ORIGINAL ARTICLE

Multicenter, randomized, controlled trial of virtual-reality simulator training in acquisition of competency in colonoscopy

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Background: The GI Mentor is a virtual reality simulator that uses force feedback technology to create a realistic training experience.

Objective: To define the benefit of training on the GI Mentor on competency acquisition in colonoscopy.

Design: Randomized, controlled, blinded, multicenter trial.

Setting: Academic medical centers with accredited gastroenterology training programs.

Patients: First-year GI fellows.

Interventions: Subjects were randomized to receive 10 hours of unsupervised training on the GI Mentor or no simulator experience during the first 8 weeks of fellowship. After this period, both groups began performing real colonoscopies. The first 200 colonoscopies performed by each fellow were graded by proctors to measure technical and cognitive success, and patient comfort level during the procedure.

Main Outcome Measurements: A mixed-effects model comparison between the 2 groups of objective and subjective competency scores and patient discomfort in the performance of real colonoscopies over time.

Results: Forty-five fellows were randomized from 16 hospitals over 2 years. Fellows in the simulator group had significantly higher objective competency rates during the first 100 cases. A mixed-effects model demonstrated a higher objective competence overall in the simulator group ($P < .0001$), with the difference between groups being significantly greater during the first 80 cases performed. The median number of cases needed to reach 90% competency was 160 in both groups. The patient comfort level was similar.

Conclusions: Fellows who underwent GI Mentor training performed significantly better during the early phase of real colonoscopy training. (Gastrointest Endosc 2006;64:361-8.)

Learning to perform colonoscopy requires a mastery of technical and cognitive skills. Virtual-reality computer simulators are among the tools that have been used to enhance traditional endoscopy teaching.[1-9] These consist of an endoscope with real dials and buttons, and a closed tip that contains forced feedback sensors. The trainee experiences the "feel" of resistance as the endoscope is advanced through a mannequin. A computer displays preprocedure clinical information; generates endoscopic images, including a variety of pathologic findings; and provides real-time feedback about looping and pressure. Individuals can work independently on these simulators and can view information about their performance and the pathology encountered.

The colonoscopy simulators currently available commercially include the Simbionix GI Mentor (Simbionix USA Corporation, Cleveland, Ohio)(Fig. 1) and the Immersion Medical AccuTouch Endoscopy Simulator (Immersion Corporation, Gaithersburg, Md). These models allow practice of both technical maneuvers and cognitive recognition skills without any inconvenience, discomfort, or risk to patients. On the GI Mentor, special hand-eye coordination exercises are incorporated, which can be integrated into the training program.

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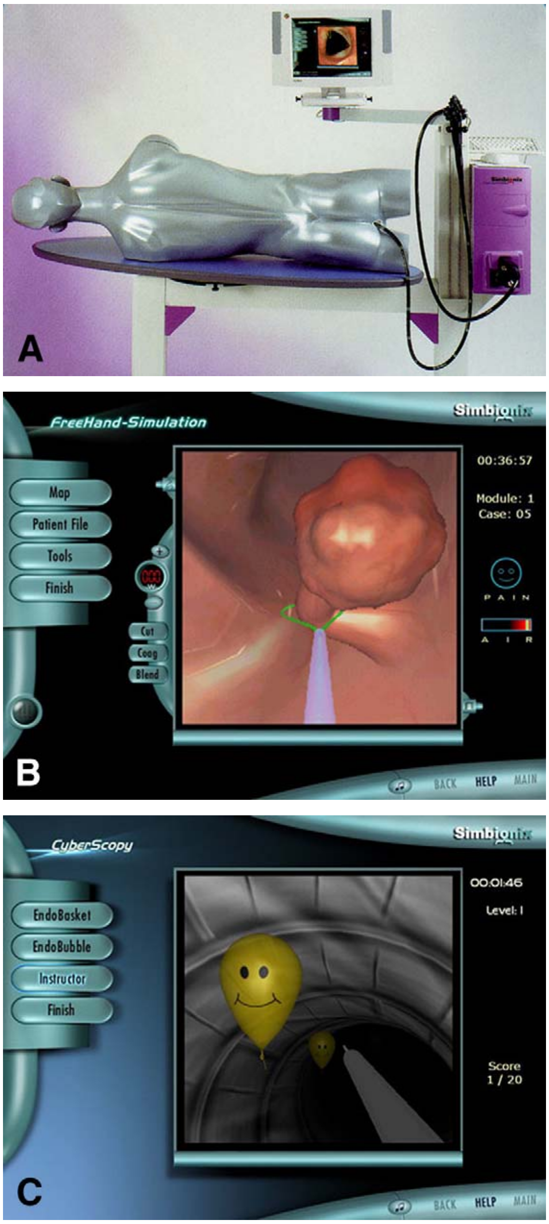

Figure 1. A, Simbionix GI Mentor Simulator: exterior view. **B,** Simbionix GI Mentor Simulator: polypectomy image. **C,** Simbionix GI Mentor Simulator: hand–eye coordination exercise.

Validation data establishing a benefit for simulator training in colonoscopy are limited to 1 prospective controlled trial involving 8 novice fellows. In this pilot study, 4 trainees who spent 6 hours on the AccuTouch simulator before performing a real colonoscopy did better than 4 counterparts without simulator experience during the first 30 cases, but performed similarly thereafter.[10] Two studies that compared simulator-based training to traditional bedside flexible sigmoidoscopy instruction showed an inferior or comparable performance after simulator training.[11,12] In both of these studies, actual simulator time was limited to ≤3 hours.

Capsule Summary

What is already known on this topic

- Competency in colonoscopy can be achieved by completing as many as 200 supervised cases.
- Virtual reality computer simulator training may improve trainees' performance.

What this study adds to our knowledge

- In a multicenter, randomized, controlled trial by using a virtual-reality computer simulator, the median number of cases required to reach 90% objective competency was identical in the simulator and no-simulator groups, but the simulator group proved to be 20 cases ahead of the no-simulator group at several points along the learning curve, with most of the benefit occurring in the first 80 cases.
- Regardless of whether the fellows received simulator training, 200 real cases were still required before the 45 trainees were fully competent.

The aim of this study was to determine whether a 10-hour structured training program that used the GI Mentor simulator provided an objective benefit to novice gastroenterology fellows who are learning to perform colonoscopy.

MATERIALS AND METHODS

All incoming gastroenterology fellows at participating teaching institutions in the New York metropolitan area over 2 years were invited to participate in the study. For inclusion, each program's training director had to agree to adhere to the protocol and to delay any first-year performance of colonoscopy for the first 8 weeks of the fellowship, and institutional review board approval had to be obtained. Exclusion criteria for fellows consisted of previous formal training in colonoscopy (>10 cases) and an inability to comply with the schedule of five 2-hour training sessions over the first 8 weeks of fellowship. Those who met the entry criteria and consented to participate were randomized into 2 groups ("simulator training" or "no simulator training"), with a 50% chance of being placed in either group. The method of sequence generation was a random-number table.

Before entry into the study, all fellows filled out a brief questionnaire, including demographics, such as age, gender, and the year of graduation from medical school; gastroenterology training program; and the number of flexible sigmoidoscopies performed before the GI fellowship. All fellows attended general lectures on colonoscopy as part of a didactic endoscopy course given to all regional incoming fellows, which emphasized key principles, such as application of torque, reduction of loops, and careful examination for pathology during scope withdrawal.

The simulator training group (group A) was given a supervised orientation to the GI Mentor simulator during the first week of fellowship, along with instructions about the simulator training sessions to be completed during the first 8 weeks of fellowship.

During the next 8 weeks, each fellow assigned to the simulator training group completed five 2-hour private sessions on the simulator. Each hour of training followed a standard protocol of activities. These included warm-up hand–eye coordination exercises and the performance of 2 specific simulated procedures each hour. In all, 10 different cases were used during the simulator training program. Fellows kept a log of attempted simulated procedures performed during each 2-hour session and a log of all actual sigmoidoscopies and gastroscopies performed during the study period. Participating fellows did not perform any real colonoscopies until they completed all 10 hours on the simulator. GI-simulator stations were housed in teaching hospitals at 2 locations in the city.

Fellows in the simulator training group were asked to fill out a simple questionnaire on completion of the 10th hour of simulation to elicit their impression about the usefulness of the training sessions. During the second year of the study only, it was possible to extract data automatically recorded on the simulators to compare performance variables from fellows in the simulator training group between hour 1 and hour 10 on the model. To facilitate this comparison, the same simulated cases were selected for the fellows to perform during hour 1 and hour 10. Variables measured included total procedure time, time to reach the cecum, percentage of mucosal surface examined, and number of episodes of excessive pressure noted. The GI Mentor provides visual and audible feedback on discomfort but does not distinguish overinsufflation from looping as the cause. In addition, efficiency scores (ES) that assessed how much of the mucosal surface was seen in relation to the total procedure time were automatically calculated by the simulator after each case that a trainee performed.

After completing 10 hours on the model, fellows in the simulator training group were allowed to begin supervised, actual colonoscopy at their home hospital.

Fellows randomized to the no-simulator training group (group B) received colonoscopy training exactly as fellows typically learn the procedure, by performing real procedures under supervision. This began approximately 8 weeks into the start of their fellowship. Fellows in the no-simulator training group from an individual training program did not begin performing supervised colonoscopy training until the same time that the fellows in the simulator training group at their institution completed their simulator training.

For each real colonoscopy performed by fellows participating in the study, the fellows were responsible for having their proctor fill out a short evaluation form. This form was the same one used to evaluate colonoscopy competency in the 1996 multicenter study by Cass et al.[13] The data recorded included the procedure number for the fellow, the ability to reach the transverse colon and the cecum without assistance, and the ability to correctly recognize and identify abnormalities, as well as an overall subjective rating of competency on a 5-point scale. For those cases in which the trainee was not able to reach the cecum without assistance, the supervising endoscopist was asked to indicate whether or not the examination was difficult for the proctor to complete. Proctors were also asked to rate patient discomfort for each colonoscopy on an analog scale from 1 (no discomfort) to 5 (extreme discomfort). Each month, forms were sent to a central site for data entry. Forms were collected until each fellow reached 200 procedures or the study time period was over (whichever happened first).

No fellow's name appeared on the study evaluation forms. All fellows were given code numbers to identify them on all study forms. The key to these code numbers was maintained by the principal investigator and was not made available to any program directors or individuals involved in data entry. Proctors filling out the individual evaluation forms remained blinded as to whether the particular fellows did or did not receive prior simulator training. This protocol was approved by the institutional review boards of the participating institutions.

Study outcomes

The primary outcome for this study was a comparison of the simulator and no-simulator groups in the development of objective and subjective measurement of competency in performing colonoscopies over time. Secondary outcomes were a comparison of patient-discomfort level as measured by proctors and the median number of cases required by each group to reach 90% competency.

Statistical methods

A 2-sample *t* test was used to compare the difference in objective competence, subjective competence, and observed patient discomfort between the simulator group and no-simulator group at every group of 20 cases. Each group of 20 colonoscopy cases was considered as a block of examinations.

All of the blocks' data were then combined, and a mixed-effects model was applied to compare the difference between groups at every block simultaneously: in the mixed-effects model, a random effect was used to take into consideration the correlations between the observations from same fellow over time; fixed effects included each block as a categorical variable, a group indicator (simulator and no-simulator), and the interaction between them.

In addition, Kaplan-Meier curves were generated to determine the number of blocks of 20 cases needed for each

TABLE 1. Longitudinal skill development on GI Mentor simulator

	Case 1			Case 2		
Variable	Hour 1	Hour 10	*P* value*	Hour 1	Hour 10	*P* value*
Total procedure time, s	693	301	<.001	812	399	<.001
Time to cecum, s	239	123	<.001	377	228	.022
% of mucosal surface examined	86.3	82.7	.086	83.7	84.1	.093
No. episodes of excessive pressure	0.31	0.15	.63	3.17	1.31	.075
ES	61.9	85.8	.004	52.4	85.7	<.001

No. = 13 subjects; mean values shown.
*Wilcoxon signed-rank test.

TABLE 2. Precolonoscopy experience*

	Simulator group (n = 22)	No-simulator group (n = 23)	Total
Mean gastroscopies	67	80	147
Mean flex-sigs	4	5	9
Total	71	85	156

flex-sigs, Flexible sigmoidoscopies.
*Nonsignificant differences between the 2 groups.

TABLE 3. Colonoscopy logs

	Simulator group (n = 22)	No-simulator group (n = 23)	Total
Colonoscopy forms collected	3725	3925	7650
Colonoscopies difficult for proctor	189 (5%)	171 (4.4%)	360 (4.7%)
Yield, %*	84.7	85.3	85.0

*Total no. colonoscopies logged = 200 per fellow.

group to reach a median of 90% objective and subjective competency. A log-rank test was performed to compare the 2 groups.

RESULTS

Over 2 years, 51 first-year gastroenterology fellows, from 16 hospitals, were approved to participate. Two were excluded because of prior colonoscopy experience, and 4 others dropped out after randomization because of protocol violations during the training phase, leaving 45 trainees who completed the study (simulator group, N = 22; no-simulator group, N = 23).

All 22 fellows in the simulator group completed 10 hours of training on the GI Mentor and completed the log form and the questionnaire. The respondents rated the overall satisfaction with the simulator training as moderately useful to useful, with a mean score of 3.5 (range, 1 [no use] to 5 [very useful]).

The longitudinal improvement in skills on the simulator between hour 1 and hour 10 for 13 fellows randomized to the simulator group in the second year of the study is shown in Table 1. Significantly faster time to the cecum, total procedure time, and efficiency score were observed for both case 1 and case 2 by the 10th hour of training.

Endoscopy logs before initiation of real colonoscopy experience revealed similar noncolonoscopy endoscopy experience in the simulator and no-simulator training groups (Table 2). The number of real colonoscopy evaluation forms collected from the fellows and the total number of real colonoscopies performed according to the fellows' procedure logs are shown in Table 3. The yield of colonoscopy procedures evaluated by proctors was 84.7% in the simulator group and 85.3% in the no-simulator group (Table 3). The number of colonoscopy procedures that required assistance by the proctor to complete and that were described as ''difficult for the proctor'' was similar in the 2 groups (Table 3).

The mean objective competency ratings and the mean subjective competency ratings for the 2 groups are shown in Table 4 and Table 5. When a Bonferroni correction is made on multiple comparisons, with a total of 10 comparisons (1 per session), a comparison is considered to be statistically significant if the *P* value is below .005. Based on this criterion, it still shows that the simulator group is doing significantly better in some of the earlier sessions. However, a Bonferroni correction may be too conservative in some instances.[14]

There were no observed significant differences in proctor-assessed patient discomfort between the 2 groups at any time during the training (Table 6).

The mixed-effects model indicated that the simulator group performed significantly better overall in terms of

TABLE 4. Comparison between simulator and no-simulator group in objective competence*

Group	Session 1	Session 2	Session 3	Session 4	Session 5	Session 6	Session 7	Session 8	Session 9	Session 10
Mean in simulator (n = 23)	50.4	64.5	74.0	76.7	76.8	77.8	80.8	89.5	87.8	92.7
Mean in no-simulator (n = 22)	40.9	52.0	62.0	64.4	70.2	77.6	80.5	83.7	85.2	90.9
P value based on *t* test	.06	<.0001	<.0001	<.0001	.03	.91	.89	.01	.02	.04

*Objective competency is the ability to reach the transverse colon and the cecum without assistance, and the ability to correctly recognize and identify abnormalities.

TABLE 5. Comparison between simulator and no-simulator group in subjective competence*

Group	Session 1	Session 2	Session 3	Session 4	Session 5	Session 6	Session 7	Session 8	Session 9	Session 10
Mean in simulator (n = 23)	47.6	68.6	76.3	78.0	81.3	82.0	86.1	88.8	88.9	90.8
Mean in no-simulator (n = 22)	36.6	57.4	68.4	75.4	79.4	82.3	84.1	86.4	86.8	90.5
P value based on *t* test	.08	.004	.005	.32	.28	.88	.32	.11	.32	.82

*Subjective competency is on a 5-point scale; 1 (totally unskilled) to 5 (competent and expedient).

TABLE 6. Comparison between simulator and no-simulator group in discomfort*

Group	Session 1	Session 2	Session 3	Session 4	Session 5	Session 6	Session 7	Session 8	Session 9	Session 10
Mean in simulator (n = 22)	25.7	23.2	16.7	16.0	16.7	13.4	11.9	10.5	10.7	8.9
Mean in no-simulator (n = 23)	31.4	19.1	19.5	18.2	16.5	13.9	11.3	10.4	11.8	9.2
P value based on *t* test	.42	.14	.22	.39	.94	.85	.74	.99	.55	.81

*Discomfort is rated on a scale of 1 to 5 with 1 (very comfortable) to 5 (severe pain to patient).

objective competence ($P < .0001$). The difference between groups was significantly larger in earlier blocks (up to the 4th block) than during the latter blocks of 20 cases ($P < .001$) (Fig. 2). The mixed-effects model showed similar significant improvement in subjective performance overall for the simulator group ($P \leq .001$), with a greater difference between groups during the first 40 cases compared with the latter 160 cases ($P = .02$). For discomfort, the simulator group did not do significantly better overall. Within each group, the more blocks the fellow had, the less discomfort and the greater objective and subjective competencies were observed. The performance improved the most in the earlier blocks and the least in the later blocks.

The survival analysis performed to compare the number of procedures required for trainees to reach 90% objective competency rates is shown in Table 7. There was no significant difference in the number of blocks needed

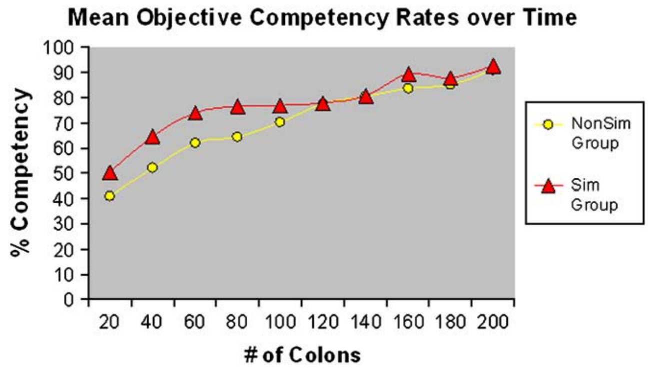

Figure 2. Learning curve of acquisition of objective competency. Improvement in the simulator group occurred primarily in the early phase of training. Objective competency is defined as the ability to reach the transverse colon and the cecum without assistance and the ability to correctly recognize and identify abnormalities.

for fellows to reach the 90% mark for the simulator vs no-simulator groups (median, 8 [95% CI, 8, 9] vs 8 [8, 9]), $P = .25$] by the log-rank test. The Kaplan-Meier curve (Fig. 3) did show a lead time of approximately 20 cases for reaching 90% objective competency in the simulator group. For example, about 10% of fellows in the simulator group vs none of those in the no-simulator group reached 90% objective competence after 6 blocks, and 10% of the no-simulator group reached 90% competence after 7 blocks. Similarly, 70% of the simulator group vs 50% of the no-simulator group reached 90% competence after 8 blocks, and 70% of the no-simulator group reached 90% competence after 9 blocks. Similar results were seen for subjective competence. By the end of 200 cases, the percentage of fellows reaching 90% competency was 100% in the simulator group and 96% in the no-simulator group.

DISCUSSION

Much of the data published to date validating the use of computer simulators have been limited to qualitative assessment of simulator realism and small studies looking at performance on either the models themselves or on limited numbers of real procedures.[15-20]

In this study, both objective and subjective assessments of competency were significantly improved in the simulator group by using the mixed-effects model. This is the first prospective validation study for the GI Mentor in colonoscopy training. It differs from the Mayo study of the AccuTouch colonoscopy simulator in the longer simulator training protocol (10 vs 6 hours) and in the larger cohort of fellows enrolled (45 vs 8).[10] As Gerson and Van Dam[21] postulated in their recent review, the benefit was primarily limited to the early phase of training.

The longitudinal data on the simulator over the 8-week period demonstrated improvement in technical performance on the model. The clinical significance of this performance data is uncertain, because there are no published data that establish that a skills test on a colonoscopy simulator correlates well with an objective assessment of performance on real procedures.

One cannot control for the difficulty of the procedures performed. However, the number of examinations requiring proctor assistance that were deemed difficult for the proctor to complete was similar in the 2 groups; this supports the assumption that the fellows in the 2 groups performed cases of similar difficulty.

The yield of evaluation forms collected was relatively high and similar in the 2 groups. Because the yield was approximately 85%, one needs to infer a 15% adjustment upward in the actual median number of procedures required for the fellows to reach 90% competency.

The cumulative success curves generated from the 2 study groups provided a few important insights about the usefulness of simulator experience for colonoscopy and about colonoscopy training in general. First, the median number of cases required to reach the accepted benchmark of 90% objective competency was identical in the 2 groups. However, the simulator group proved to be 20 cases ahead of the no-simulator group at a number of the points along the curve. These curves highlight the observation that different fellows learn at different rates and that objective demonstration of competency is much more important than the surrogate marker of number of cases performed. Another important finding in this study was that, regardless of whether the fellows received simulator training, 200 real cases were still required before almost all 45 trainees were fully competent.

This corroborates the seminal work by Cass et al[13] presented at Digestive Disease Week in 1996 in which the same evaluation form used in this study was used to score the performance of consecutive colonoscopies performed by 135 fellows from 14 centers during their first year of training. In that study, more than 200 colonoscopies were required for trainees to develop the ability to perform complete and accurate examinations greater than 90% of the time.[13]

It was not the aim of this study to provide evidence to support assertions that proper training in colonoscopy should include at least 200 supervised procedures and that objective measures of competency should be a required part of any training program. Still, given the importance of these principles, it is a highly relevant consequence of our findings. In the past, some investigators outside the gastroenterology subspecialty have advocated the need for far fewer cases to be performed as part of the training; however, these recommendations were not based on objective performance measures.[22-34]

It is possible that simulator experience reduces patient discomfort during the first phase of training. Sedlack et al[12] showed a significant reduction in patient discomfort among patients undergoing flexible sigmoidoscopy

TABLE 7. Comparison of the simulator and no simulator groups in number of sessions needed to reach high competency

	Objective competence*		Subjective competence†	
Group	Median no. sessions needed to reach 90% competent (95% CI)	Log-rank test	Median no. sessions needed to reach 90% competent (95% CI)	Log-rank test
Simulator (CI)	8 (8-9)	0.25	7 (6-8)	0.94
No simulator (CI)	8 (8-9)		7 (6-8)	

*Objective competency is the ability to reach the transverse colon and the cecum without assistance and the ability to correctly recognize and identify abnormalities.
†Subjective competency is on a 5-point scale: 1 (totally unskilled) to 5 (competent and expedient).

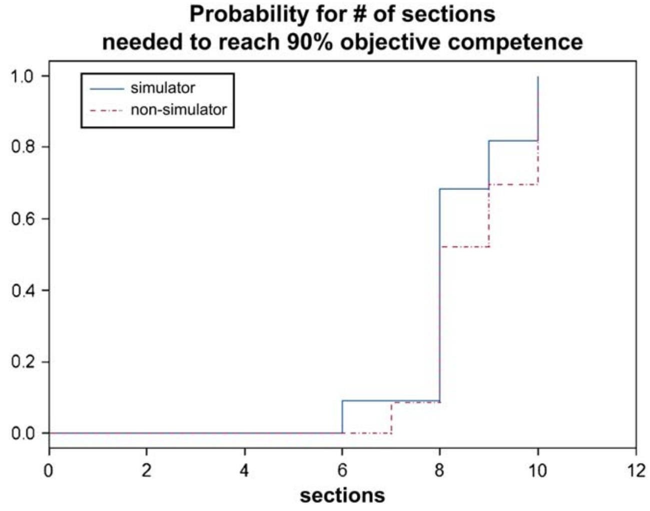

Figure 3. Probability of reaching 90% objective competency for number of sessions completed. Objective competency is defined as the ability to reach the transverse colon and the cecum without assistance, and the ability to correctly recognize and identify abnormalities.

performed by individuals who had 3 hours of AccuTouch simulator training. We did not see a significant difference in discomfort ratings in this study, although we only evaluated proctors' assessments and did not administer patient questionnaires or record the amount of sedation used. Patient assessment of discomfort is an important outcome variable, though patient recollection of pain may be influenced by the amount of sedation used. While the degree of sedation used may correspond to operator skill, it may also reflect practice patterns of the supervising gastroenterologist.

Given the fact that the benefit of simulator training levels off after 80 or so cases, is the purchase cost of $50,000 or more justified? Most 3-year gastroenterology training programs provide far more than 200 colonoscopies for fellows to perform with supervision. While simulators may not make an important long-term difference for gastroenterology fellows likely to perform more than 600 colonoscopies during their fellowship, they may have greater value in training other practitioners with access to fewer cases during their formal training.

In summary, we demonstrated a limited benefit of spending 10 hours on the GI Mentor before performing real colonoscopies. The observed benefit from simulator work likely resulted from practice of technical skills with simultaneous real-time exposure to pathology and simple feedback from the machine. The didactic components of colonoscopy instruction were introduced during a lecture, practiced on the simulator, and then reinforced during supervised real procedures. It is possible that faculty instruction during simulator sessions, while more labor intensive, might potentiate the benefit of simulator training and significantly shorten the colonoscopy learning curve. Furthermore, any additional benefit possible by integrating simulator work throughout the training process remains to be determined.

DISCLOSURE

Simulators were donated for the study by Simbionix USA, Corp, Cleveland, Ohio.

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