

Endoscopic simulators

The ASGE Technology Committee provides reviews of existing, new, or emerging endoscopic technologies that have an impact on the practice of GI endoscopy. Evidence-based methodology is used, by performing a MEDLINE literature search to identify pertinent clinical studies on the topic and a MAUDE (U.S. Food and Drug Administration Center for Devices and Radiological Health) database search to identify the reported complications of a given technology. Both are supplemented by accessing the “related articles” feature of PubMed and by scrutinizing pertinent references cited by the identified studies. Controlled clinical trials are emphasized, but in many cases, data from randomized, controlled trials are lacking. In such cases, large case series, preliminary clinical studies, and expert opinions are used. Technical data are gathered from traditional and Web-based publications, proprietary publications, and informal communications with pertinent vendors.

Technology Status Evaluation Reports are drafted by 1 or 2 members of the ASGE Technology Committee, reviewed and edited by the Committee as a whole, and approved by the Governing Board of the ASGE. When financial guidance is indicated, the most recent coding data and list prices at the time of publication are provided. For this review, the MEDLINE database was searched through August 2010 for articles related to endoscopic simulators by using the key words “endoscopy simulator,” “endoscopic simulator,” “endoscopy and simulator,” “colonoscopy and simulator,” “gastroscopy and simulator,” “ERCP and simulator,” “endoscopic ultrasound and simulator,” and “EUS and simulator.” Articles generated from this search were culled for additional articles appropriate for the review. Abstracts presented at national meetings that were not published as full articles were not included.

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BACKGROUND

Endoscopy is traditionally learned by supervised, hands-on training in the clinical setting. This teaching method has the benefit of direct, 1-on-1 mentorship, but also has drawbacks, including increased procedure duration with associated financial implications,¹ dependence on a willing patient population, and potential increased patient discomfort and risk.² Endoscopic simulators were developed to minimize these limitations.

Simulation is the imitation or modeling of a real-life situation for training or instruction. Since the first simplistic endoscopic simulators were described in 1969³ and the early 1970s,^{4,5} these instruments have evolved greatly and now include complex computerized devices. This review focuses on endoluminal GI endoscopic simulators.

TECHNOLOGY UNDER REVIEW

There are three broad categories of GI endoscopy simulators: mechanical simulators, animal models (live animals or explanted organs), and computerized simulators.

Mechanical simulators

The first mechanical simulators for endoscopic training were constructed of plastic. The most well-known of these is the Erlangen plastic mannequin described in 1974, which allowed upper endoscopic examination with a flexible endoscope.⁵ Although advances have been made, mechanical models lack realism because poor simulation of tissue properties. Additionally, there is little variety, which serves to limit the usefulness of mechanical models in general. These have largely been supplanted by better alternatives such as animal models, combined mechanical/explanted organ models, or virtual-reality simulators, although mechanical models may still be useful for the novice during the initial phase of learning.

Some of the many plastic mechanical simulators available for purchase include the Upper GI Trainer, the Biliary Endoscopy Trainer, and the Colonoscopy Trainer (Chamberlain Group LLC, Great Barrington, Mass), the Colonoscopy Training Model Type 1-B and the ERCP Training Model Type E (Koken Co, Ltd, Tokyo, Japan), and the Endo-Trainer (ECE, Erlangen, Germany).

Live animal models

Live animal models are the most realistic endoscopy simulators. The haptic feedback is identical to human

tissue, although the thickness and orientation of various organs can be different. Juvenile pigs weighing approximately 35 kg have been adopted as the animal model of choice for endoscopy simulation.⁶ Expense, infrastructure requirements, and ethical concerns limit the use of live animal models.

Composite and explanted animal organ simulators

Composite simulators are fabricated from a combination of plastic parts and explanted animal organs and have overcome some of the limitations of live animal models. The most well-known of these is the Erlangen Active Simulator for Interventional Endoscopy (EASIE)(ECE-Training GmbH, Erlangen, Germany), also known as the Erlangen Endo-Trainer, which was developed in 1997. This was the first model to simulate spurting blood in a realistic manner and was developed to aid in the training of therapeutic endoscopy.^{7,8} This device consists of an anatomically correct plastic head and torso with a plastic cover mounted on a tilting device. Before use, specially prepared porcine upper digestive organs with arteries sewn into the lining are placed into the abdominal cavity. An arterial perfusion system feeds synthetic colored fluid via an electric pump incorporated into the frame to simulate arterial bleeding. A stop-valve system allows for control of bleeding. Modified, lighter weight composite simulators include the Erlangen compactEASIE^{9,10} and the Endo X Trainer (Medical Innovations International, Rochester, Minn).¹¹ These are plastic table-top platforms on which porcine organs are placed. These simulators can be set up to mimic a variety of endoscopic scenarios including hemostasis techniques, gastroscopy, colonoscopy, EMR, polypectomy, ERCP, PEG tube insertion, EUS, and double-balloon enteroscopy, depending on the model.¹²⁻¹⁴

Limitations of ERCP simulation using the composite porcine model are that the major duodenal papilla is located 3 to 4 cm proximal to the location in the human, and the pancreatic duct orifice is separate and more distally located. The neo-papilla model was developed to simulate human anatomy more accurately. Chicken heart muscle is sewn to the porcine duodenum in the expected location of a human papilla, and porcine iliac or splenic arteries are attached to approximate the bile and pancreatic ducts.¹⁵

Advantages of ex vivo animal models include a more realistic feel compared with purely mechanical models, the opportunity to practice therapeutic endoscopy in a controlled setting, and lower cost compared with computer-based simulators. Disadvantages include lengthy preparation time, disposal of tissue, and unfavorable tissue characteristics compared with vital tissue.

Computerized or virtual-reality devices

Computer simulators were first developed in the 1980s.^{16,17} Since then, the following innovations in software technology have made computer simulators more

realistic. Interactive video technology uses endoscopic images stored on a disk and displays them in real time in response to user's endoscopic movements. Computer graphics simulation uses computerized images displayed in response to the endoscopy being performed. Videographic tool technology, a hybrid of the two, enables real-time movement of virtual endoscopic accessories relative to endoscopic images. There are two commercially available computerized endoscopy simulators and one colonoscopy simulator, which is not available for purchase.

The GI-Bronch Mentor. The GI-Bronch Mentor (Simbionix, Cleveland, Ohio) consists of a plastic mannequin on a wheeled trolley. The mannequin has a mouth and nose for upper endoscopy or bronchoscopy and an anus for lower endoscopy. The interior of the mannequin contains sensors that enable haptic feedback to the user. A 24-in, flat, LCD touch screen for image display and system operation is attached to the trolley base on a movable arm. The system comes with an endoscope (Pentax ECS-3840F) for upper and lower endoscopy and a duodenoscope (Pentax ED-3440T) if the ERCP module is used. These endoscopes are modified and cannot be used for actual patient care. The endoscope tip contains a sensor allowing the computer to generate a dynamic endoscopic view in response to the user's movements rather than an actual lens. A 25-cm master tool and two guidewires for ERCP are part of the system. The master tool handle portion is similar to standard endoscopic devices, but has sensors at its tip to simulate the procedure being performed (eg, polypectomy). The simulator is movable within a room but requires expert dismantling for moving to another location. The entire system weighs less than 170 kg (375 lb) and can be used repeatedly without special preparation between procedures. It requires a standard 120-V electrical outlet.

Currently available modules include scenarios with varying degrees of difficulty of anatomy and complexity of tasks. The basic system consists of the simulator and modules for basic tasks (cyberscopy module) as well as upper and lower endoscopy. Other modules can be purchased as add-ons, including therapeutic (hemostasis) cases, a flexible sigmoidoscopy module, ERCP (two modules), and diagnostic EUS. These come with all the equipment (eg, duodenoscope) necessary for a particular procedure. The EUS module provides a platform for hands-on practice and learning of EUS. With this module, the user maneuvers an endoscope to view a realistic US presentation in real time. The trainee learns to interpret EUS images and receives immediate objective feedback on performance. The simulator also provides on-screen visual assistance with side-by-side, split-screen EUS/3-dimensional mapping. There are more than 30 individual EUS tasks, including didactic visual explanations. Both linear and radial EUS can be simulated. The device also includes a performance evaluation including review of saved images, indication of land-

marks not properly identified, and indication of anatomy not properly identified.

CAE Healthcare AccuTouch. The AccuTouch device (CAE Healthcare, Montreal, Quebec, Canada; previously marketed by Immersion Medical, San Jose, Calif) is another virtual-reality endoscopy simulator. Like the Symbionix simulator, it is a trolley-mounted, computerized device with a flat-screen display on a movable arm. It has an opening with a removable plate to represent either the face or the buttocks for upper and lower endoscopy. A model endoscope is provided with the system. A robotic interface provides the user with haptic feedback to simulate the feel of actual endoscopy. Several modules are available for basic EGD and colonoscopy, ERCP, and flexible sigmoidoscopy. Supplemental modules include cases for polypectomy, biopsy, and hemostasis. The AccuTouch device also simulates patient vital signs and responses to administration of sedation and to pain. There are comprehensive metrics available for evaluation of user performance (eg, percentage of mucosa visualized). There is no EUS module as of this writing.

Other Virtual-Reality Simulators. Other prototype computer simulators have been evaluated in trials (eg, the Olympus Endo TS-1 colonoscopy simulator)¹⁸ but are not available for purchase.

Technique

To use the Erlangen Endo-Trainer and table-top composite simulators, the animal specimens for the models are deep frozen and are removed 5 to 6 hours before a workshop and are then sewn onto the baseplate.¹⁹ The endoscopist inserts the endoscope through a mouthpiece or through the plastic portion of the compact model in standard fashion. Advancement of the endoscope through the simulator may be more difficult than in an actual patient because of tissue rigidity and loss of elasticity.

The virtual-reality simulators have an initial tutorial with didactic sessions including 3-dimensional videos of anatomy, an atlas of pathologic findings, indications, contraindications, and complications associated with a particular procedure. Live video segments instruct the trainee on how to use the endoscope, including insertion, retroflexion, biopsy, polypectomy, and cannulation of the common bile duct during ERCP. For each type of endoscopy, simulated patient procedures follow, which include a variety of pathologic findings, patient types, and increasing degree of technical difficulty.

Both the Symbionix and the AccuTouch systems feature a virtual attending physician who can advise the trainee how to proceed during the examination, as well as external views of the procedure to demonstrate technical difficulties such as loop formation during colonoscopy. The virtual lumen expands or collapses with air insufflation or suction, and the patient can report audibly discomfort or even demand cessation of the examination. Biopsy techniques and advanced procedures, such as polypectomy

and ERCP, are available in additional modules. Polypectomy equipment, including snares, mini-snares, hot-biopsy forceps, electrocautery probes, and an electro-surgical unit are simulated.

Simulated potential complications include uncontrolled bleeding when the polyp head is guillotined during polypectomy, electrocautery-induced perforation, and vasovagal reactions by the patient. At the completion of the simulated examination, a critique is provided to the trainee that describes several performance parameters, including the total time of the examination, recognition of pathologic findings, degree of air insufflation, patient degree of discomfort, percentage of mucosa visualized, time spent in red out (collisions with the bowel wall), use of the virtual attending physician, and ability to perform retroflexion or other therapeutic maneuvers. If perforation occurs, the procedure is immediately terminated.

COMPARATIVE STUDIES AND EFFICACY

There are two types of simulator studies: validity studies and clinical trials. Construct validity refers to whether a simulator can distinguish between novices and experts as measured by variables such as procedure time, extent of procedure achieved, and recognition of pathology. Validity studies are important in the initial evaluation of a simulator, but clinical trials are necessary to determine whether use of the simulator translates into improved endoscopy in the clinical setting.

Other than a pilot study to validate a noncommercially available mechanical ERCP simulator,²⁰ there are no published validity or clinical (outcomes) studies for any mechanical simulators. Both types of studies are published for ex vivo animal simulators and computer simulators.

Upper endoscopy and therapeutic endoscopy

Two studies have demonstrated that the computer simulators are valid instruments for upper endoscopy in that they can distinguish between expert and novice endoscopists.^{21,22} A clinical trial randomized 22 GI fellows with no previous upper endoscopy experience to pretraining with the Symbionix computer simulator or to usual bedside training. The simulator-trained group performed more complete examinations and required less assistance in 19 or 20 subsequent patient examinations.²³ Clinical trials have also evaluated whether simulator training improves hemostasis skills using ex vivo composite animal models. A randomized, controlled trial randomized 37 novice gastroenterology fellows to three sessions of training in endoscopic hemostatic techniques or to purely clinical training. On final testing with the simulator, the overall skill of the intensively trained group improved significantly compared with baseline; the overall skill in the control group was not significantly different except for variceal ligation. However, when the groups were compared with each other, the only skill that reached significant difference was

hemoclip application.²⁴ Another study of 28 trainees randomized to either lectures or hands-on training with a composite ex vivo animal simulator showed significant improvement in therapeutic techniques (eg, polypectomy, control of hemorrhage) for the hands-on training group compared with controls.²⁵ However, endoscopic skills were tested on the simulator itself rather than on actual patients. Finally, a French study of 35 GI fellows showed similar results²⁶; again final testing was performed on the simulator. There have been no validation or clinical studies for therapeutic endoscopy using the computer simulators.

The Erlangen Endo-Trainer was found to be valid for simulation of double-balloon enteroscopy in one observational study of 97 participants who were able to accurately assess the depth of insertion after training.²⁷ No clinical trials have been performed for enteroscopy.

A validation study was recently performed for ERCP by using the Symbionix computer simulator. Two simulated ERCP procedures were performed by expert and novice endoscopists, and the simulator could differentiate between the two groups based on mean total procedure time only for the first procedure and for the ability to cannulate the common bile duct plus procedure time for the second procedure.²⁸ Most participants thought that the simulator was realistic. For performance of ERCP, an ex vivo porcine simulator was thought to be more realistic compared with the Symbionix computer model in a comparison trial during a one-day therapeutic endoscopy course.²⁹ The Erlangen-type ex vivo porcine simulator was found to be a valid instrument for ERCP simulation in another study.³⁰ No clinical trials for ERCP have been performed. There have been no EUS validation studies or clinical trials to date.

Colonoscopy

Multiple validation studies have been performed for colonoscopy using the computer simulators. All but one³¹ found these to be valid simulation instruments in that they could distinguish between expert and novice endoscopists.³²⁻³⁶ One validation study showed that trainees failed to improve without feedback from a mentor.³⁷ Several clinical trials have also been performed for colonoscopy and showed benefit in the early phase of training. A small study of eight surgical residents showed that monthly training on the simulator over two years improved examination efficiency compared with usual clinical training. However, testing was on the simulator rather than on actual patients, limiting the applicability of these data.³⁸ A multicenter trial randomized 45 GI fellows to 10 hours of simulator training during their first eight weeks of fellowship or to no training at all (clinical or simulator) and evaluated their performance on 200 subsequent patient colonoscopies.³⁹ The simulator-trained group demonstrated significantly higher overall competence during the first 80 clinical cases, but both groups required similar numbers of procedures (mean 160) to reach 90% competence. A randomized, controlled trial of eight novice GI fellows found

that the group with six hours of simulator training significantly outperformed the control group in all areas except insertion time. The benefit in depth of insertion, independent completion, and ability to identify landmarks extended to 30 procedures, beyond which the groups were similar.⁴⁰ Finally, a recent study using the Endo TS-1 (Olympus Medical Systems, Center Valley, Pa) computer simulator randomized 36 trainees with no previous colonoscopy experience to 16 hours on the simulator or to usual patient-based training. The primary outcome was performance on three test cases on the simulator and three actual colonoscopies, as assessed by blinded experts. The simulator group had significantly higher completion rates and technical skills on the simulator test cases. Although the simulator group had performed no live patient colonoscopies, there was no difference between the groups in the live patient test cases, demonstrating transfer of simulator skills to live procedures.⁴¹

Flexible sigmoidoscopy

The AccuTouch flexible sigmoidoscopy simulator was found to be able to distinguish between novices and experts in two validation studies.^{42,43} However, subsequent clinical trials did not show an improvement in skills in simulator groups compared with clinically trained groups.^{44,45} In 1 of these studies, the bedside-trained fellows performed significantly better.⁴⁵ Notably, however, the test group received only 2.3 hours of training on the simulator. In the other study,⁴⁴ patients reported less discomfort with examinations performed by the simulator-trained endoscopists.

EASE OF USE

Purely mechanical simulators are easy to use and require minimal preparation, but lack realism. Composite mechanical/explanted animal organ simulators are easy to use but require more extensive preparation and disposal after use. Live animal models are highly realistic but require special facilities and are more expensive than mechanical or composite systems. Computerized virtual-reality simulators have the advantage of prolonged use at minimal additional expense after a one-time startup cost. They are reasonably user-friendly once one has been proctored in their use. They continue to lack of realism.

SAFETY

There are no reports of hazard to operators using simulators. There are no published data addressing whether simulator training improves patient safety in the clinical setting.

FINANCIAL CONSIDERATIONS

Use of composite animal simulators requires the initial costs of the unit plus purchase of prepared porcine organs for each simulator. Computerized simulators require pur-

TABLE 1. Simulators

Manufacturer	Name	Simulator type	Available models/modules	List price, \$	Comments
Medical Innovations International Inc	Endo X Trainer	Composite plastic/animal	EGD/colonoscopy/ERCP/polyps/bleeding Porcine organ package	3449	Erlangen-type model with porcine organs
Endosim, LLC	EASIE-R	Composite plastic/animal	EGD/colonoscopy/ERCP/polyps EUS/Roux-en-Y ERCP/enteroscopy Porcine organ package	2100	Erlangen-type model with porcine organs Organ packages in various configurations must be purchased separately; available for \$250-750
Delegge Medical	Various Erlangen-type endoscopy models (eg, Endo Billy, Endo Eddy)	Composite plastic/animal	EGD/colonoscopy/ERCP/polyps GI bleeding Porcine organ package	2250-2850	Erlangen-type model with porcine organs Organ packages in various configurations must be purchased separately; available for \$135-250
Simbionix	GI Branch Mentor	Virtual reality	Gastroscopy & colonoscopy modules	64,500	Standard package does not include duodenoscopy
			Gastric emergency bleeding module	6000	
			Flexible sigmoidoscopy	5000	
			Duodenoscope	6000	Required for ERCP and EUS modules
			ERCP modules (2)	15,000	
			EUS module	15,000	
			Shipping & handling	2500	Installation, training, calibration, 10-y warranty included
			Total	114,000	
CAE Healthcare	AccuTouch	Virtual reality	UGI package	76,750	Includes UGI scope head, EGD module, ERCP module
			LGI package	45,750	Added to UGI package, includes LGI scope head, flex sig module, flex sig supplemental module, colonoscopy module, colonoscopy biopsy module, polypectomy module
			Upper GI bleed upgrade package	19,000	Includes 2 22-in flat-panel monitors, computer
			Total	141,500	
			Modules can be purchased separately:		
			Intro to Flex Sig module	7175	
			Flex Sig Supplemental Module	7175	
			Colonoscopy intro module	7175	
			Colonoscopy biopsy module	8650	
			Colonoscopy polypectomy module	8650	
			Intor to EGD module	8650	
			ERCP module	8650	

UGI, upper GI; LGI, lower GI.

chase of the unit, which comes with basic modules and equipment. Advanced modules such as ERCP and EUS must be purchased separately for the Simbionix device. Prices of available simulators are listed in Table 1.

AREAS OF FUTURE RESEARCH

Before competence can be assessed, a minimum number of procedures must be performed. Because some pro-

cedures (eg, ERCP) are infrequently performed, trainees may have a difficult time obtaining the required number. Further research is needed to address whether simulated procedures could replace some of these required actual procedures performed on patients; this did not appear to be true for colonoscopy in one study.³⁹ It is unknown whether endoscopic simulators can be used to assess procedure competence and/or granting of hospital privileges. Cost-effectiveness studies are needed to determine whether simulators decrease training time and subsequent procedure time enough to offset their cost. Studies are needed to determine whether there is a benefit of using simulators beyond the initial phases of learning. It is unknown whether the computer simulators improve recognition of pathology in the clinical setting. Outcomes studies and further validation studies are needed on the computer simulators for ERCP and EUS. Virtual-reality simulators of sufficient sophistication could be used to simulate unusual or challenging procedures that have not yet been performed by the operator.⁴⁶ However, existing simulators are limited to preprogrammed scenarios of varying difficulty. Simulators with programmable capability or artificial intelligence do not yet exist for GI endoscopy.

SUMMARY

Simulators have been shown to improve colonoscopy skills in the clinical setting for the initial phases of training, but their long-term benefit is uncertain. They also improve hemostasis skills, but transfer of these skills to the clinical setting has not yet been demonstrated. A computerized EUS simulator is now available, but studies on its use have not yet been published. More randomized trials are needed to assess the role of simulation in endoscopy training programs. In the future, it is conceivable that simulators might be used to assess the competence of trainees graduating from fellowship or residency programs or of those applying for hospital privileges. Furthermore, it could be envisioned that simulation could be used to “train the trainers” or even to evaluate the skills of the trainer. However, additional research is necessary to determine whether simulators can be used in these capacities.

DISCLOSURE

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