical units along the longitudinal axis. The three-unit module was chosen as the straight modular base for realizing a complete colon simulator.

B. DESIGN OF THE MOLDS

A set of mechanical molds dedicated to silicon pouring was built to provide a modular, reusable, customized fabrication method compatible with any anatomical configuration to replicate. This method enables both a customizable arrangement of the colon in the 3D space and the versatility of design modifications. Assuming one taeniae-unit as the smallest module that can be manufactured, we designed a series of *ad-hoc* molds with SolidWorks (Dassault Systèmes, Vélizy-Villacoublay, France). All the ensembles share a common configuration, *i.e.*, interlocking of an inner mold and three outer molds to comply with the clover triadic symmetry without any screw mechanism. The upper outer mold is equipped with a cylindrical hollow reservoir to accommodate silicone pouring and a pair of 4 mm holes to enable airflow.

The set of mechanical components needed for the development of a complete colon simulator consists of the following:

- *segment molds* (Fig. 2.a), devoted to fabricating stand-alone straight colonic segments of N units (*i.e.*, N = 3);

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- *connection molds* meant to fuse several modular colon units together.

There are two types of connection molds:

- *straight connectors* (Fig. 2.b) to generate a straight single-unit link between two colonic segments;
- *curved connectors* (Fig. 2.c-d) conceived as a flexion of a straight connection mold to create curves of the colon.

The design of a straight connection mechanism is necessary for fabricating longer colonic segments based on a modular concept. Instead of developing a specific mold for each module length, a straight connector is a versatile tool to bond any pair of fabricated colonic segments. Regarding the curved connectors, given the limited set of angles offered by the flexion of a single unit, two-unit and three-unit curves were selected to offer a range of flexion up to 40° and 180° and a minimum radius of curvature of 24.39 mm and 28.45 mm, respectively. Thus, the two types of curved molds allow sharper or smoother colon curvatures. Mold sets for connecting two colonic segments by adding double-unit links of 45° and 90°, for the sake of examples, are shown in Fig. 2.c and Fig. 2.d, respectively (videos of molds assemblies in Supplementary Material).

As a complementary feature of the colon simulator, we also considered the realization of artificial polyps, which expand colonoscopy training to intervention, including polypectomy. Three types of polyps, *i.e.*, pedunculated, sessile, and flat, were considered, and their corresponding molds were designed as shown in Fig. 2.e-g. To make these extensions modular in their arrangement along the simulator, a magnetic connection was devised as a suitable and simple technique for repositioning polyps after removal. By integrating a cylindrical magnet (diameter: 3 mm; height: 1 mm) within the stalk channel before silicone pouring, the polyp is suitable for being installed in any location of the inner lumen placing an equivalent external magnet on the outer surface of the synthetic colon (video of the polyp attachment in Supplementary Material).

III. FABRICATION AND VALIDATION OF A MODULAR COLON SIMULATOR

The set of molds described in the previous section has been envisaged to offer a methodology for assembling and constructing a colon simulator without any constraints on the level of complexity, tortuosity, or 3D configuration of its anatomy. To obtain a full colon anatomy or a portion of it, the next step is to create different colon segments and connect them as “pieces of a puzzle”. This section presents the full fabrication process of a colon model herein named the Modular Colon Simulator (MCS). The described colon model represents only an example of the possible simulators that can be generated following the proposed methodology and is herein reported to explain the overall methodology. Indeed, the whole design process is flexible regarding the complexity of the colon to be replicated and fidelity to the real anatomy. In this case, the MCS aims at replicating a real colon anatomy, starting with CT colonography images. Firstly, the real colon centerline is extracted, and the main building blocks, *i.e.*, colon units, are derived (*Section III.A*). Secondly, the finite element analysis is run to select a material with characteristics similar to the colon tissue (*Section III.B*). Thirdly, the colon molds are printed and the simulator is fabricated by repeatedly generating colon segments and connecting them (*Section III.C*). Later, a custom-made sensorized anatomical replica of the abdominal cavity is fabricated as an add-on to make the

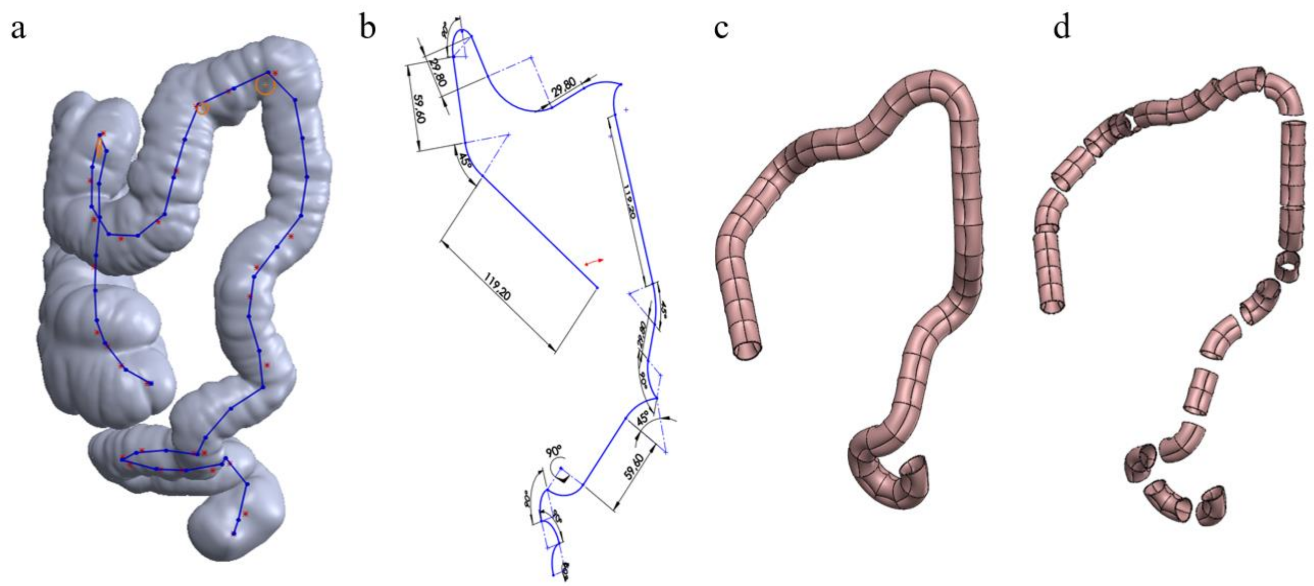

FIGURE 3. Modular segmentation of a colon centerline to generate the Modular Colon Simulator (MCS): (a) a colon model derived from CT colonography images and its extracted centerline is used as a reference; (b) the colon geometry is simplified and described through a spline; (c-d) based on the spline, the colon is segmented into different colon modules (*i.e.,* building blocks), which can be generated with the silicon molding technique.

colonoscopy simulator even more realistic (*Section III.D*). The abdominal cavity simulator is endowed with force sensors to track the forces applied by trainees on the colon walls. Finally, the fabricated MCS embedded in the abdominal cavity simulator is clinically validated with a group of GI endoscopists (*Section III.E*).

A. MODULARIZATION OF A COLON ANATOMY

In this section, we present an example of the modularization of a colon model, *i.e.*, segmentation of a colon centerline and derivation of the units to create the corresponding simulator. It is important to note that the methodology described here to replicate the colon anatomy serves as an example. Indeed, the "building blocks", *i.e.*, colon modules, presented in this paper allow the creation of any type of colon, as complex as desired.

For this study, a colon derived from real colonography images (*i.e.*, Cancer Imaging Archive [25]) was chosen as a reference model to be replicated. After 3D reconstruction of the colon, the centerline was extracted using the VMTK extension of the open-source 3D Slicer software [29] (Fig. 3.a). By explicitly specifying an input surface (*i.e.*, the 3D reconstructed colon) and a start point, a centerline tree extraction can be performed using the Centerline Computation module of the VMTK extension (*i.e.*, a centrical point in the cecum surface). Dimensional analysis of the reference model was performed with SolidWorks (Dassault Systèmes, Vélizy-Villacoublay, France), to retrieve the lengths of each colonic tract along the centerline and to measure the angles between adjacent segments. The segments were sketched along the centerline, considering a length equal to the taeniae-unit. For reasons of simplicity and ease of fabrication, we decided to design and fabricate curved connection molds of 45° to reproduce angles greater-than or equal-to 40°, whereas molds of 90° curve for angles lower than 40°. After curing, silicone softness enables it to adapt and further the curvature. Finally, we derived a global 3D spline to have a complete overview that summarizes the lengths, curvatures, and orientation of each colonic tract to be reproduced (Fig. 3.b). This trace was the main reference for identifying the number of equivalent straight segments and connections that were needed and supposed to be assembled in a modular way, as shown in Fig. 3.c-d (video of the colon segmentation concept in Supplementary Material).

It is worth mentioning that this approach provides a general pipeline for modularization and production, that can be changed based on different needs (*e.g.*, complexity and arrangement of anatomical configuration). For instance, the colon centerline could be sketched manually, and additional molds with different curved angles could be used to reproduce the colon tortuosity with higher or lower fidelity.

B. MATERIAL ANALYSIS

The colon can be made out of any kind of polymer that can be used for silicon casting. In this section, we present a finite element analysis (FEA) conducted to compare the performances of different silicones to those of human colon tissue. The goal is to detect the stress-strain behavior of available and affordable silicone rubber materials (Smooth-On Inc., Macungie, PA, US) and select one that has similar mechanical properties to those of the human colon [30]. The FEA simulations were performed on Ansys (Ansys Inc., Canonsburg, PA, US). Specimen dimensions and loading conditions were derived by *Massalou et al.* [31], where uniaxial stress-strain tests were performed on human colonic samples. Bone-shaped specimens had been modeled according to the same dimensions specified by the authors of [31], namely a gauge length of 40 mm, a width of 25 mm, and a total sample length of 100 mm. Samples were subjected to the uniaxial quasi-static loading condition, which consists of a tensile load of 10 mm/s up to 100 mm of displacement applied on one grip edge with a fixed support on the opposite grip edge. Intermediate or dynamic loading speeds were not evaluated, as they are less representative of the true interaction between the colonoscope and the colonic tissue. Eight materials were selected and examined, including Ecoflex series 00-10, 00-30, 00-50, 5, Dragon Skin series 10M, 20, 30, and Smooth-Sil 940 [32]. Constitutive hyperelastic models of the silicones were retrieved from the mechanical characterization of *Marechal et al.* [33]. The boundary conditions and the deformed specimen after 100

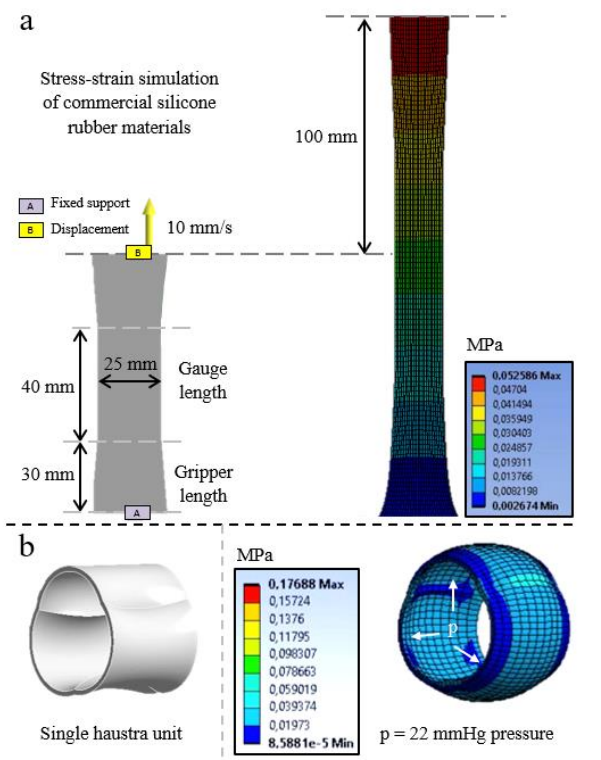

FIGURE 4. Finite Element Analysis of commercial silicon materials: (a) stress-strain evaluation of silicone rubber specimen under quasi-static loading condition; (b) deformation of a single haustra unit made of Ecoflex 00-50, at a fixed pressure of the range, *i.e.*, 22 mmHg.

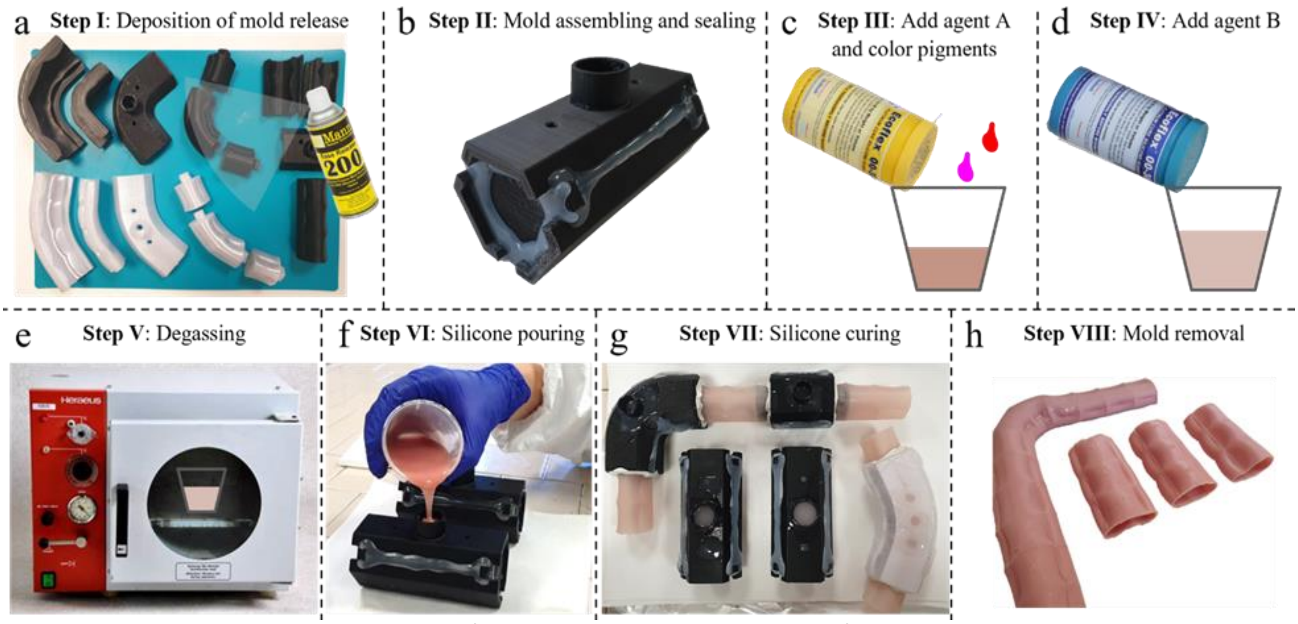

FIGURE 5. **Colon fabrication steps: (a) deposition of Ease Release™ 200 on the inner side of molds; (b) molds assembly and closing, including the addition of parafilm and hot glue; (c) Ecoflex 00-50 part A mixed with 1 drop of pink and 1 drop of blood pigments (other silicon materials could be used); (d) Ecoflex 00-50 part B added to the mixture; (e) vacuum-chamber degassing (5-8 min); (f) pouring of the product into the central reservoir (pot life: 18 min); (g) waiting for curing time (3 h); and (h) delicate removal of molds and silicone residuals.**

mm displacement are shown in Fig. 4.a.

As explained in *Section IV*, Ecoflex 00-50 was chosen as the best candidate for colon fabrication. Consequently, to choose a material that imitates the mechanical and viscoelastic properties of the human colon, the Ecoflex 00-50 underwent validation through simulation under insufflation conditions. The simulation followed the quasi-static loading condition protocol outlined in [33], where controlled inflation is applied linearly from 0 mmHg to 44 mmHg at a rate of 5.33 Pa/s (equivalent to an increase of 4 mmHg every 100 s). The deformation and stress performance of a single-unit colon model was evaluated using this protocol to minimize the computational cost of the solver. For simplicity, a single average equilibrium time of 100 s for each incremental pressure step was chosen. Fixed supports impeded the displacement of the terminal delimiting sections of the model. Fig. 4.b shows the single haustra unit and the color map of equivalent Von Mises stress at a fixed pressure.

C. FABRICATION OF THE COLON SIMULATOR

Once the design of the set of molds has been completed and the appropriate silicone has been selected, the final step is the fabrication of the complete simulator. In this case, the molds were manufactured by means of a Zortrax M200 3D printer (Zortrax, Olsztyn, Poland) with a nozzle diameter of 0.4 mm. The employed materials for printing were chosen according to the availability and affordability of rigid plastic filaments, *i.e.*, Z-HIPS (Zortrax, Olsztyn, Poland).

The general fabrication steps for the colon simulator are as follows: (Step I) deposition of mold release, *i.e.*, Ease Release™ 200 (Smooth-On Inc., Macungie, PA, US) on the inner surfaces of the molds (Fig. 5.a); (Step II) assembling and sealing of the mold (additional parafilm and hot glue were applied to mitigate the leakages of silicon through the gaps between the mold pieces) (Fig. 5.b); (Step III) addition of calculated weight of Ecoflex 00-50 agent A in a container (with translucent white color) and mix with a drop of pink and a drop of red colored pigment for replicating natural colors (Fig. 5.c); (Step IV) addition of the same amount of Ecoflex 00-50 agent B in the container as agent A and stirring evenly the mixed solution with a stick (Fig. 5.d); (Step V) placement of the mixed solution in the Heraeus VTR5022 vacuum machine (Heraeus, Germany) for degassing to avoid bubble formation in the final prototype (Fig. 5.e); (Step VI); pouring the mixed solution into the mold through the dedicated inlet port (Fig. 5.f, video of pouring process in Supplementary Material); (Step VII) curing the silicon at room temperature for the three hours after filling all the mold (Fig. 5.g); and (Step VIII) removal of the silicon made colon segments from the molds (Fig. 5.h).

The above fabrication steps were repeated for fabricating all the modular colonic segments that, when assembled together, generated a complete colon simulator. It is worth mentioning that the pot life of Ecoflex 00-50 before curing is 18 minutes at room temperature. Therefore, due to the intrinsic viscosity of the silicone rubber during pouring, it may occur that the silicone will start curing even before completely filling the reservoir of the mold. Thus, agents A and B were preserved in the fridge to ensure a longer pot life.

D. FABRICATION OF THE ABDOMINAL SUPPORT

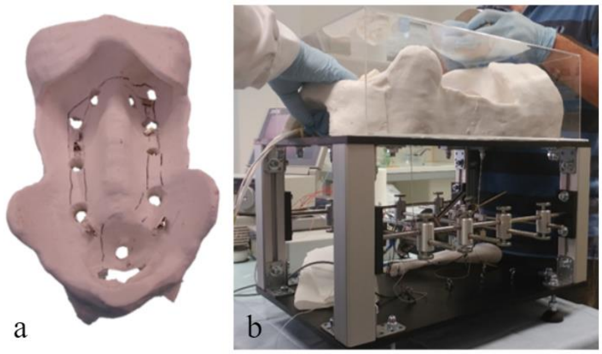

FIGURE 6. Custom-made abdominal cavity support: (a) silicon replica of the abdominal cavity; (b) support rack including the abdominal cavity replica (at the top) and the strain gauges force cells (at the bottom).

In order to create a stand-alone, complete and realistic colonoscopy simulator, a sensorized abdominal support was designed and developed to accommodate the *in-vitro* silicone colon. The abdominal support reproduces the rigid osseous anatomy in contact with the colon, *e.g.*, the spine, hip bones, and costal arches, as well as the soft tissue surrounding the colon. The replica of the abdominal cavity was obtained by generating a master mold made with clay, which was then molded and duplicated with silicone. Plastic replicas of the bones surrounding the abdomen, coming from a human-size commercial skeleton model (*Oscar*, Erler Zimmer, Lauf, Germany), were used as a scaffold. Therefore, the skeleton was embedded in modeling clay, which was shaped appropriately to represent the tissue surrounding the bones. For replicating the clay model with silicone, a negative mold was created. Thus, the final abdominal platform was obtained by silicone molding on the negative mold using KDSV 25 silicone (R&G Faserverbundwerkstoffe GmbH, Waldenbuch, Germany) (Fig. 6.a). The replica of the abdominal cavity was then fixed on top of a supporting rack embedding four monoaxial strain gauge cells (OMEGA LCL-005, OMEGA Engineering Inc., Karvina, Czech Republic). A National Instruments DAQ (USB-6363, National Instruments, Austin, TX, US) was used to acquire the sensor signals and then transferred to a laptop for online tracking. Additionally, a thin, soft cushion with the same shape and collinear holes as the abdominal cavity was applied on top of the abdomen to better mimic the material properties of the soft tissues around the colon. Thus, once the colon is placed on top of the cushion, specific portions of the lumen, surrounded by bracers, can be connected via inextensible nylon wires to the force sensors below the abdomen (Fig. 6.b). This way, the force exerted on the colon walls during the procedure can be acquired in four regions of interest, *i.e.*, the rectum, splenic flexure, hepatic flexure, and cecum. The supportive rack also fixes the colon in place, mimicking the role of the mesentery, *i.e.*, the organ attaching the colon to the posterior abdominal wall. Finally, a rigid transparent plastic case and a surgical towel complete the simulator to guarantee the integrity of the lumen arrangement from external contacts (apart from the rectum

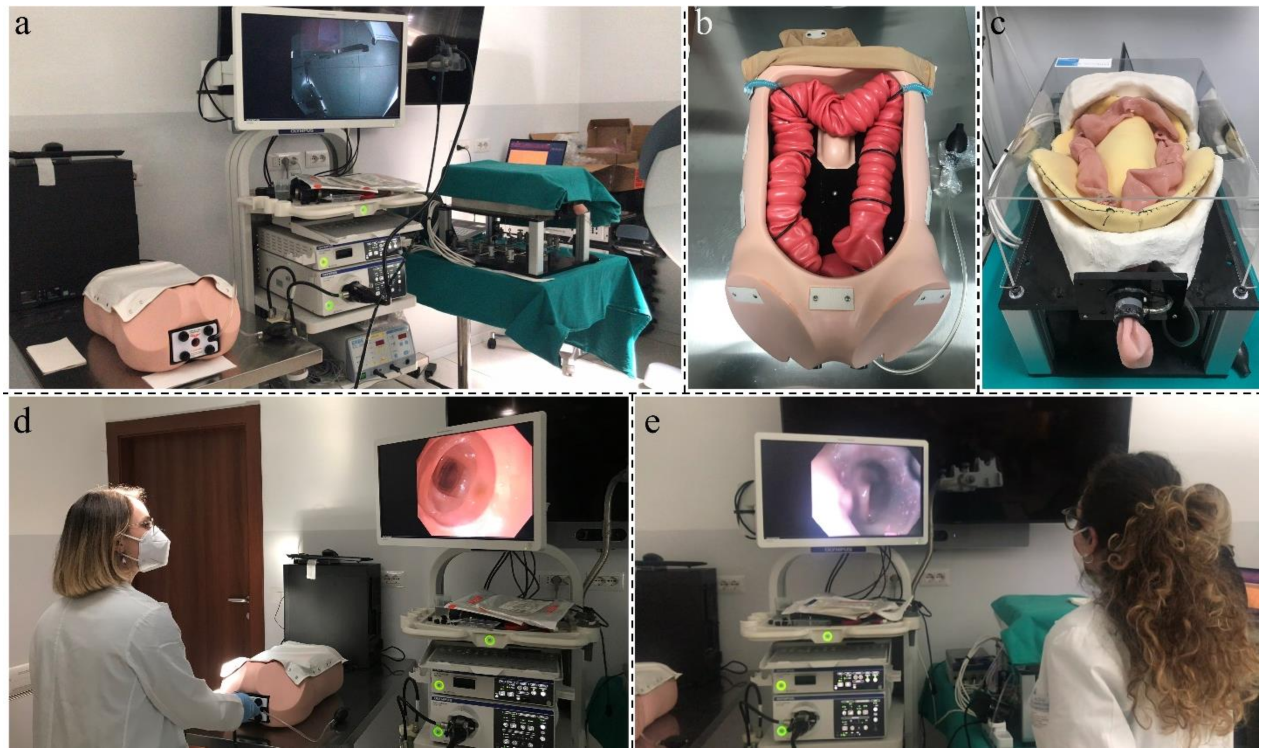

FIGURE 7. Pilot study comparing the MCS and Kyoto Kagaku simulator. (a) Test setup with both simulator platforms and the colonoscopy system. Detailed view of the Kyoto Kagaku simulator (b) and our proposed simulator embedded in the sensorized abdominal platform (c). Endoscopist performing the colonoscopy training with the Kyoto Kagaku simulator (d) and our proposed simulator (e).

access) and the complete obscuring of the colon layout during a simulation. In summary, the abdominal cavity simulator serves both as an anatomical case to accommodate the colon during the simulation and as a sensorized platform to measure the forces exerted by the trainees on the colon walls. This information can be used to track the trainees' advancements and objectively assess the clinicians' skills.

E. CLINICAL VALIDATION OF THE SIMULATOR

The content, phase, and construct validity of the fabricated MCS embedded in the custom-made sensorized abdominal platform were evaluated in a clinical study involving a group of 17 medical doctors (*i.e.*, 8 experts and 9 novices). Informed consent from all the subjects was obtained prior to the experiments. Novices were defined as participants with no prior experience in colonoscopy, and experts as medical specialists with at least six months of practice. In addition, the MCS was compared with the well-known Kyoto Kagaku Colonoscope Training Model (Kyoto Kagaku Co. Ltd., Kyoto, Japan). The Kyoto Kagaku is a commercial and validated training simulator, that can be used as the gold standard for physical colonoscopy simulation [6], [13]. After recording personal and professional information, the clinicians were asked to perform one complete colonoscopy (cecum intubation and withdrawal) in both the Kyoto Kagaku and our MCS (Fig. 7.a). The procedures were performed using a clinical colonoscope (Olympus GIF-HQ190, Tokyo, Japan), the associated equipment and connected modules. Before the test, five minutes for each clinician were dedicated to gaining confidence and familiarity with both simulators. The Kyoto Kagaku simulator was mounted and prepared according to the instruction manual (Kyoto Kagaku Co. Ltd., Kyoto, Japan). Accessories, such as rubber bands, guide frames, and the sphincter included in the simulator, were employed (Fig. 7.b). The MCS was installed on the custom-made abdominal simulator with a profile reproducing the human abdominal anatomy. The arrangement of the colon lumen through the prefixed path was obtained through custom silicon-made rings, and inextensible nylon wires were used to connect with the mono-axial load eyelets. The load cells were connected to four distinctive portions of the intestine, *i.e.*, the rectum, splenic flexure, hepatic flexure, and cecum (Fig. 7.c). In addition, a pedunculated polyp was magnetically connected to the inner surface of the colon lumen in the cecum region.

Data, *i.e.*, i) total procedural time, ii) cecum intubation time, and iii) withdrawal time, were recorded in both simulators. In addition, the clinicians were asked to detect and remove with a snare one polyp placed on the MCS simulator to evaluate the realism of the polypectomy module. Only one polyp was placed on the MCS simulator since the Kyoto Kagaku model does not include polyps. The polyp was attached to the final portion of the colon (*i.e.*, the cecum) avoiding interference with the navigation or withdrawal task and avoiding the generation of a bias for the Kyoto Kagaku simulator. Therefore, in the MCS case, also the iv) polyp detection (whether the polyp was detected or not) and v) time of removal were recorded. Finally, the MCS also allowed vi) to record the force exerted on the mucosa walls thanks to the sensorized abdominal support. Before performing the colonoscopy, both simulators were lubricated with the dedicated solutions provided by the Kyoto Kagaku simulator platform package. Both the simulators were covered to avoid any biases due to appearance or visual cues (video of cecum incubation and polypectomy during validation is available in Supplementary Material).

Following the testing phase, the clinicians were asked to fill out a custom-made survey expressing their opinion on a 5-point Likert scale for the two tested simulators regarding i) the overall simulation setup, ii) the anatomical realism of each part of the colon simulator, iii) the mechanical and haptic response, iv) the complexity of the procedure, and v) the simulator appropriateness and usefulness in real training.

Data from the surveys and recorded endpoints were extracted and analyzed using MATLAB (MathWorks, Inc., Natick, MA, US) to assess the overall realism of the MCS platform (*i.e.*, content, phase, and construct validity). The Wilcoxon Signed Rank Test was used to compare the two simulators both in terms of their performances (*i.e.*, data acquired during the experiments) and on the basis of medical doctors' opinions expressed in the survey. Additionally, the Wilcoxon Rank Sum Test was performed to evaluate any difference in performances between experts and novices (construct validity) and among the survey results on the MCS. Finally, the consensus measure [34] was used to assess the dispersion of the clinicians' answers to the survey.

IV. RESULTS

A. FEA SIMULATION RESULTS AND MATERIAL SELECTION

Equivalent Von Mises stress-strain curves were acquired from the central 3D element of each bone-shaped silicone sample (Fig. 8). As a first approximation, silicone selection was driven by Young's modulus metric to qualitatively comply with the tensile response of human colon samples

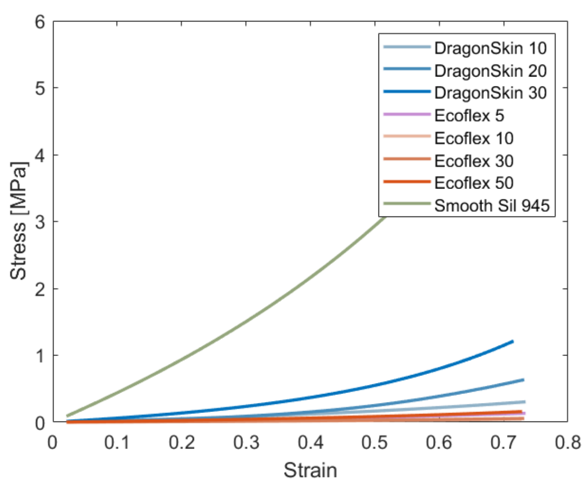

FIGURE 8. Stress-strain curve of eight silicone materials.

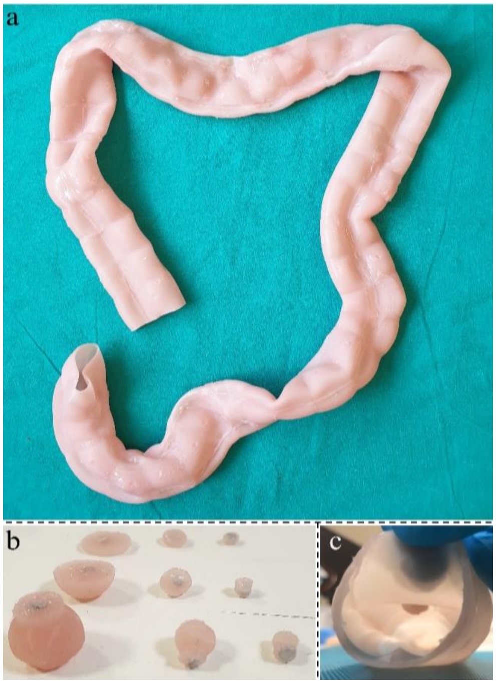

FIGURE 9. **Fabricated colon simulator: (a) complete Modular Colon Simulator (MCS); (b) magnetic-based artificial polyps with various geometry; (c) artificial polyp attached to the inner wall of the colon simulator.**

when loaded quasi-statically in the circumferential direction, *i.e.*, 0.63±1.25 MPa [31] (assuming that stronger interactions between the colonoscope and colon walls occur mainly along this trajectory). The approximated elastic modulus of each silicone was computed by linearizing the stress-strain curves. Dragon Skin 10 Medium and Dragon Skin 20 showed the nearest linearized elastic module to the colon tissue, *i.e.*, 0.427 MPa and 0.894 MPa, respectively. Nevertheless, neither of these two candidate silicones was suitable for filling all the mold cavities homogeneously because of their high viscosities (23000 and 20000 cps, respectively). In this regard, taking a step back along the elastic response, Ecoflex 00-50 was assumed to be the optimal trade-off in terms of the order of magnitude of the elastic modulus (0.224 MPa) and also the feasibility of fabrication thanks to its sufficient pot life (18 minutes), lower viscosity (8000 cps), and relatively short curing time (3 hours). FEA insufflation entails the validation of Ecoflex 00-50 as the potential material for fabrication: the maximum pressure before high distortion without convergence was 39.6 mmHg. This value was considered acceptable compared to the reference bound of 44 mmHg in the human colon [33].

B. COMPLETE INTEGRATED COLON SIMULATOR

A complete colon simulator, resulting from the execution of sequential conjunctions, is shown in Fig. 9.a. The final prototype can be mounted and adjusted in commercial abdominal simulators, *e.g.*, the Kyoto Kagaku abdominal *phantom*, or in custom-made supports, *e.g.*, the sensorized abdominal support. Mounting the phantom is possible using supplied rubber bands or custom-made silicone bands. These bands can be made from fabrication residuals and offer softer support, particularly at the splenic and hepatic flexures. The silicone lumen of the simulator is naturally collapsed under gravity, similar to the behavior of a non-insufflated human colon.

This MCS includes a set of nine different magnetic polyps (Fig. 9.b) with various morphologies and dimensions, ensuring a safe, stable, and ready-to-use installation, in addition to re-utilization once removed. Each of them is cured with a small permanent magnet to realize an easy yet robust integration with the simulator at any location through an external twin magnet. Consequently, modularity is accomplished through the colon fabrication methodology and the installation of pathological modules, *e.g.*, polyps. A sessile polyp integrated into the simulator is shown in Fig. 9.c.

C. RESULTS OF THE VALIDATION STUDY

Out of the 17 participants in the experiments, three novices could not finish the colonoscopy procedure using the MCS simulator. Therefore, they were excluded from the analysis. For all the other participants, no sign of tear or perforation was evident along the lumen, and no accidental detachment of the polyp at the level of the caecum tract was observed in case of a collision with the endoscope during the procedure. The answers distribution from the validation survey is shown in Fig. 10 for both simulators. The last 8 questions are related to the MCS only (polypectomy and usefulness). Ratings for the MSC were higher than 2.5 for all the questions (both for all the participants and for only the experts), confirming the face and content validity. The MSC simulators received higher average scores for all the questions with respect to the Kyoto Kagaku platform, with statistical differences confirmed by the Wilcoxon paired test for most of the aspects inquired (p-value < 0.05, Table II). The average consensus for all the questions is greater than 0.6, suggesting a high level of agreement between the clinicians.

Regarding the construct validity, the Wilcoxon unpaired test reveals that the MSC simulator can discriminate between experts and novices in terms of intubation time and total time, as for the Kyoto Kagaku one (p-values available in Table II; the mean and standard deviation of the timings recorded are available in Table III and Fig. 11).

Additionally, a statistical difference was detected for i) the time of intubation, ii) withdrawal, iii) and overall procedure between the two simulators for all the participants and the expert groups. Indeed, the time spent performing the procedure with the MSC was higher than with the Kyoto Kagaku platform (Table II-III and Fig. 11), suggesting the major complexity of the MCS. This point is also confirmed by the survey, in which the procedure with the MCS was rated as more complex to perform.

Regarding the force analysis, which was performed only with the MCS, no significant difference was detected between novices and experts. However, the forces recorded were in line with the data published in [35], where the same

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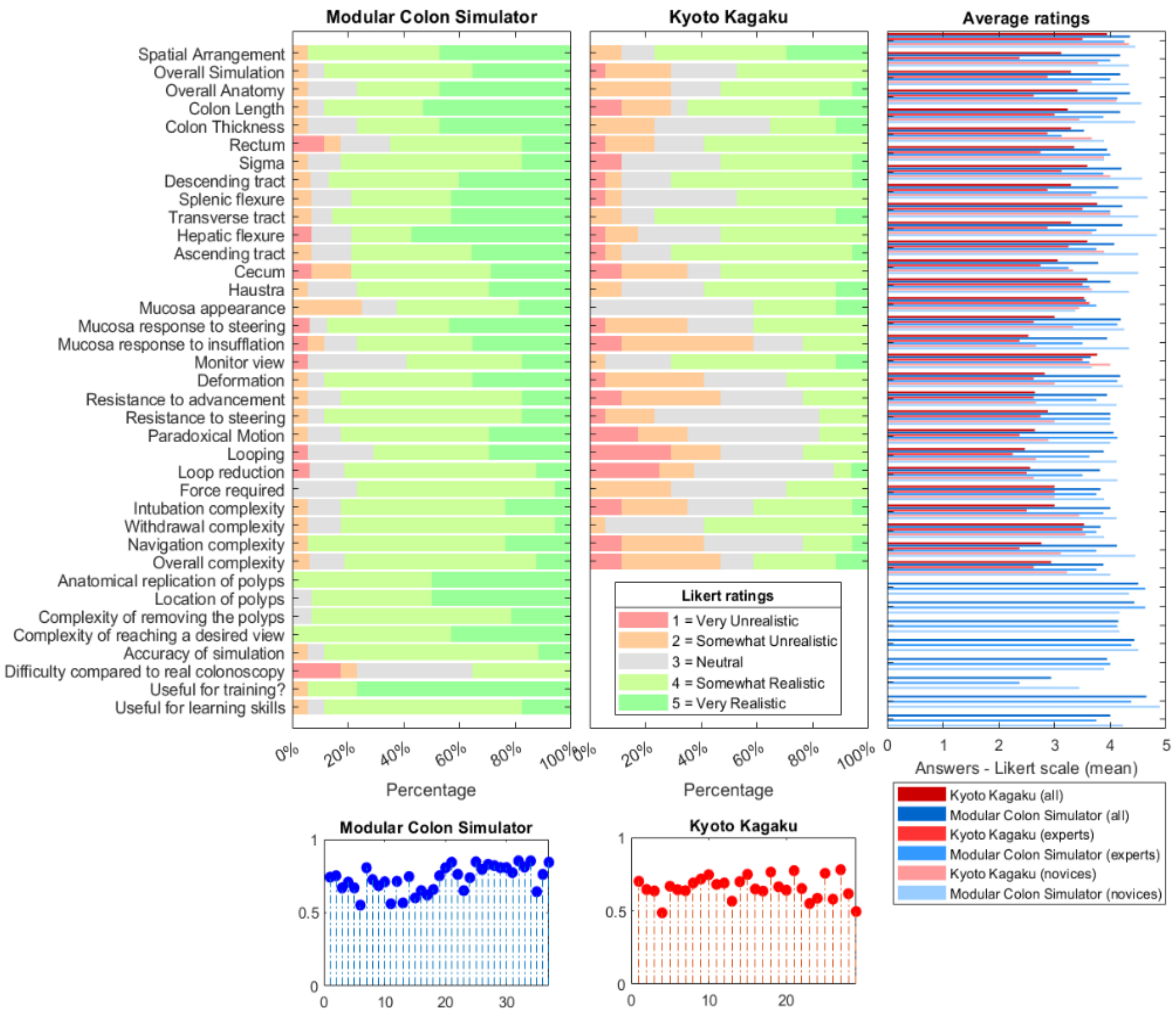

FIGURE 10. **Results of the validation tests. At the top-left, summary of the 37 questions and answers provided by 15 endoscopists using a 5-point Likert scale for the Modular Colonoscopy Simulator (top left) and the Kyoto Kagaku (top center). On the top right, average rating for all the questions related to both simulators, divided per experience level. At the bottom, consensus values for all the question, in both simulators.**

sensorized abdominal support was used with an *ex-vivo* porcine colon. Concerning the polypectomy, all the participants detected the polyp on the MCS simulator and successfully removed it using the snare. The i) polyp visual appearance, ii) location and iii) complexity associated with its removal were rated highly realistic by the clinicians (average rating of each question > 4, Fig. 10). No statistical difference was detected when analyzing the time spent for the removal of the polyp between novices and experts (Table II).

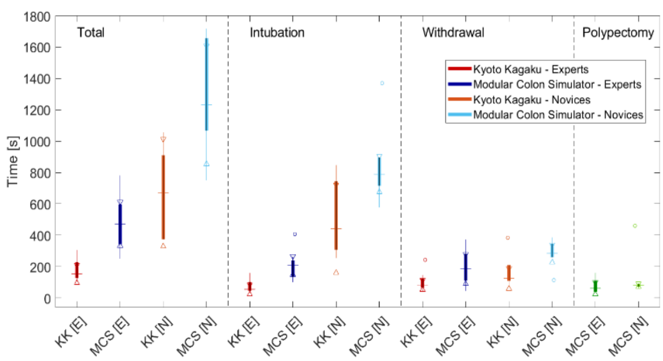

FIGURE 11. **Boxplot of timing metrics for the two simulators (Kyoto Kagaku vs. MSC) and the two levels of expertise (novices vs. experts).**

V. CONCLUSIONS AND DISCUSSION

The present work shows a modular, reproducible, and adaptable mechanical approach for fabricating customized physical colon simulators with successful replication of colon geometry. Modularity is maximized in i) the straightforward design of the molds, requiring few and simple commands (number of units and angle of flexion) for modifying curvatures and connections, and ii) in the installation of magnetic polyps, which enables prompt reuse and reinsertion at any location. Therefore, any user equipped with a 3D printer can easily fabricate colon simulators of different anatomies, either referring to existing models or creating random configurations, either simple or curvy. Moreover, the FEA conducted in this study demonstrates that low-cost silicon (*i.e.*, Ecoflex 00-50) can be used to reproduce the colon to satisfy both affordability and biomechanical similarity. Indeed, the only expenses associated with the production of the simulator are the cost of the printed material and the silicon. Overall, the simulator fabricated in this study, *i.e.*, MCS, costs about 100 € (printed plastic filaments, sealing material and silicone, *i.e.*, less than 1/10 the cost of commercially available products), although both the anatomy and the silicon can be changed, having an impact on the final costs. Finally, face, content, and construct validity tests have

assessed the level of anatomical realism, teaching content, and capability of identifying different levels of gastroenterologists' expertise in the fabricated simulator. Hence, the colon fabricated with the method proposed, together with the abdominal anatomical platform, can be used for the training of endoscopists, especially at an early stage.

The validation study also demonstrates that the MCS outperforms the well-known Kyoto Kakagu colonoscopy simulator in terms of the realism of the simulation and complexity of the procedure (*i.e.*, the complexity of the MCS procedure was rated as being more similar to that of a real colonoscopy).

Indeed, the MCS was more complex to navigate than the Kyoto Kagaku, as confirmed by the recorded timings (*i.e.*, the MCS required more time for intubation and withdrawal). Moreover, three novices were not able to complete a full colonoscopy on their first attempt with the MCS, but they could do it with the Kyoto Kagaku. This event realistically represents a clinical situation where a full colonoscopy is complex to perform and, in most cases, impossible for novices with little training [36].

However, the inherited modularity of the MCS design allows for easily creation of different simulators with increased complexity, which can enable personalized training. Therefore, the complexity of the procedure can increase with the doctor's experience. Furthermore, the possibility of implanting polyps even in difficult areas of the colon resembles one of the ideal objectives in colonoscopy for novice training. Finally, the ease of placing the fabricated colon on different supports allows the use of a sensorized platform such as the one adopted here to track metrics related to the procedure, *e.g.*, the force applied to the colon walls, allowing to measure the level of competence reached by the trainees to tune the colonic tract complexity lately to provide

TABLE II.
P-VALUES OF THE WILCOXON PAIRED TEST BETWEEN THE KYOTO KAGAKU AND THE MSC

Survey			
	All	Experts	Novices
Spatial Arrangement	0.1093	0.1250	1.000
Overall Simulation	<0.001	0.0078	0.0625
Overall Anatomy	0.0072	0.0312	0.1875
Colon Length	0.0083	0.0156	0.4062
Colon Thickness	0.0039	0.2500	0.0312
Rectum	0.3593	0.7500	0.6250
Sigma	0.0458	0.0156	1.000
Descending tract	0.0039	0.0625	0.1250
Splenic flexure	0.0019	0.0625	0.0625
Transverse tract	0.1562	0.5000	0.2500
Hepatic flexure	0.0019	0.0625	0.0625
Ascending tract	0.0312	0.2500	0.2500
Cecum	0.0156	0.2500	0.1250
Haustra	0.1289	1.000	0.1562
Mucosa appearance	1.000	0.8828	1.000
Mucosa response to steering	0.0029	0.03125	0.1250
Mucosa response to insufflation	<0.001	0.0625	0.0078
Monitor view	0.6699	0.9375	0.4531
Deformation	<0.001	0.0156	0.0078
Resistance to advancement	<0.001	0.0625	0.0156
Resistance to steering	<0.001	0.0625	0.0156
Paradoxical Motion	<0.001	0.0156	0.0156
Looping	0.0019	0.0625	0.0625
Loop reduction	0.0039	0.2500	0.0078
Force required	0.0078	0.2500	0.0312
Intubation complexity	0.0019	0.0312	0.1250
Withdrawal complexity	0.1875	1.000	0.3750
Navigation complexity	<0.001	0.0156	0.0156
Overall complexity	0.0053	0.0859	0.0625
Timings			
	All	Experts	Novices
Intubation time	0.0052	0.0078	0.0937
Withdrawal time	0.0039	0.0234	0.0937
Total time	0.0017	0.0078	0.0937
Insertion length	0.2297	0.4375	0.3437
Construct validity			
	KK	MCS	
Intubation time	<0.001	<0.001	
Withdrawal time	0.2358	0.1711	
Total time	<0.001	0.0013	
Insertion length	0.1341	0.9183	
Polypectomy	N.A.	0.3449	
Snare width	N.A.	1.000	

P-values for each question of the validation survey and for the timings grouped on the different level of expertise (*i.e.*, all, only experts and only novices). At the bottom, p-values of the Wilcoxon unpaired test between the performances of novices and experts with the Kyoto Kagaku (KK) and the Modular Colonoscopy Simulator (MCS). Statistical significance is highlighted in orange (p-values < 0.05).

TABLE III.
TIMING OF VALIDATION TESTS

		Experts		Novices		All	
		Mean [s]	SD [s]	Mean [s]	SD [s]	Mean [s]	SD [s]
Intubation	KK	74,9	45,7	506,3	244,2	259,8	270,5
	MSC	209,0	97,2	856,3	273,1	486,4	379,8
Withdrawal	KK	103,3	64,4	169,8	114,9	131,8	92,1
	MSC	196,5	115,4	279,0	93,5	231,9	111,0
Total	KK	178,1	75,9	676,2	305,1	391,6	323,0
	MSC	481,9	177,2	1275,5	368,3	822,0	485,0
Polypectomy	MSC	76,4	46,2	140,2	157,0	103,7	108,2

KK: Kyoto Kagaku simulator; MCS: Modular Colon Simulator.

an indication of patient discomfort as in clinical setting. This study presented one possible anatomy of the many that can be developed using this method. Indeed, the strength of the system relies on the modularity of materials and anatomies that can be generated depending on the final use. The modular CAD files of the molds and a complete guidebook about creating the simulator are open source and will be sent upon request to the authors.

Future work will focus on improving the realism of the simulator and enhancing the training experience for clinicians. One of the ways this goal will be achieved is by adding a mechanism to simulate intestinal peristalsis, which is the contraction and relaxation of the intestinal muscles that move food and waste through the digestive system. This improvement will make the simulator more realistic and provide a more accurate representation of what clinicians may encounter during real procedures. Additionally, the training experience will be improved by better tracking the clinicians' skills acquired with the simulator. One potential method for doing it is by embedding stretchable sensors on the intestinal walls to measure the forces exerted on the lumen with high accuracy. This system will provide valuable data on how well clinicians are performing and will allow for targeted training to improve any areas that need work.

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