Introduction

Polyp size assessment during flexible endoscopy is crucial for therapeutic decision making [1–3]. Indeed, polyp size affects several factors during the diagnosis and treatment cycle: (a) it is correlated with the likelihood of malignancy within the polyp; (b) it affects the choice of treatment for polypectomy; and (c) it is the main determinant in post-polypectomy surveillance risk stratification. In daily clinical practice, endoscopists estimate the diameter of polyps only by visual inspection, relying on their own experience. Expertise may increase precision, but dis-
crepans between endoscopic and pathologic measurements have been shown in several studies [4–6]. Pathological assessment of polyp size is usually advised. However, this may be done only after endoscopy, thus preventing immediate feedback. Furthermore, it is impossible to perform this accurately for large polyps removed piecemeal, and the results may be affected by formalin fixation. Usually, endoscopists overestimate the real size of the polyp and this is particularly true for the left colon. Gupta et al. [7] showed how size estimations of advanced adenomas detected in the right colon were smaller than in the left colon. Open biopsy forceps of known size and endoscopic rulers have been proposed to improve precision, as well as comparison with an open snare, but results are often inconsistent [8, 9]. A study of 100 polyps measured by the aforementioned methods compared to ruler measurement after excision showed the lack of accuracy of current techniques [10]. Despite the importance of in vivo polyp size estimation, a validated and easily reproducible technology allowing precise measurement has not been developed so far [11].

While computer visualization techniques have found some success for polyp detection [12], there are currently no methods for size assessment on standard monocular endoscopes, as a stereo endoscope would be required to retrieve three-dimensional size information [13].

In this paper, we present a preliminary study of a novel structured light (SL) laser probe for one-shot size measurement that can be embedded into a conventional endoscope.

Materials and methods
The primary aim of the study was to verify the accuracy of the proposed SL technology for determining polyp size in the stomach during flexible endoscopy in an ex vivo model and compare it against current methods. The performance of the probe was assessed in terms of accuracy, timing, and user satisfaction, against conventional measurement techniques on porcine stomachs. Tests have been carried out by experienced and novice endoscopists.

The proposed system consists of a flexible SL laser pattern projector (Fig. 1). A 532 nm laser is transmitted through a plastic optical fiber (Ø 2.8 mm) up to its tip where a micro pattern chip is set. The pattern on the chip consists of a sinusoidal grid of known shape and size, and it is projected through an aspherical lens onto the tissue. The choice of an aspherical lens over a common thin lens is because of its ability to project the pattern over a wider depth range while maintaining its sharpness. The pattern is projected with a beam width of 30°, as shown in Fig. 3d.

The basic principle of the system is illustrated in Fig. 2. A grid with known shape and size is projected onto the tissue,
where it will appear deformed due to the local tissue morphology. The image of the tissue with the projected grid is captured by the scope camera. The algorithm presented in Ref. [14] then finds correspondences between the points in the projected grid with the points in the captured image. Given a corresponding pair and the relative position of camera and projector, it is possible to reconstruct the position in 3D and the distance in millimeters of each grid point. To calculate the polyp size, the clinician traces a line roughly corresponding to the polyp diameter with the mouse on a standard screen showing the scope images, and the 3D polyp size is automatically calculated. The system only requires a short calibration before operation, with no specialized equipment [15].

To assess the performance of the SL projector, two porcine stomachs (Fig. 4) were prepared with 10 and 12 polyps, respectively, and insufflated at a constant pressure using standard endoscopic luminal distension. The polyps were created by tying the stomach wall in sites randomly distributed along the antrum, the body, and the fundus, including curvatures. Polyp size was determined after the experiment by opening the stomachs and measuring the polyps with a manual caliper (Fig. 4). The polyps were approximately elliptical in shape, where the short axis measured between 0 and 5 mm in four cases and between 5 and 10 mm in 18 cases, while the long axis measured between 5 and 10 mm in nine cases and over 10 mm in 13 cases.

Nine test subjects (five endoscopists with 1.5–15 years of experience, four novices), split into mixed ability groups of five and four for the two stomachs, were asked to visit the polyp sites in an established order and assess their size by (a) visual inspection (Fig. 3a), (b) comparison with open biopsy forceps of known size (Fig. 3b), (c) a ruled snare (Fig. 3c), and (d) the SL projector (Fig. 3d), for a total of four runs per subject and 392 independent polyp size measurements.

To minimize bias from previous runs with explicit readings, the visual inspection run was performed first for each subject. The order of polyp sites was established in advance to guarantee uniform maneuvers and viewing angles across subjects. Subjects familiarized themselves with the route with a brief navigation pass, and a supervising endoscopist was present to enforce the order of navigation.

The pattern projector requires a short calibration every time it is set in place. Hence, to avoid repeating the calibration sequence every time the probe is switched with a different measuring tool, the probe is fixed outside the scope (Fig. 1b) instead of set inside the tool channel. Calibration was performed once at the beginning of each day of trials. An Olympus GIF-HQ190 endoscope was used and connected to an Olympus Evis Exera III (CV-190) endoscopic system; the scope focus was kept fixed at 5 mm.

Timing was also recorded for each test subject. Finally, subjects were asked to report the confidence in their measurement accuracy, as well as their overall satisfaction with the ease of use of each technique via a visual analogue scale. Marks recorded on the visual analogue scale were then manually measured and normalized to a 0–10 range. For statistical analysis of the numerical results on measurement accuracy, timing, and satisfaction, an ANOVA post-hoc analysis with Tukey’s range test was carried out.
Results

Fig. 5 shows accuracy for polyp size assessment in terms of absolute and relative error with the techniques described above. In the graphs, boxes cover from the 25th to the 75th percentile, the red lines represent the medians, and the whiskers cover all points not considered outliers. The red crosses are outliers which lie more than 1.5 times the interquartile range beyond the 75th percentile. Data are grouped by measurement technique and subject experience. The median absolute and relative errors (ε, ε%) using visual inspection only were 2.2 mm and 27.4%, respectively, 1.2 mm and 12.8% using a reference forceps, 1.17 mm and 11.7% using a snare, and...
1.52 mm and 15.5% using SL. Visual assessment showed a significant split in accuracy between experienced ($\varepsilon = 1.80$ mm, $\varepsilon% = 17.59$%) and novice ($\varepsilon = 3.00$ mm, $\varepsilon% = 36.70$%) test subjects, while the other techniques showed little variation. All methods using tools were shown to have a significantly different performance compared to visual assessment ($P < 0.001$ for reference forceps, snare, and SL, 95%CI). The probe was found to perform similarly to the reference forceps ($P = 0.81$) and ruled snare ($P = 0.99$) at a 95% confidence level.

**Fig.6** illustrates the average time required to maneuver the tool and endoscope, and to estimate the size of each polyp. Visual assessment scored the shortest median time to complete the estimation with a median of 20.7 seconds, while the forceps, SL, and snare methods scored 32.0 seconds, 54.8 seconds, and 68.5 seconds, respectively. Timing with the SL probe was found to be significantly different from timing by visual assessment and reference forceps ($P = 0.005$ and $0.023$, respectively, 95%CI). Conversely, differences between SL probe and snare were not found to be statistically significant ($P = 0.73$, 95%CI). Timing results are summarized in **Table 1**.

**Fig.7** reports the users’ feedback. **Fig.7 a** shows the average confidence on the measurement accuracy, as reported by test subjects, normalized to a score 0 – 10 for the techniques that required a subjective assessment of the scope images from the endoscopists. Visual assessment and snare scored the lowest (4.5 and 5.0, respectively), while the use of a reference tool considerably boosted the confidence in the correctness of the estimate (median confidence = 7.0). Since the SL does not depend on subjective interpretation, confidence in the estimate was not collected. In **Fig.7 b**, the overall satisfaction with the technique is represented, reported on a normalized 0 – 10 score range. SL scored the highest (7.9), followed by reference forceps (7.8), and visual assessment (7.0), while snare scored the lowest (4.4). Indeed, satisfaction with the SL probe and snare was found to be significantly different ($P = 0.035$, 95%CI), while no statistically significant differences were detected when comparing visual assessment and reference forceps against SL ($P = 0.84$ and 0.99, respectively, 95%CI). User confidence and satisfaction results are summarized in **Table 2**.

![Fig.6](image-url) **Fig.6** Time (in seconds) required to estimate the size of each polyp, grouped by measurement technique and experience level of the test subject.

<table>
<thead>
<tr>
<th>Table 1</th>
<th>Numerical values for <strong>Fig.6</strong> indicating the median time per polyp.</th>
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<tbody>
<tr>
<td></td>
<td>Median time per polyp / s</td>
</tr>
<tr>
<td>Eye</td>
<td>20.70</td>
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<tr>
<td>Reference tool</td>
<td>32.00</td>
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<tr>
<td>Snare</td>
<td>68.50</td>
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<td>Structured light</td>
<td>54.75</td>
</tr>
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</table>

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Discussion

Results show that the accuracy of visual inspection, which is the most common method used to estimate polyp size, is poor, since it showed almost twice the absolute and relative error of the other techniques. The gap in accuracy is further exacer-

bated for novices, since visual assessment relies heavily on experience.

Among the three remaining techniques, accuracy was found to be statistically similar, with the main advantage of the proposed tool that it does not occlude the tool channel. Snare users also reported a low satisfaction and confidence due to lack of familiarity with the technique and difficulties in encir-
clinging the head of the polyp for size measurement, rather than its base for polypectomy. This also resulted in the longest time to complete the procedure. While snares can be argued to be the natural choice for size assessment because of their role in polypectomies, it must be noted that snares are not ideal for measurement purposes. Also, in this study, the snare did not meet the appreciation of the users as a method of polyp measurement as shown by the significantly lower satisfaction scores. This is related to the difficulty in encircling the polyp with a large snare, such as those used routinely for standard polypectomy. This is particularly true for pedunculated and large polyps.

The lack of satisfaction with the snare also translated to a low perceived confidence in the measurement accuracy, due to difficulties in knowing whether polyps were encircled correctly. Visual assessment measurements recorded a similar low confidence, while satisfaction was comparatively higher due to the lack of complex maneuvers required. Together, visual assessment, reference forceps, and the proposed SL probe received the highest satisfaction ratings with no statistically significant differences.

In terms of time required to complete the procedure, SL lags the two faster techniques. This is due to issues related to cleaning of the probe lens that required complex maneuvers, since no cleaning mechanism is currently built into the probe. This resulted in a particularly poor performance, creating outliers with time per polyp exceeding 100 seconds and increasing the median time for all patients. In this study, our focus was on proving the validity of our system by comparing its accuracy to the gold standard, while usability issues will be addressed in the next iteration of system design. Future work with a larger pool of users will focus on improving the design and the overall user experience.

Acknowledgements

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Competing interests

None

References


Table 2 Numerical values for Fig. 7 indicating user confidence and satisfaction for each method.

<table>
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<th></th>
<th>Median confidence</th>
<th>Median satisfaction</th>
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<td>Overall</td>
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</tr>
<tr>
<td>Eye</td>
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<td>5.00</td>
</tr>
<tr>
<td>Reference tool</td>
<td>7.00</td>
<td>7.00</td>
</tr>
<tr>
<td>Snare</td>
<td>5.00</td>
<td>5.00</td>
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<tr>
<td>Structured light</td>
<td>N/A</td>
<td>N/A</td>
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