

Comparing size measurement of colorectal polyps using a novel virtual scale endoscope, endoscopic ruler or forceps: A preclinical randomized trial



Authors

Roupen Djinbachian^{1,2}, Mahsa Taghiakbari^{1,2}, Claire Haumesser^{2,3}, Melissa Zarandi-Nowroozi⁴, Maria Abou Khalil^{1,2}, Sacha Sidani^{1,2}, Jeremy Liu^{1,2}, Benoit Panzini^{1,2}, Daniel von Renteln^{1,2}

Institutions

- 1 Division of Gastroenterology, Montreal University Hospital Center (CHUM), Montreal, Quebec, Canada
- 2 Montreal University Hospital Research Center (CRCHUM), Montreal, Quebec, Canada
- 3 University of Montreal Medical School, Montreal, Quebec, Canada
- 4 Division of Internal Medicine, Montreal University Hospital Center (CHUM), Montreal, Quebec, Canada

submitted 1.9.2022

accepted after revision 29.12.2022

published online 2.1.2023

Bibliography

Endosc Int Open 2023; 11: E128–E135

DOI 10.1055/a-2005-7548

ISSN 2364-3722

© 2023. The Author(s).

This is an open access article published by Thieme under the terms of the Creative Commons Attribution-NonDerivative-NonCommercial License, permitting copying and reproduction so long as the original work is given appropriate credit. Contents may not be used for commercial purposes, or adapted, remixed, transformed or built upon. (<https://creativecommons.org/licenses/by-nc-nd/4.0/>)


Georg Thieme Verlag KG, Rüdigerstraße 14,
70469 Stuttgart, Germany

Corresponding author

Daniel von Renteln, MD, Department of Medicine, Division of Gastroenterology, Montreal University Hospital Center (CHUM) and Montreal University Hospital Research Center (CRCHUM), 900 rue St-Denis, Montreal, Quebec, Canada, H2X 0A9

Fax: +1-5145607752

danielrenteln@gmail.com

 Supplementary material is available under
<https://doi.org/10.1055/a-2005-7548>

ABSTRACT

Background and study aims Accurate polyp size measurement is important for guideline conforming choice of polypectomy techniques and subsequent surveillance interval assignments. Some endoscopic tools (biopsy forceps [BF] or endoscopic rulers [ER]) exist to help with visual size estimation. A virtual scale endoscope (VSE) has been developed that allows superimposing a virtual measurement scale during live endoscopies. Our aim was to evaluate the performance of VSE when compared to ER and BF-based measurement.

Methods We conducted a preclinical randomized trial to evaluate the relative accuracy of size measurement of simulated colorectal polyps when using: VSE, ER, and BF. Six endoscopists performed 60 measurements randomized at a 1:1:1 ratio using each method. Primary outcome was relative accuracy in polyp size measurement. Secondary outcomes included misclassification of sizes at the 5-, 10-, and 20-mm thresholds.

Results A total of 360 measurements were performed. The relative accuracy of BF, ER, and VSE was 78.9% (95%CI=76.2–81.5), 78.4% (95%CI=76.0–80.8), and 82.7% (95%CI=80.8–84.8). VSE had significantly higher accuracy compared to BF ($P=0.02$) and ER ($P=0.006$). VSE misclassified a lower percentage of polyps >5 mm as ≤ 5 mm (9.4%) compared to BF (15.7%) and ER (20.9%). VSE misclassified a lower percentage of ≥ 20 mm polyps as <20 mm (8.3%) compared with BF (66.7%) and ER (75.0%). Of polyps ≥ 10 mm, 25.6%, 25.5%, and 22.5% were misclassified as <10 mm with ER, BF, and VSE, respectively.

Conclusions VSE had significantly higher relative accuracy in measuring polyps compared to ER or BF assisted measurement. VSE improves correct classification of polyps at clinically important size thresholds.

Introduction

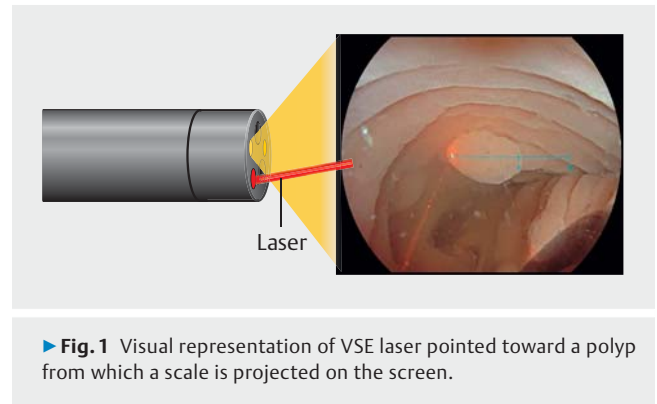
Colorectal cancer (CRC) is the third most common cancer in terms of incidence worldwide and the second leading cause of cancer-related mortality [1]. The risk of colorectal polyps harboring advanced pathology increases with their size. Furthermore, larger (≥ 10 mm) colorectal polyps are been associated with higher risks of metachronous advanced neoplasia and subsequent CRC [2]. Multiple guidelines, therefore adjust surveillance intervals based on whether a polyp is ≥ 10 mm or <10 mm for the same pathology subtypes (tubular adenomas or serrated lesions) [3]. Furthermore, the recommendation for optimal polyp resection and specific resection tools (biopsy forceps [BF], cold snare, or hot snare) have been based on polyp sizes across society guidelines [4, 5].

Accurate colorectal polyp size measurement is therefore crucial for the adequate choice of resection technique and surveillance interval assignments. In clinical practice, the most common way to determine polyp size remains subjective visual assessment. Not surprisingly subjective visual judgment of polyp size is fraught with inaccurate size estimation [6,7]. Some studies have used specific single-use instruments such as BF, snares or rulers that are introduced through the working channel and held next to the polyps to have a reference size to better guide visual assessment [8,9]. However, measurement accuracy is highly variable for these methods, and as they require utilizing a separate tool during the procedure, they have never found widespread adoption outside of research studies [10,11]. Recently, a virtual scale endoscope (VSE) has been developed that can superimpose a virtual scale during live endoscopy (► Fig. 1, ► Fig. 2, ► Video 1). The VSE emits a laser beam diagonally from its tip, with the position and reflection of the laser changing according to the distance between the tip of the endoscope and the target (► Fig. 1). A software then detects the position and distance of the laser spot and can adjust the superimposed virtual scale.

Two preliminary studies have been published using this device so far [6, 12]. The first study demonstrated theoretical feasibility of measurement device and the second study demonstrated that VSE measures simulated polyps with higher accuracy compared to subjective visual size estimation [6, 12]. Given the subjective nature and poor accuracy of visual size estimation, these results are not surprising. Furthermore, the previous model used completely symmetrical and hemispherical polyps placed so that frontal assessment (which likely improves VSE measurements) was possible. We were interested in comparing VSE measurement accuracy in comparison to measuring tools (BF and dedicated ERs) in a set of simulated polyps that simulate different polyp sizes and Paris morphology and measured mostly tangentially, thus better reflecting conditions found during colonoscopy.

Methods

The study does not meet International Committee of Medical Journal Editors (ICMJE) definition of clinical trials as no human subjects were involved in the conduction of this study; how-



► Fig. 1 Visual representation of VSE laser pointed toward a polyp from which a scale is projected on the screen.

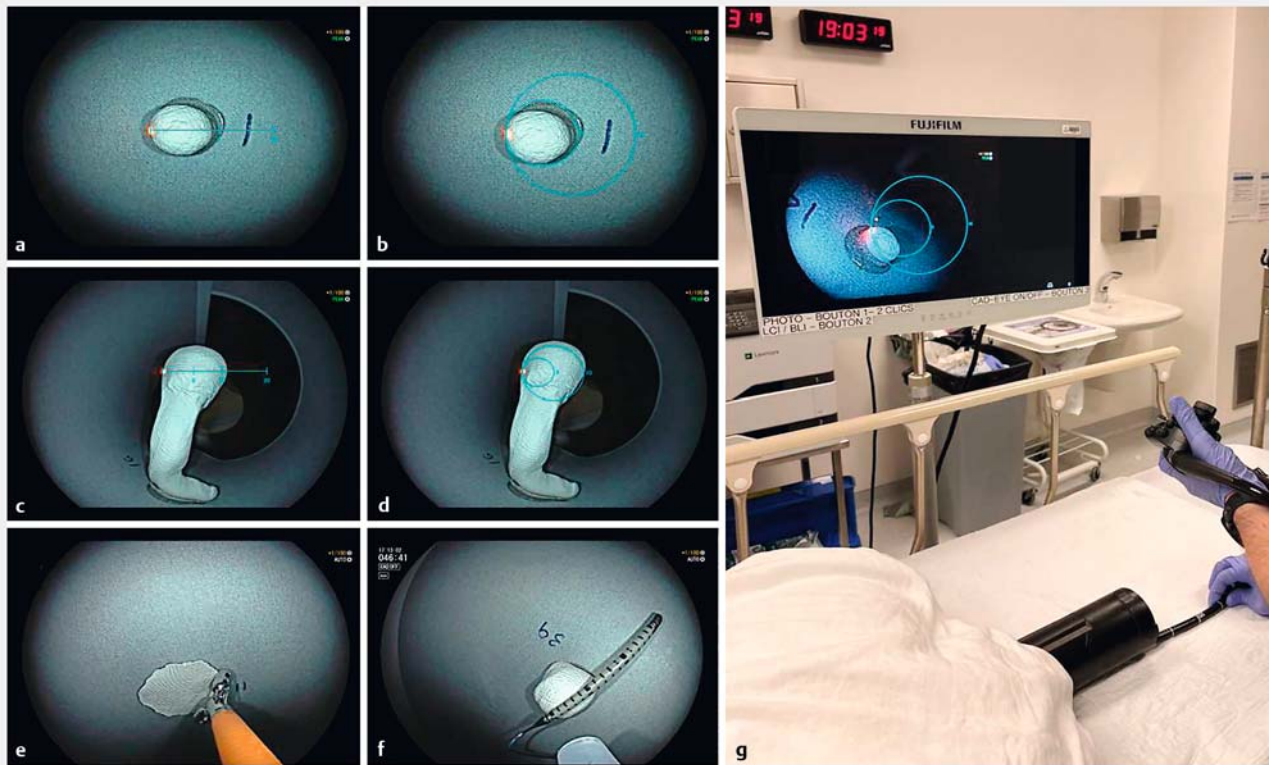
ever, we chose to report our study according to the CONSORT checklist regardless to ensure completeness of reporting [13].

Study design

We performed a preclinical randomized trial of size determination of simulated colorectal polyps using three methods for polyp size measurements: a VSE, an endoscopic ruler (ER), and BF measurement. The study was conducted at the Montreal University Hospital Center in July 2022. Polyps were randomized (computer-generated, concealed randomization list) per included endoscopist on a 1:1:1 ratio to undergo measurements using either VSE, ER, or BF assistance so that each endoscopist performed measurements on 20 polyps using each method, for a total of 60 polyps per endoscopist. Six endoscopists (3 fellows (RD, MAK, JL) with previous experience of 100 to 500 colonoscopies, three experienced gastroenterologists (SS, BP, DvR) having each performed >5000 career colonoscopies, performed the study procedures. Endoscopists were blinded to polyp sizes and randomization assignment. Randomization assignment was revealed to the endoscopist only immediately before the measurement of each polyp. Randomization assignment was pregenerated by one researcher (CH) and kept on an excel sheet with only that researcher having access to the data (CH).

Simulated polyps and colon

Artificial polyps were created by a researcher (CH) utilizing modeling clay simulating varying sizes of 1 to 40 mm (► Fig. 2, ► Video 1) and simulating varying morphologies using the Paris classification as reference. The researcher creating the polyps was instructed to create most polyps within the 1 to 20 mm range with a focus on 1 to 10 mm polyps with Paris Is morphology, as these represent the most common polyp types and sizes found during a colonoscopy. After creation, polyps were fixed within cylindrical plastic tubing of 9 cm diameter representing a simulated colon. The tubing diameter was chosen to allow enough space for maneuvering the endoscope as the rigid tubing does not stretch to accommodate for tip deflection and maneuvering as a real colon (► Fig. 2). We sampled several test tubes before initiation of the study and chose a diameter in which most polyps were encountered tangentially with enough space for the endoscopists to position the endoscope to aim for a frontal vision. The final choice of test tube diameter and set-



► **Fig. 2** **a** Polyp size estimation using the visual scale endoscope with linear scale. **b** Polyp size estimation using the visual scale endoscope with circular scale. **c** Pedunculated polyp size estimation using the visual scale endoscope with linear scale. **d** Pedunculated polyp size estimation using the visual scale endoscope with circular scale. **e** Polyp size estimation using BF. **f** Polyp size estimation using ERs. **g** Virtual scale projected on a live endoscopy screen during conduction of the study.

VIDEO



► **Video 1** Live polyp size measurements using BF, ERs, and VSE.

ting was based on subjective impression and consensus of adequate simulation of conditions encountered during live endoscopy. The researchers have used the VSE in live patient cases before developing the simulated environment to gain experience measuring polyps in real time (NCT05236790). An initial set of simulated polyps were developed and used for testing and training purposes. The final study was conducted in a set

of simulated polyps that had not been seen or measured by the endoscopists before conducting the study measurements.

Study procedures

Real-time examples of polyp measurement during the conduction of the study are presented in ► **Fig. 2** and ► **Video 1**. Endoscopists performed measurement of polyps using three different measuring aids. The VSE (SCALE EYE, Fujifilm, Tokyo, Japan) is a novel endoscope utilizing a laser to triangulate polyp distance and projecting a virtual scale on the endoscopy screen that adjusts in size to the polyp distance (► **Fig. 1**). The scales can be cycled through four modes using the endoscope: 1 to 10 mm linear, 1 to 20 mm linear, 1 to 10 mm circular (projection of a 5- and 10-mm circle on the screen), 1 to 20 mm circular (projection of a 10- and 20-mm circle on the screen, ► **Fig. 2**). These scales originate from the point of contact of the laser with the polyp and change in size according to the distance of the endoscope with the polyp to project an accurate scale in real time as the endoscope moves within the colon (► **Video 1**). The ER (Napoleon measuring device, Micro-Tech Endoscopy, Michigan, United States) is a small measuring device that can be inserted through the channel of an endoscope, with small graduations 1 mm apart up to a total of 15 mm (► **Fig. 2**). The opening wing-span of the BF used for the study (Single-Use Radial Jaw Biopsy

Forceps, Boston Scientific, Massachusetts, United States) was measured with a caliper as being 9 mm wide (► Fig. 2).

Before participation, endoscopists were given a 10 min trial where they individually measured tests polyps not included in the study to familiarize themselves with all the tools before their participation. No feedback was given as to polyp sizes or correctness of their measurements during this time and no other endoscopist was present during the trial or the study measurements to prevent the risk of bias. Endoscopists started the procedure by inserting the colonoscope inside the plastic tubing and identifying the first polyp through numbering placed next to each polyp (► Fig. 2). Once the polyp was visualized, the endoscopist asked the research assistant who had knowledge of true polyp sizes and concealed randomization assignment (CH) to be made aware of the randomization assignment for the polyp, and a timer was initiated to indicate the start of the measuring process. The endoscopist then used the tool assigned to measure the largest diameter of the polyp and assign the dimension of the polyp. Once the endoscopist stated the dimension of the polyp, the timer was stopped, and the measurement documented by the researcher (CH). The endoscopist then proceeded to measure each subsequent polyp using the next randomly assigned tool until all 60 polyps were measured. Each tool (ER, BF) was completely removed from the endoscope and laid on the endoscopy table after each measurement and reinserted after the timer has started to capture the time needed to deploy the tool as part of the measurement process. A second research assistant (MT) assisted all endoscopists in deploying, opening, and closing the measuring devices and was also blinded to polyp sizes and randomization assignment. At the end of the endoscopist participation in the study, polyp sizes were unblinded only to endoscopists having completed the measurements. Endoscopists were not allowed to communicate to each other about their experience before having finished all measurements and endoscopists were not allowed to be present in the room to observe other study cases before they finished their experiments in order to prevent introduction of bias in outcomes or expectations.

Data collection and outcomes

Data was collected during the study by a researcher (CH) and entered in an excel sheet. Primary outcome was relative accuracy in polyp size measurement defined as $100 * (1 - |measurements\ by\ each\ tool - true\ value| / true\ value)$. Secondary outcomes included mean difference from true size stratified by measurement method; mean difference from true size stratified by endoscopist experience; correlation between each measurement methods and actual size; interobserver agreement among trainees and experienced endoscopists for each measurement method; misclassification of sizes at the 5-, 10-, and 20-mm thresholds; required time for size measurement with each method for trainees and experienced endoscopists; the changes in the relative accuracies of measurements with each methods and for trainees and experienced endoscopists.

Sample size and statistical analysis

A simulation study determined that the relative accuracy VSE for estimating size was 84% [6]. There is no report for accuracy of the Napoleon ruler compared to actual size. In order to detect a 5% difference in relative accuracy (power 92% and $\alpha = 0.05$), each group required 120 measurements (20 measurements by 6 endoscopists). Descriptive statistics were presented as crude number and frequency. The relative accuracy, the mean difference with actual size, and required time for measurement by each method were presented as mean and standard deviations. The interobserver agreements were calculated by the interclass coefficient and presented with the *P* value of significance. Paired *t*-test was used to estimate the differences between relative accuracies, mean differences, and the required time for polyp size measurement. The difference in mean measurements from the true value for every measurement tool was compared using a one-way ANOVA test. Proportions of misclassification of polyps for given sizes were compared using chi-square tests. Scatter plots were used to present the changes in the relative accuracies of measurements by each method during the simulation. A two-tailed $P < 0.05$ was considered as statistically significant for the primary outcomes. SPSS version 27.0 was used for analyses.

Results

Polyp characteristics

Polyp characteristics are shown in ► Table 1. The majority of polyps were 1–9 mm in size (61.6%) and sessile (Is) in morphology (78.3%). There was no clinically significant difference between for size and morphology features of polyps after random assignment to the three measurement methods. No polyp was excluded from our analyses.

Performance for polyp measurement

Six endoscopists performed a total of 360 measurements. A total of 120 measurements were performed with each method (VSE, BF and ER). The relative accuracy of BF, ER, and VSE was 78.9% (95% CI = 76.2–81.5), 78.4% (95% CI = 76.0–80.8), and 82.7% (95% CI = 80.8–84.8). There was no statistically significant difference between the accuracy of BF and ER ($P = 0.8$; 95% CI = –3.09–4.02). VSE had statistically significantly higher accuracy compared to BF ($P = 0.02$) and ER ($P = 0.006$) (► Table 2). The interclass coefficient for estimating interobserver agreements among all endoscopists for BF and ER were 0.93 and for VSE was 0.96. Moreover, the interclass coefficient among three trainees for BF and ER was 0.93 and for VSE was 0.98. The interclass coefficient among three experienced endoscopists for BF and ER was 0.93 and was 0.94 for VSE. All coefficients were statistically significant ($P < 0.001$) (► Table 2). The difference in mean measurements from the true value was smaller for VSE (1.1 mm) compared to BF (1.9 mm) and ER (2.2 mm). VSE had statistically less difference between the measurements obtained and the true polyps size compared to the other measurement methods ($P = 0.007$). Endoscopists overall tended to underestimate polyp size. Size underestima-

► **Table 1** Polyp characteristics.

Variables N (%)	All measurement methods	Biopsy forceps	Napoleon ruler	VSE
Polyp size	60 (100.0)	120 (100.0)	120 (100.0)	120 (100.0)
1–5 mm	14 (23.3)	31 (25.8)	29 (24.2)	24 (20.0)
6–9 mm	23 (38.3)	42 (35.0)	50 (41.7)	46 (38.3)
10–19 mm	17 (28.3)	35 (29.2)	29 (24.2)	38 (31.7)
≥20 mm	6 (10.0)	12 (10.0)	12 (10.0)	12 (10.0)
Paris classifications	60 (100.0)	120 (100.0)	120 (100.0)	120 (100.0)
Is	47 (78.3)	95 (79.2)	98 (81.7)	89 (74.2)
Ip	2 (3.3)	4 (3.3)	1 (0.8)	7 (5.8)
Isp	1 (1.7)	1 (0.8)	4 (3.3)	1 (0.8)
Ila	7 (11.7)	15 (12.5)	13 (10.8)	14 (11.7)
Ilc	3 (5.0)	5 (4.2)	4 (3.3)	9 (7.5)

VSE, virtual scale endoscope.

► **Table 2** Performance of biopsy forceps, Napoleon ruler and virtual scale for polyp size estimation.

Tools	Mean difference of measurements by each tool against the true measurements mm, (SD); P value	Correlation between measurements by each measurement tool and the true measurements; P value	Relative accuracy of measurements by each tool against the true measurements, % (95% confidence interval)
Biopsy forceps	1.9 (2.9); <0.001	0.91 (<0.001)	78.9% (76.2–81.5)
Napoleon ruler	2.2 (2.9); <0.001	0.92 (<0.001)	78.4% (76.0–80.8)
VSE	1.1 (2.1); <0.001	0.94 (<0.001)	82.7% (80.8–84.8)

VSE, virtual scale endoscope; SD, standard deviation.

tion by at least 1 mm occurred in 57.5%, 65.0%, and 52.5% of cases when using BF, ER, and VSE respectively. 37.5%, 30.8%, and 38.3% of sizes were correct within 0.9 mm for BF, ER, and VSE respectively.

Size misclassification

The percentages of polyps >5 mm misclassified as ≤5 mm in size was higher with ER (20.9%) compared to BF and VSE (15.7%, 9.4%, respectively). BF and ER did not misclassify polyps ≤5 mm as >5 mm, but VSE misclassified 4.2% of polyps ≤5 mm as >5 mm. Moreover, 25.6%, 25.5%, and 22.5% of polyps ≥10 mm were misclassified as <10 mm with ER, BF, and VSE, respectively. No polyp <10 mm was misclassified as ≥10 mm with ER whereas 5.5% and 7.1% polyps were misclassified with BF and VSE, respectively. The percentage of misclassifications of polyps ≥20 mm as <20 mm was high with most methods, however, VSE misclassified a lower percentage of these polyps (8.3%) compared with BF and ER (66.7%, 75.0%, respectively) (► **Table 3**).

Variation in accuracy depending on time and experience level

Trainees had lower relative accuracies compared with experienced endoscopists when using either BF or ER. Experienced endoscopists showed more consistent measurements over time for BF measurements than trainees, whose relative accuracies decreased overtime (**Supplementary Fig. 1a**). The relative accuracies of measurements with ER did not change overtime (**Supplementary Fig. 1b**). Interestingly, experienced endoscopists had lower relative accuracies compared to trainees with VSE, but they approached trainee accuracies at the end of the simulation (**Supplementary Fig. 1c**).

Duration of size measurement

There was no statistically significant difference for duration of measurements by three methods when all endoscopists were included in the analysis. Trainees spent more time for measurements with BF and experienced endoscopists spend more time for measurements with ER. Experienced endoscopists spent statistically significantly less time for size measurements than trainees using ER or BF, however there was no statistically significant difference when using VSE (► **Table 4**).

► **Table 3** Polyp misclassification according to the cut-off of 5, 10, 20 mm with each measurement method.

Polyp size misclassifications, N (%)	Biopsy forceps	Napoleon ruler	VSE	P value
> 5 mm misclassified as ≤ 5 mm	14/89 (15.7)	19/91 (20.9)	9/96 (9.4)	0.09
≤ 5 mm misclassified as > 5 mm	0/31 (0.0)	0/26 (0.0)	1/24 (4.2)	0.29
≥ 10 mm misclassified as < 10 mm	12/47 (25.5)	11/41 (26.8)	11/50 (22.0)	0.86
< 10 mm misclassified as ≥ 10 mm	4/73 (5.5)	0/79 (0.0)	5/70 (7.1)	0.07
≥ 20 mm misclassified as < 20 mm	8/12 (66.7)	9/12 (75.0)	1/12 (8.3)	0.002
< 20 mm misclassified as ≥ 20 mm	0/108 (0.0)	0/108 (0.0)	2/108 (1.2)	0.13

VSE, virtual scale endoscope.

► **Table 4** Required time for complete measurement with each measurement method for trainees and gastroenterologists.

Measurement method/required time	All endoscopists, seconds (SD)	Trainees, seconds (SD)	Gastroenterologists, seconds (SD)	P value
Biopsy forceps	50.9 (24.7)	61.4 (26.9)	40.4 (16.8)	<0.001
Napoleon ruler	50.9 (21.5)	56.1 (22.4)	45.7 (19.3)	0.007
VSE	49.4 (30.2)	54.2 (27.7)	32.1 (4.1)	0.09

SD, standard deviation; VSE, virtual scale endoscope.

Discussion

In this blinded, randomized controlled trial measuring the size of simulated colorectal polyps, we found that VSE had statistically significantly higher relative measurement accuracy when compared with other routinely used measurement methods such as BF or dedicated ERs. To our knowledge, this study presents the first head-to-head comparison of VSE to other measurements with robust methodology controlling for potential bias. We did not include a control group using visual estimation of polyp sizes without assisting devices since it has already proven to be generally fraught with measurement errors (one study found that 62% of polyp sizes were misestimated by >20%) and another found much lower accuracy when compared to VSE [6, 14]. Two studies found 62.5% and 63.9% accuracy using visual estimation as the only means of determining polyp size [6, 7]. Given these significant differences between true polyp size and visual estimation as well as previous data showing superiority of VSE to visual assessment, endoscopists could consider utilizing tools that can provide objective criteria to guide size estimations if clinically significant results are found in confirmatory studies reporting real world outcomes [7–9]. Multiple tools have been proposed to aid in estimating polyp sizes. For biopsy forceps-based measurements, performance is highly variable with one study showing only 37% of polyps measured correctly within 1 mm [9]. Another found 75% accuracy using biopsy forceps-based measurement [7]. For the ER, there is currently no large study establishing performance. One small proof of concept study using the ER in 36 polyps found that one polyp visually assessed as 6 to 9 mm was measured as ≤ 5 mm using the ER and two polyps visually assessed

as ≥ 10 mm were measured as 6 to 9 mm [8]. However, the study lacked gold standard measurement of polyps after resection to determine true size [8]. For the VSE, one proof of concept study found a 84% relative accuracy that was superior to visual estimation (63.9%) when using symmetrical silicone polyps placed on simulated colonic folds for frontal visualization [6]. Our study adds to the available literature by demonstrating that among measurement devices, VSE yields significantly more accurate measurements within a blinded randomized trial. Our study also utilized polyps of various sizes and Paris class morphology with more lateral placements which more closely resembles routine clinical experience as opposed to symmetrical Paris Is polyps visualized in frontal view as used in a previous study [6]. We have created our simulation environment based on our initial clinical experience with VSE or single-use instrument guided polyps size measurement in patients (NCT05236790). Our simulated environment, with its higher variety in polyp shapes, sizes, and positioning, was likely more challenging in comparison to the previous VSE study which likely explains the relatively lower accuracy observed in our study (84% vs 82.7%). However, we found that relative measurement accuracy remained high independent of polyp size, Paris morphology, or endoscopist experience level, outperforming other measurement devices. Furthermore, activation of VSE functionality contributes to easier uptake, feasibility in routine clinical practice and less waste generation compared to single-use instruments [15].

One important aspect of correct polyp size measurement lies in the implementation of resect-and-discard and diagnose-and-leave strategies [16]. To allow for implementation, polyps need to be correctly classified at the 5-mm threshold. Oversiz-

ing will lead to suboptimal implementation of the strategies, however, undersizing would more importantly lead to larger polyps left in situ or discarded without pathology analysis, potentially increasing the risk of interval CRC in patients. In our study, VSE misclassified one polyp as >5 mm vs 0 for ER and BF, however, it incorrectly classified a lower percentage (9.4%) of polyps as diminutive when compared with ER (20.9%) or BF (15.7%). This could lead to potentially safer implementation of resect-and-discard and diagnose-and-leave strategies [16].

In our study, fellows performed at a similar level as experienced endoscopists with no statistically significant differences in relative accuracy using the three tools. There was a slight learning curve for experts when using the VSE with improvements in their relative accuracy throughout polyp size determination whereas fellows had relatively stable accuracies throughout the study when using VSE. Both fellows and experts had decreases in their relative accuracies when using BF as the study progressed with a more significant decrease for fellows. This could be explained by the relative difficulty in estimating polyp sizes using BF and fatigue playing a larger role in inexperienced endoscopists. The VSE, therefore, CAN be a potentially useful tool across all experience levels and could counteract endoscopist fatigue in inexperienced endoscopists especially for afternoon procedures when endoscopists are most likely to be tired.

Artificial Intelligence (AI) has been proposed as an alternative for polyp size measurement in one study [17]. However, the authors state that due to the difficulty of acquiring datasets with ground truth information on polyp size AI based systems are difficult to develop. Instead of presenting measurement accuracy based on deviation of obtained measurement from true size, the authors chose to test if the AI-based system can distinguish >5 mm polyps from diminutive polyps which was possible in 80% [17]. Similar to VSE, AI-based technology would have the advantage of not necessitating additional tools for polyp sizing. However, to date no AI system that can be used in live endoscopy is available and systems for clinical implementation will have to provide measurement granularity in millimeter size ranges. Another AI study found improved performance over open BF; however, it did not report on relative accuracy or clinical outcomes such as misclassification at the 5-, 10-, or 20-mm threshold or superiority over measurements with BF or ERs [18]. Given the ability of VSE to provide reliable measurements, it could be also used as a tool to capture ground truth information datasets to advance AI or integrate AI technology into future VSE updates. In the future, a combination of laser-based distance measurement and AI could prove useful for determining accurate polyp sizes. Studies to evaluate VSE performance in live endoscopy cases are currently underway.

The strength of our study lies in the inclusion of a robust design with adequate power to undertake subgroup analysis for endoscopists of varying experience and polyp sizes and morphologies. The large number of measurements randomized between the three tools with endoscopists being rigorously blinded to the true size reduced the potential for bias. The included polyp sizes and morphologies reflecting the distribution observed in clinical practice is an added strength. Limitations of

our study include the simulated nature of the study, although a real-time measurement study in patients is currently ongoing (NCT05236790). In vivo studies are important for validation of these tools, however, specimen shrinkage, fragmentation of specimens, difficulty of en-bloc resection and retrieval of larger polyps pose challenges for evaluating size measurement tools in vivo. Performing studies on artificial polyps of known size can therefore provide valuable insights to establish the size measurement accuracy of these tools. Furthermore, our study is limited by our selection of single-use size measurement devices. We chose BF and ERs because it incorporated the most commonly used device (BF) and a dedicated endoscopic measurement device. However, there are other measuring tools available and further head-to-head comparison with VSE might be warranted. Another limitation is the relatively small number of polyps ≥ 10 mm and ≥ 20 mm which limits interpretation of analyses for these size categories. A subsequent study with larger numbers of polyps ≥ 10 mm and ≥ 20 mm will be performed by our group to provide adequate power in determining misclassification of these tools at the 10- and 20-mm threshold. Last, future studies will need to establish clinical significance of endoscopic measurement devices beyond showing pure measurement accuracy. Future studies will have to evaluate if endoscopic measurement devices such as VSE have an impact on classifying polyps correctly based on size thresholds that influence clinical decision making (i.e. 3, 5, 10 and 20 mm) [19, 20]. Accurate classification has implications for choosing appropriate polypectomy methods and appropriate surveillance intervals while misclassification of <10 and ≥ 10 mm polyps could pose a risk of assigning much longer surveillance intervals thus incurring the risk of interval CRC [3, 21, 22]. Our study was not designed to evaluate misclassification of polyp sizes and further research is warranted.

Conclusions

In conclusion, in a blinded, randomized trial using simulated polyps we found that VSE had statistically significant higher relative accuracy in measuring polyps compared to ER or BF assisted measurement. VSE improves correct classification of polyps at clinically important size thresholds. Further studies evaluating clinical use of VSE and clinical implications of this technology have been initiated.

Competing interests

Daniel von Renteln has received research funding from ERBE Elektromedizin GmbH, Ventage, Pendopharm, Fuji and Pentax, and has received consultant or speaker fees from Boston Scientific Inc., ERBE Elektromedizin GmbH, and Pendopharm. The remaining authors declare that they have no conflict of interest.

Funding

Fond de Recherche du Quebec Santé
Université de Montréal Programme d'Excellence en Médecine pour l'Initiation En Recherche

References

- [1] Sung H, Ferlay J, Siegel RL et al. Global Cancer Statistics 2020: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries. *American Cancer Society* 2021; 71: 209–249
- [2] He X, Hang D, Wu K et al. Long-term risk of colorectal cancer after removal of conventional adenomas and serrated polyps. *Gastroenterology* 2020; 158: 852–861 e854
- [3] Gupta S, Lieberman D, Anderson JC et al. Recommendations for Follow-up after colonoscopy and polypectomy: a consensus update by the US Multi-Society Task Force on Colorectal Cancer. *Gastroenterology* 2020; 158: 1131–1153.e1135
- [4] Rex DK, Kahi C, O'Brien M et al. The American Society for Gastrointestinal Endoscopy PIVI (Preservation and Incorporation of Valuable Endoscopic Innovations) on real-time endoscopic assessment of the histology of diminutive colorectal polyps. *Gastrointest Endosc* 2011; 73: 419–422
- [5] Kaltenbach T, Anderson JC, Burke CA et al. Endoscopic removal of colorectal lesions; Recommendations by the US Multi-Society Task Force on Colorectal Cancer. *Gastroenterology* 2020; 158: 1095–1129
- [6] Shimoda R, Akutagawa T, Tomonaga M et al. Estimating colorectal polyp size with a virtual scale endoscope and visual estimation during colonoscopy: Prospective, preliminary comparison of accuracy. *Dig Endosc* 2022; 34: 1471–1477
- [7] Kim JH, Park SJ, Lee JH et al. Is forceps more useful than visualization for measurement of colon polyp size? *World J Gastroenterol* 2016; 22: 3220–3226
- [8] Pochapin MB, Khan A, Rosenberg J et al. S0520 the Napoleon: A pilot feasibility study of a small endoscopic ruler for accurate polyp measurement. *Am J Gastroenterol* 2020; 115: S259
- [9] Rex DK, Rabinovitz R. Variable interpretation of polyp size by using open forceps by experienced colonoscopists. *Gastrointest Endosc* 2014; 79: 402–407
- [10] Izzy M, Virk MA, Saund A et al. Accuracy of endoscopists' estimate of polyp size: A continuous dilemma. *World J Gastrointest Endosc* 2015; 7: 824–829
- [11] Turner JK, Wright M, Morgan M et al. A prospective study of the accuracy and concordance between in-situ and postfixation measurements of colorectal polyp size and their potential impact upon surveillance. *Eur J Gastroenterol Hepatol* 2013; 25: 562–567
- [12] Masato Y, Yuichi S, Daisuke U et al. Virtual scale function of gastrointestinal endoscopy for accurate polyp size estimation in real-time: a preliminary study. *J Biomed Optics* 2021; 26: 1–10
- [13] Schulz KF, Altman DG, Moher D. CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials. *BMC Med* 2010; 8: 18
- [14] Chaptini L, Chaaya A, Depalma F et al. Variation in polyp size estimation among endoscopists and impact on surveillance intervals. *Gastrointest Endosc* 2014; 80: 652–659
- [15] Namburam S, von Renteln D, Damianos J et al. Estimating the environmental impact of disposable endoscopic equipment and endoscopes. *Gut* 2022; 71: 1326
- [16] Abu Dayyeh BK, Thosani N, Konda V et al. ASGE Technology Committee systematic review and meta-analysis assessing the ASGE PIVI thresholds for adopting real-time endoscopic assessment of the histology of diminutive colorectal polyps. *Gastrointest Endosc* 2015; 81: 502.e501–502.e516
- [17] Abdelrahim M, Saiga H, Maeda N et al. Automated sizing of colorectal polyps using computer vision. *Gut* 2022; 71: 7
- [18] Kwak MS, Cha JM, Jeon JW et al. Artificial intelligence-based measurement outperforms current methods for colorectal polyp size measurement. *Digest Endosc* 2022; 34: 1188–1195
- [19] Taghiakbari M, Pohl H, Djinbachian R et al. What size cutoff level should be used to implement optical polyp diagnosis? *Endoscopy* 2022; 54: 1182–1190
- [20] Djinbachian R, Marchand E, Pohl H et al. Optical diagnosis of colorectal polyps: a randomized controlled trial comparing endoscopic image-enhancing modalities. *Gastrointest Endosc* 2021; 93: 712–719 e711
- [21] Zarandi-Nowroozi M, Djinbachian R, von Renteln D. Polypectomy for diminutive and small colorectal polyps. *Gastrointest Endosc Clin North Am* 2022; 32: 241–257
- [22] Djinbachian R, Iratni R, Durand M et al. Rates of incomplete resection of 1- to 20-mm colorectal polyps: a systematic review and meta-analysis. *Gastroenterology* 2020; 159: 904–914 e912