

Face validity of a virtual reality simulation platform to improve competency in endoscopy: a prospective observational cohort study



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ABSTRACT

Background and study aims Virtual reality endoscopic simulation training has the potential to expedite competency development in novice trainees. However, simulation platforms must be realistic and confer face validity. This study aimed to determine the face validity of high-fidelity virtual reality simulation (EndoSim, Surgical Science, Gothenburg), and establish benchmark metrics to guide the development of a Simulation Pathway to Improve Competency in Endoscopy (SPICE).

Methods A pilot cohort of four experts rated simulated exercises (Likert scale score 1–5) and following iterative development, 10 experts completed 13 simulator-based endoscopy exercises amounting to 859 total metric values.

Results Expert metric performance demonstrated equivalence ($P=0.992$). In contrast, face validity of each exercise varied among experts (median 4 (interquartile range [IQR] 3–5), $P<0.003$) with Mucosal Examination receiving the highest scores (median 5 [IQR 4.5–5], $P=1.000$) and Loop Management and Intubation exercises receiving the lowest scores (median 3 [IQR 1–3], $P<0.001$, $P=0.004$), respectively. The provisional validated SPICE comprised 13 exercises with pass marks and allowance buffers defined by median and IQR expert performance.

Conclusions EndoSim Face Validity was very good related to early scope handling skills, but more advanced competencies and translation of acquired clinical skills require further research within an established training program. The existing training deficit with superadded adverse effects of the COVID pandemic make this initiative an urgent priority.

Introduction

Certification for esophagogastroduodenoscopy (EGD) can be long and arduous, with a median time to certification of 1.7 years for gastroenterologists, and 2.9 years for surgical trainees

[1]. A preexisting concern associated with the Shape of Training era was a reduction in gastroenterology specialty training time from 5 to 4 years [2]. This has been compounded by the COVID-19 pandemic, with endoscopy training activity initially falling from a mean of 1,930 to 133 procedures per week, and ser-

vice provision collapsing to 5% of pre-COVID levels [3]. Contemporary recovery, now approaching 50% [4], is predominantly service related to address the accumulated clinical backlog. The associated training deficit remains unaddressed and with surely require additional measures [5, 6].

In the surgical arena, simulation training has been shown to significantly augment learning curves in a range of surgical specialities, with two-fold left-shift learning curve trajectory shifts described in minimally invasive general surgery [7], gynecology [8], urology [9] and orthopedic surgery [10]. Existing learning curve analysis of skill acquisition in EGD has highlighted several factors, including total procedure count, that influence trainee competence [11, 12], yet the potential simulator-based training impact on learning curve trajectory shift in EGD is unknown. Supporting evidence is sparse, and although simulation curricula exist, verification is limited by scant and unvalidated longitudinal performance [13, 14].

A recent UK survey reported that 93.4% of trainees were concerned regarding their acquisition of competencies, and 82.6% required an extension of specialty training [13]: demonstrating a plain and pressing need for iterative high-quality, validated training adjuncts [6]. Simulation has been reported to enhance training more than any other modality and its benefit is inversely proportional to experience [15, 16]. The provision of endoscopy simulation-exposure varies across centers: a validated simulation pathway to improve competencies, aimed at novice endoscopists, would be invaluable in supporting the role out of this modality should simulator-acquired skill translate into clinical practice.

EndoSim (Surgical Science, Gothenburg, Sweden) is a novel endoscopic virtual reality (VR) simulator which incorporates a flexible curriculum that generates task-specific metrics, incorporating iterative development, mapped to specific areas of the Joint Advisory Group on Gastrointestinal Endoscopy (JAG) Direct Observation of Procedural Skill (DOPS) tool [17]. Confirming the face validity of the EndoSim SPICE, which focuses on basic scope handling and OGD skill acquisition, using a series of benchmarked exercises, would enable further study into the relevance of observed differences in clinical practice.

Methods

A prospective observational cohort validation study of the EndoSim VR endoscopic simulator (Surgical Science, Gothenburg, Sweden) was performed between January 1, and April 30, 2021.

Participants and setting

A pilot cohort of four independent expert endoscopists, defined as a healthcare professional with a job-plan including a routine weekly independent endoscopy session, with no prior EndoSim experience, tested 12 EndoSim exercises and rated the face validity of each exercise on a Likert scale of 1 to 5 (1 very poor, 5 very good). Feedback regarding the face validity of each exercise was assessed by means of bespoke questionnaires, including free-text comment and suggestions for improvement. Iterative development resulted in a provisional final 13-exercise simulation-based pathway.

A cohort of 10 experts subsequently completed the 13-exercise pathway twice. The first familiarization run was disregarded, and the metric values for the second run was analyzed to determine validated benchmark values. The sample size was informed by a previous study reported by Brown et al of the Surgical Science LapSim simulator; a sibling high-fidelity surgical simulation training platform [7]. Ethical approval was granted by Cardiff University, School of Medicine (SMREC 20/117).

Description of simulator, procedural module, and simulator measurements

A Simcart, table-mounted, and height-adjustable EndoSim VR endoscopy simulator with integrated haptic technology was used (EndoSim: Surgical Science Sweden AB) (► Fig. 1).

The system consisted of a software program run on an Intel Core i7 processor (Intel Corporation, Santa Clara, California, United States) using Windows 10 Pro (Microsoft Corporation, Redmond, Washington, United States). The computer was equipped with 8 GB of internal RAM, a NVIDIA GeForce RTX 2060 graphics card (NVIDIA Corporation, Santa Clara, California, United States), a 27-inch monitor, and a virtual endoscopic interface, including a gastroscope or colonoscope with accessory channel and accessory tool. In this study, the 2020 version of the system was utilized. Exercises from Fundamental Endoscopy Skills 1, Fundamental Endoscopy Skills 2 and Upper GI Gastroscopy Intubation were chosen by a focus group consisting of a consultant gastroenterologist, surgical registrar, and surgical science software development representative. Each exercise was mapped against the JAG DOPS tool to determine each examined skill through as many domains as possible. Where multiple exercises assessed the same skill, the focus group agreed upon the optimum exercise to include in the simulation pathway. The exercises were further deconstructed, by metric, to provide immediate computer-generated feedback presented, aligned to DOPS the following domains: scope handling, angulation and tip control, pace and progress, visualization, and patient comfort.

Pilot exercises can be found in ► Table 1. Some exercises were modified to improve the face validity: the degree in which the exercise replicates the skills being tested; and a new course was developed, named Validation Study. The included exercises for the proposed training pathway are listed in ► Table 2 and can be seen at: https://www.youtube.com/watch?v=SFI3Mqz4StQ&list=PLUjxB-uznJ-Wbryk64lxG_9WR5SEvh1kg. Two identical EndoSim machines were used: one in the Welsh Institute of Minimal Access Therapy (WIMAT), Cardiff, and one at Southmead Hospital, Bristol. This was an independent study; Surgical Science had no access to the study data.

Statistical analysis

Statistical analysis appropriate for nonparametric data (Kruskal-Wallis, Mann-Whitney U) was performed using SPSS 27 (IBM SPSS Statistics for MacOS, Version 27.0. IBM Corp., Armonk, New York, United States). Statistical significance was taken at $P < 0.05$.



► **Fig. 1** A Simcart, table-mounted, height-adjustable EndoSim Virtual Reality (VR) endoscopy simulator with integrated haptic technology. (EndoSim: Surgical Science Sweden AB).

Results

Pilot exercise

Four experts completed the 11 pilot exercises. Median Likert scores related to each exercise can be found in ► **Fig. 2**, with qualitative feedback presented in **Supplementary Table 1**. There was a variation in Likert scores across exercises (median [IQR] 4 [3–4.75]; $P < 0.005$), with the face validity of Loop Management 1, Loop Management 2, and European Society of Gastrointestinal Endoscopy photo exercises receiving the lowest scores (median 2, 1.5, and 2 respectively; $P = 0.029$, ► **Table 1**).

► **Table 1** Variation in expert Likert scores related to pilot exercises.

Exercise	Median score [IQR]	P value
Mucosal examination	5 [4.5–5]	1.000
Examination	4.5 [4–5]	0.686
Knob handling	4.5 [4–5]	0.686
Visualize colon 1	4 [4–4.5]	0.343
Scope handling	4 [4–4.5]	0.343
Navigation skill	4 [3.75–4]	0.057
Retroflexion	4 [3.5–4]	0.057
Photo and Probing	3.5 [2–5]	0.486
Navigation tip/torque	3.5 [2.5–4.5]	0.200
ESGE photo	2 [1–3.5]	0.029¹
Loop management 1	2 [1–3]	0.029¹
Loop management 2	1.5 [1–2.5]	0.029¹

ESGE, European Society of Gastrointestinal Endoscopy.

¹ P values were generated using Mann-Whitney U test to compare Likert score per exercise against the highest rated (Mucosal Examination).

► **Table 2** Variation in expert Likert scores across validation study exercises.

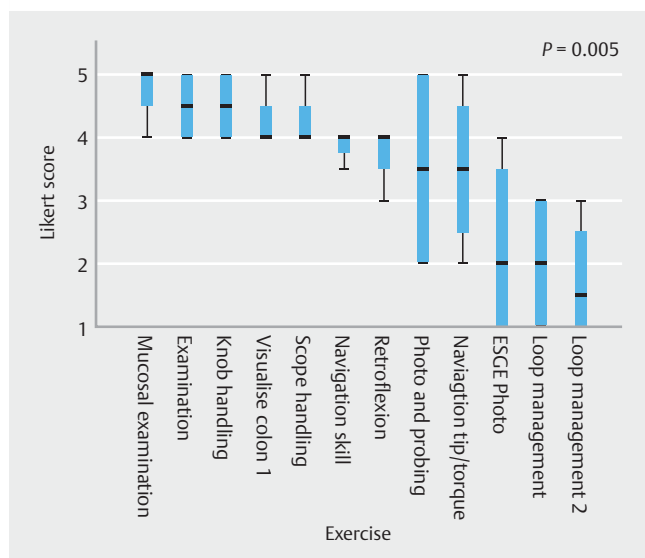
Exercise	Median score [IQR]	P value
Visualize colon 1	4.5 [4–5]	1.00
Visualize colon 2	4.5 [4–5]	1.00
Scope handling	4.5 [3–5]	0.796
Examination	4 [4–5]	0.796
Navigation skill	4 [4–5]	0.853
Mucosal examination	4 [4–5]	0.739
Knob handling	4 [4–5]	0.529
Photo and probing	4 [3.5–5]	0.579
Retroflexion	4 [2–5]	0.218
Navigation tip/torque	3.75 [3–4]	0.105
ESGE photo	3.75 [3–4]	0.105
Intubation case 3	3 [2–3]	0.004¹
Loop management	3 [1–3]	0.001¹

ESGE, European Society of Gastrointestinal Endoscopy.

¹ P values were generated using Mann-Whitney U test to compare Likert score per exercise against the highest rated (Visualize Colon 1).

Validation study

Ten experts completed the 13-exercise simulator-based training pathway with 35 individual metrics: amounting to a total of 859 metric values. Overall expert performance demonstrated equivalence ($P = 0.992$). Variation in individual metric values related to individual expert performance can be found in ► **Ta-**



► **Fig. 2** Evaluation of each pilot exercise by 4 expert endoscopists (Likert scores – 1: Very poor to 5: Very good)

ble 3. There was an equal representation of consultant gastroenterologists to consultant surgeons with no variation in performance between specialty roles ($P=0.472$). All experts had performed more or equal numbers of OGDs (median 2500 [2000–5000]), compared with colonoscopies (1500 [100–2500]). The face validity of each exercise varied among experts (median Likert score 4 [3–4.75], $P=0.003$) with Loop Management and Intubation Case 3 exercises receiving the lowest scores (median Likert score 3 in both cases, $P<0.001$, $P=0.004$ respectively, ► **Table 3**). Median Likert scores related to each exercise can be found in ► **Fig. 3**.

A validated training pathway (SPICE) of VR endoscopy training, with clearly defined performance metrics (pass marks) was developed and the benchmark metric values populating the EndoSim simulator can be found in **Supplementary Table 2**.

Achieving the median expert performance was deemed equivalent to full marks i. e., 100%. Allowance buffers were created after review of the relevant published literature [7, 18–20]. For metrics where higher scores related to improved performance, for example percentage of mucosa visualized, the lower quartile provided a buffer to achieve the minimum pass mark, with scores increasing incrementally up to a maximum of 100% – the expert median value. Where higher scores relate to poorer performance, for example more mucosal collisions, the upper quartile provided the buffer to achieve a minimum pass. Participants must pass all metrics in every exercise to achieve an overall pass.

Discussion

This is the first study to investigate the potential of a validated VR simulation pathway with benchmark performance metrics providing computer-generated feedback set by expert operators and linked with specific domains of DOPS global task performance. The principal findings were equivalent and consis-

tent expert performance across all 13 set simulation exercises. Thirty-one of 35 metrics (89%) were equivalent with four (11%) exhibiting variation, namely: rotation control, mucosal collision, luminal visualization, and side view assistance – an EndoSim training tool offered to visualize intraluminal scope position.

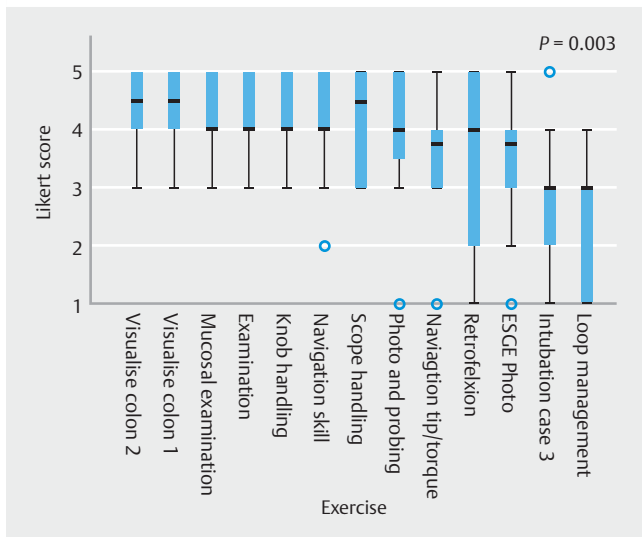
These findings bolster those reported by Siau et al when the construct validity of EndoSim to discriminate between expert, intermediate and novice performance was confirmed [21], though further work was suggested to appraise the face validity and explore the relevance of the observed differences to clinical practice: leading to the development of expert benchmark scores in this study.

Simulation-based curricula have existed since the 1980s, incorporating a human body Cardiology Patient Simulator named “Harvey” [22] alongside a simulated core-curriculum, supported by an additional slide deck [23]. The simulator-trained group achieved a two-fold performance improvement in their multiple-choice knowledge and skills tests, in both simulator and live clinical settings when compared with standard patient-based training [24]. With specific regard to endoscopy simulation curricula the historical focus has predominantly examined colonoscopy. Grover et al reported a structured progressive learning curriculum of increasing difficulty using the EndoVR endoscopy simulator, resulting in improved performance at colonoscopy, as measured by a 10% improvement in JAG DOPS scores, in a single-blinded randomized control trial of 37 novice endoscopists [25,26]. This improvement was further augmented by over 10% when incorporating simulated non-technical skills training, which was sustained at 6 weeks [27]. With regard to VR training across the three procedures of OGD, flexible sigmoidoscopy and colonoscopy, the most pertinent study is the Cochrane systematic review reported by Khan et al in 2018 [14]. Eighteen trials were included (421 participants; 3817 endoscopic procedures). The quality of evidence was rated as moderate, low, or very-low due to risk of bias, imprecision, and heterogeneity, and consequently, a meta-analysis was not performed. There was insufficient evidence to determine the effect on competency composite score (mean difference 3.10, 95% CI –0.16 to 6.36; 1 trial, 24 procedures; low-quality evidence). The most positive conclusion was that VR training compared with no training likely provided participants with some benefit, as measured by independent procedure completion (RR 1.62, 95% CI 1.15 to 2.26; 6 trials, 815 procedures; moderate-quality evidence). Moreover, Virtual Reality training in combination with conventional training appeared to be advantageous over VR training alone. With specific regard to upper gastrointestinal endoscopy simulation, there has been debate regarding the face and content validity of the Symbionix GI Mentor II [28] and the ability to draw conclusions regarding concurrent validity in a pilot study of eight novice endoscopists. Ferlitsch and colleagues [29] have since reported that the same simulator shortened the time taken to intubate the duodenum and improved technical accuracy in the simulator-trained group: with results maintained up until 60 endoscopies. This study sought to establish the face validity of the EndoSim simu-

► **Table 3** Variation in metric values related to performance of 10 experts.

DOPS category	Metric	Value	Median [IQR]	P value
Scope handling	Colonoscope rotation	Degrees	2758 [1540–4142]	0.912
	Slot collisions	Number	3 [2–5]	0.437
	Insertion path length	mm	1114 [883–1664]	0.434
	Targets photographed	%	100 [100–100]	1.000
	All photo targets complete	Yes/no	1 [1–1]	0.437
	Deviations from 45 degrees	Number	3 [3–12]	0.437
Angulation tip control	Missed target	Number	0 [0–1]	0.437
	Knob rotation left/right	Degrees	240 [63–964]	0.026
	Knob rotation up/down	Degrees	1622 [846–3655]	0.268
	Probed outside of target	Number	3 [2–6]	0.437
	Targets probed	%	100 [100–100]	1.000
	Into trachea	Yes/no	0 [0–0]	1.000
	Collisions against mucosa	Number	5 [4–9]	0.038
	Average photo quality	%	100 [95–100]	0.437
	Tip path length	mm	3102 [2383–6266]	0.955
	Targets aligned	%	100 [100–100]	1.000
	Red out	Number	0 [0–1]	0.437
	Time in red out	Seconds	0 [0–1.25]	0.437
	Pace and Progress	Total time	Seconds	163 [101–227]
Time to papilla		Seconds	62 [44–74]	0.187
Visualisation	Targets seen	%	100 [100–100]	0.437
	Targets inspected	%	95 [90–100]	0.126
	Lumen seen	%	100 [100–100]	0.037
	Lumen inspected	%	99 [98–99]	0.109
	Stomach visualized	%	97 [93–99]	0.259
	Duodenum visualized	%	46 [42–49]	0.365
	Papilla reached	Yes/no	1 [1–1]	1.000
Patient comfort	Max Torque	Newton	0.3 [–0.1–3.4]	0.437
	Max insertion force	Newton	7.5 [2.9–19.3]	0.437
Miscellaneous	Tool unprotected	mm	1212 [277–3602]	0.849
	Side view assistance	Seconds	0 [0–11]	0.027
	Net insufflation		0 [0–0]	1.000
	Time in excess insufflation	Seconds	0 [0–0]	0.423
	Percentage of time insufflation	%	1.5 [0–7]	0.075
	Excess insufflations	Number	0 [0–0]	0.423

DOPS, direct observation of procedural skills; IQR, interquartile range.



► **Fig. 3** Evaluation of each exercise by 10 expert endoscopists (Likert scores – 1: Very poor to 5: Very good)

lator over a wider range of endoscopic handling domains, mapped to the JAG DOPS parameters.

The study has several inherent limitations. Any simulator-based training pathway represents an adjunct, and not a replacement for live clinical hands-on learning. The EndoSim simulator does not replace scenarios best experienced in front-line medical practice such as: consent, gastrointestinal lesion recognition, the management of complications and does not address pre- and post-procedure skills as recorded by the DOPS tool. Similarly, management of findings is beyond the scope of this simulator, which focuses on acquisition of scope handling skill: this skill is addressed both clinically and in other areas of Health Education and Improvement Wales' SPRINT program. SPRINT: a Structured PRogramme for INduction and Training, is an existing initiative to improve OGD training delivery to novice endoscopists and incorporates integrated simulator and lesion recognition training, with endoscopic non-technical skills, and has been reported to shorten the time taken for trainees to complete the requisite 200 procedures as stipulated for JAG accreditation [30]. The EndoSim SPICE development focused on basic scope handling and the examination of the upper gastrointestinal tract. The pilot study revealed poorer face validity of the representative lower gastrointestinal exercises, which measure very limited metrics. Loop Management and Intubation Case 3 scoring less well, poor-fair (Likert scale 1–3), in both the pilot and validation study.

Face validity is subjective. The Loop Management exercise measured only the time taken to complete the procedure and was not considered by experts to be able to discriminate between poor or good performance, and consequently should not contribute to the overall score and pass mark equating to competency. Loop management, an important skill in lower gastrointestinal endoscopy, falls outside the basic scope handling remit of this training pathway and requires extra-simulator techniques such as patient positioning and abdominal pressure

[31]. This corroborates Dyke et al reported findings that the requirements for teaching loop resolution is difficult to achieve through simulation alone [32]. Intubation Case 3 exercise was developed from loop management and measured maximum insertion force and maximum torque as well as time taken – nevertheless the face validity was still considered poor when compared with other exercises. Arguably, an alternative measure of face validity for lower gastrointestinal exercises could use a trainer's subjective opinion of the lower gastrointestinal exercises as a training tool in individual trainee specific cases. Such an approach however would not provide expert level metrics or benchmarks, and moreover would require equal number of faculty trainers to trainees, removing one potential benefit and efficiency of a simulator-based training pathway. The scope handling skills developed in other exercises are transferrable, and therefore, applicable, conferring benefit to all groups of novice trainees in both upper and lower gastrointestinal endoscopy.

Issenberg et al. supports the importance of feedback in facilitating simulated learning, alongside repetitive practice and curriculum integration [33] Cross-referencing the deconstructed skills, as measured by metric, per exercise against the JAG validated DOPS tool has allowed focused simulator-generated feedback grouped into the following domains: scope handling, angulation and tip control, pace and progress, visualization, and patient comfort.

Conclusions

This study demonstrated very good face validity of the EndoSim SPICE for providing early skills development for OGD, despite the inherent limitations in using computer-based programs to teach patient-based skills. Moreover, the training pathway provides immediate, computer-generated feedback, aligned with specific domains of DOPS global task performance – adding value to existing simulation curricula. Simulators offer a valuable aide to the modalities available for education in high-risk, reproducible training scenarios. Better understanding of their role in early training and optimization and incorporation into the wider elements of the emerging curriculum alongside knowledge acquisition is critical, especially during recovery from the impact of the COVID-19 pandemic and the resultant deficit in endoscopy service and training provision. A validated VR endoscopy SPICE, informed by expert level benchmarks and aligned to JAG DOPS domains, provides the basis to define simulation's training role. The training pathway should be evaluated in a novice endoscopist setting to assess the translation of simulator-learned skill into clinical practice, when compared with simulator-naïve novice control endoscopists. Such an approach will be an essential component to successfully embed such programs into endoscopy training.

Competing interests

The authors declare that they have no conflict of interest.

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