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Development of a Low-Cost Gastroscope Prototype (GP) for Potential Cost-Effective Gastric Cancer Screening in Prevalent Regions

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Abstract

Background Screening for gastric cancer is known to be associated with reduced mortality in populations with high prevalence. However, many countries with high prevalence do not screen, with high costs being a significant reason for this.

Aims To describe, develop, and assess the potential for a low-cost gastroscope for early cancer screening and patient risk stratification.

Methods Our interdisciplinary team used both off-the-shelf and fabricated components to create multiple gastroscope prototypes (GP) in iterative fashion based off clinician feedback. Clinician endoscopists were surveyed using Likert scales regarding device potential, video quality, and handling when testing on a GI training device. Video quality comparison to clinically standard high-definition white light endoscopy (HD-WLE) was done using the absolute categorical ratings (ACR) method.

Results A candidate cost-effective GP with clinical potential was developed. Although initial versions were scored as inferior via ACR on all views tested when compared to HD-WLE ($p < 0.001$), participants agreed the concept may be beneficial (M = 4.52/5, SD = 0.72). In testing improved versions, participants agreed the device had the ability to identify discrete (M = 4.62/5, SD = 0.51) and subtle lesions (M = 4/5, SD = 0.7) but most felt video quality, although improved, was still less than HD-WLE. Sufficiency of maneuverability of device to visualize gastric views was rated as equivocal (M = 2.69/5, SD = 1.25).

Keywords
- endoscopy
- gastric cancer
- screening

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Conclusion The presented low-cost gastroscopic devices have potential for clinical application. With further device development and refinement including the possible addition of technologies in telemedicine and artificial intelligence, we hope the GP can help expand gastric cancer screening for populations in need.

Introduction

Gastric cancer is one of the most common cancers in the world with 70% incidence in developing countries in East Asia, South America, and Eastern Europe.[1] In 2018, there were approximately 1 million new worldwide diagnoses and 780,000 deaths.[2] Japan, South Korea, and China are amongst the countries most affected, and mortality varies significantly between these countries. In most parts of the world, 5-year survival is around 20%.[3] In China, 5-year survival has ranged from 30 to 57%, compared to 63 to 77% in Japan.[4] This greater survival has been attributed to increased diagnosis of early disease, which offers better prognosis but is challenging, given its asymptomatic or nonspecific presentation.[4,5] Retrospective comparisons have shown 15.4% of gastric cancers being diagnosed at an early stage in China compared to 68.6% in Japan.[6] Many tumors diagnosed in Chinese patients were larger and demonstrated more nodal involvement.[6] Differences in the diagnosis of early-stage disease can at least be partially explained by Japan and South Korea, being amongst the few countries that have implemented large scale, population-wide screening programs for detection of early gastric cancer.[1,3]

Considerations in the implementation of organized screening include the costs of screening and economic benefits anticipated from screening. Cost-effectiveness considerations are a major reason why gastric cancer screening programs have been limited to a few countries even though gastric cancer affects populations across the globe.[7] Efforts to reduce costs have included the use of ultrathin trans-nasal endoscopy, which is used in Japan to screen for early gastric cancer and has the benefit of decreased need for conscious sedation and increased tolerability when compared to conventional trans-oral endoscopy.[8,9]

However, even with the development of trans-nasal endoscopy, many countries in Asia, the Middle East, and Latin America that have high disease burden still do not have widespread organized or opportunistic screening programs. One example is China, where in 2015 there was an estimated 680,000 new diagnoses and approximately 500,000 deaths.[10] Some challenges that have prevented Chinese adoption of widespread organized screening include the disparities in endoscopist training of advanced technologies such as narrow-band imaging between rural and urban areas and the financial cost for screening this population.[11,12] Currently, opportunistic screening in China is not supported through social health programs or insurance, leaving patients to shoulder the entire costs.[13] If the costs of screening could be reduced by using cheaper and thus more accessible endoscopic devices in a tiered screening protocol, that would be one less barrier for China and other countries with less-extensive healthcare resources and training to move toward successful gastric cancer screening.

The aims of this study were to develop a low-cost gastroscope prototype using iterative feedback from clinician endoscopists and assess the potential of the developed prototype for gastric cancer screening and patient risk stratification by surveying clinician endoscopists about device characteristics such as image quality and handling.

Methods

GP Development and Design Criteria

An interdisciplinary team of medical students, expert endoscopists, and engineering researchers developed the GP. Design criteria were generated after literature review and discussion with expert endoscopists. Focus was placed on minimizing the potential cost of device production and clinical costs of use including the need for expensive equipment and infrastructure as well as the costs of anesthesia, and additional clinician staffing. Other important design criteria included maintaining adequate visual quality, and device maneuverability necessary to visualize all relevant anatomical areas of the stomach. Throughout the development process of the GP, feedback and data were continuously collected from clinicians to guide the improvements needed in subsequent prototypes.

Gastroenterology faculty and fellows from the University of Wisconsin School of Medicine and Public Health, Department of Medicine and Division of Gastroenterology and Hepatology were recruited to participate in surveys. Participants provided informed consent and were given adequate time to ask questions before and after participation in this study. The University of Wisconsin IRB approved this study.

Video Quality Assessment

For GP version 1, 21 participants viewed pre-recorded videos from an early prototype and HD-WLE captured on an upper GI training model device and assessed video quality subjectively via the blinded absolute category rating (ACR) method, which has been used in previous studies[14] (Supplement 1). Recordings were captured from four anatomical areas. Participants were surveyed via 5-point Likert scale questions (1= poor, 5 = excellent) on seven different imaging quality metrics using the ACR method for subjective ratings of video quality, which has been shown to give reliable and reproducible results for video quality ratings.[15,16] In addition to the ACR assessment of video quality, participants answered the Likert scale (1= strongly disagree, 5 = strongly agree) level of agreement to the following statements: "The image quality/fidelity of the two systems were generally

comparable," "I could tell the difference between standard endoscopic image and the new device."

Supplementary Video S1

This video walks through use of the GP Version 2.1 in a training model. Online content including video sequences viewable at: https://www.thieme-connect.com/products/ejournals/html/10.1055/s-0043-1762574.

For GP version 2, 13 participants navigated the GP in the same upper GI training model. They then answered the Likert scale (1= strongly disagree, 5 = strongly agree) level of agreement with the following statements regarding imaging quality: "The image quality is adequate for identifying discrete and/or targeted lesions (ulcers, AVMs)," "The picture quality is adequate for identifying subtle lesions (e.g., mucosal erosions, mild gastritis, mild mucosal irregularities)." They were also asked to subjectively compare image quality to standard adult gastroscopy as inferior, equivocal, or superior.

GP Feedback and Maneuverability

For the GP version 1 participants ($n = 21$) answered Likert scale (1 = strongly disagree, 5 = strongly agree) level of agreement with the following statement, "This device concept and its future iterations/improvements may be beneficial for screening upper GI pathology in resource-limited countries." In GP version 2, participants ($n = 13$) handled the device in the GI training model and answered Likert scale (1 = strongly disagree, 5 = strongly agree) level of agreement to the following statement. "The handling/maneuverability of the device is sufficient for visualizing anatomy in the stomach including the retroflexion view." During each interaction between our participants the GP and at every stage of its development, participants also had the ability to provide verbal and written feedback regarding concerns and suggestions.

Statistical Methods

Statistical analysis of subjectively rated video quality via ACR methodology used paired *t*-tests and a linear mixed-effects modeling. A p-value < 0.05 was considered statistically significant. Statistical analysis was not performed on subsequent image quality comparisons or on assessment of device handling as these were based on more descriptive surveys.

Results

GP Device

Iterations in the design of the GP device are shown in ►**Fig. 1**. Components utilized, and assembly, and features of the various versions are included in Supplement 2. Version 2.1 is shown in ►**Fig. 2**. This version featured a diameter of approximately 7 mm at its head and widest point, leading to

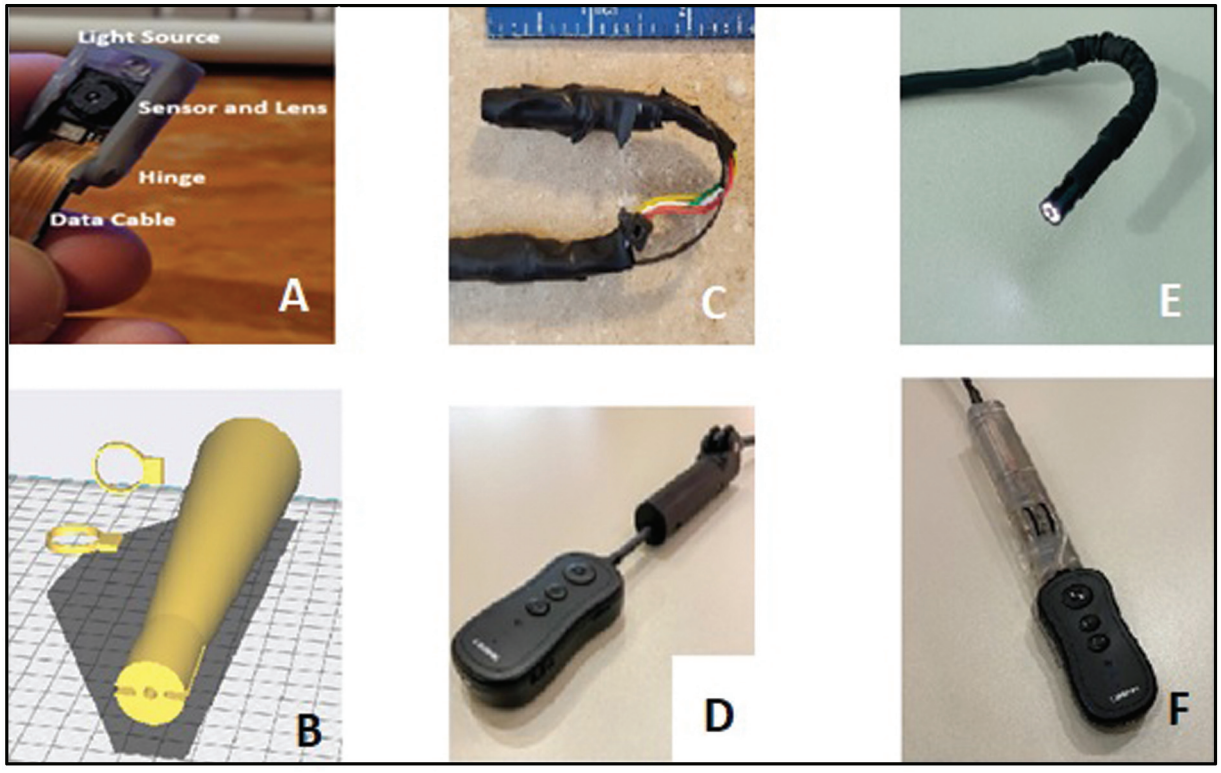

Fig. 1 Iterations in the design and development of a low-cost gastroscope prototype. Panel A: Version 1 prototype head. Panel B: Version 1 prototype handle. Panel C: Version 2 head with improved optics Panel D: Version 2 handle Panel E: Version 2.1 improved retroflexion head. Panel F: Version 2.1 improved retroflexion handle.

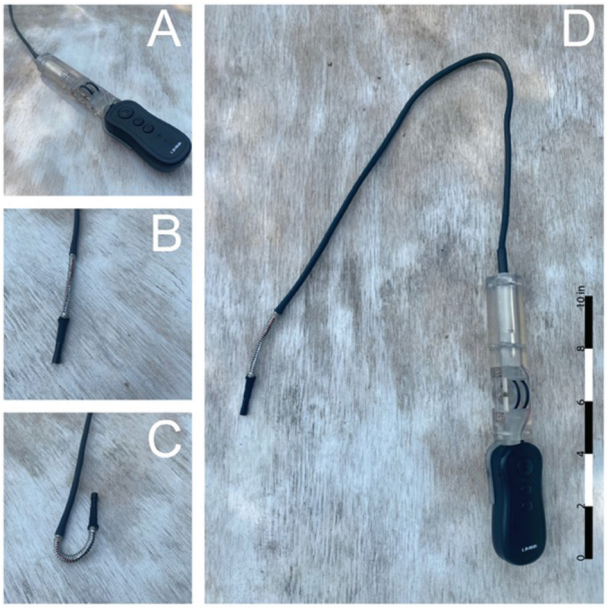

Fig. 2 Version 2.1 prototype. Panels **A–D** highlight different aspects of the device from the handle to the head to the entire device.

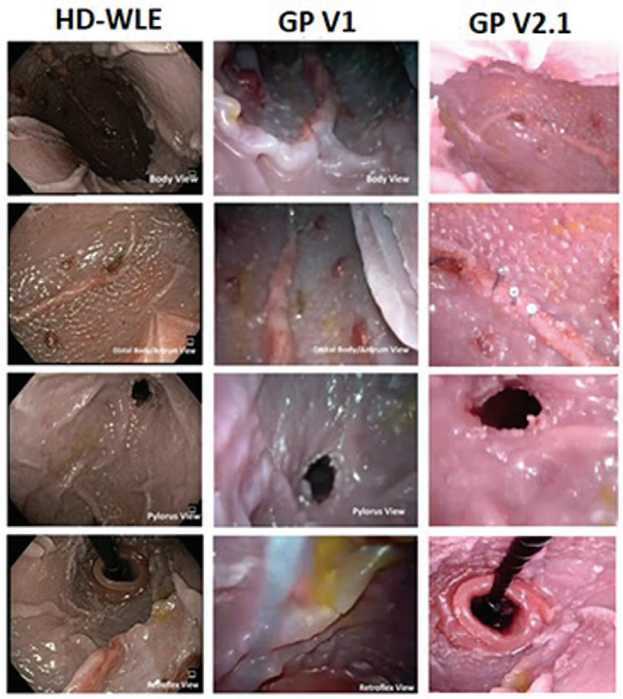

Fig. 3 Select still Images from HD-WLE, Version 1 and Version 2.1; 4 different anatomic regions are shown. A portion of the externalized pull wire is seen on retroflexion in the Version 1 (out of focus). Metal clips are seen as part of the upper GI training model in the revised GP views.

a cross-sectional dimension approximating 40 mm^2 compared to the version 1 GP at 108 mm^2. The final design was based on the modification of a commercial borescope device with video capabilities of 1080 p resolution at 30 fps capture with built in lighting and digital zoom functionality. Modifications included the addition of a 63.5 mm compression spring support with actuation wires strung inside, plus a handle to manipulate the tension of the wires, which facilitate greater than 180 degrees of retroflexion.

ACR Video Quality Assessment

Selected images taken from HD WLE and version 1 and 2 GPs are shown in ►**Fig. 3**. In the ACR video quality comparison to HD-WLE, paired *t*-test showed that a statistically significant lower video quality rating for the initial GP across all 7-image metrics in each of the four image views (all $p < 0.001$). The ratings for all image metrics and views are represented in ►**Fig. 4**. The linear mixed-effects model examining the overall difference between GP and HD-WLE systems across all metrics and all anatomic views showed that the ratings of HD-WLE were significantly higher with a mean difference of 1.4150 ($p < 0.0001$). The largest effect size was seen in overall video ratings for the retroflexion view for a mean of 1.9.

Likert Scale Video Quality Assessment

Participants showed a low level of agreement with the statement that the image fidelity of the GP version 1 and HD-WLE were generally comparable (M = 2.05, SD = 1.02) (►**Fig. 5**). Accordingly, there was also a high level of agreement with the statement that they could tell a difference between the two imaging systems (M = 4.52, SD = 0.93) (►**Fig. 5**).

Video quality assessments for GP version 2 using Likert scale agreements showed a strong level of agreement for ability to identify discrete and or targeted lesions (ulcers, arteriovenous malformation [AVMS]) (M = 4.62, SD = 0.51) and subtle lesions (mucosal erosions, mild gastritis, mucosal irregularities) (M = 4, SD = 0.7) (►**Fig. 6**). Overall, most participants still felt image quality was inferior to adult gastroscopy (►**Fig. 6**).

GP Device Feedback and Maneuverability

For the design of GP version 1, participants also collectively agreed with a statement that this concept and future iterations may be beneficial for upper GI screening (►**Fig. 5**, M = 4.29, SD =0.72) (►**Fig. 5**). Participants also shared high enthusiasm at the relatively good level of visual fidelity for the cost but had concerns about their inability to visualize a full retroflexed view of the lower esophageal sphincter and hiatus. Given the overall positive feedback for the initial GP design, but poor retroflexion performance seen on ACR and in general feedback, GPs version 2 and 2.1 focused on improving retroflexion capability and having participants handle the device.

After iterative design of the GP, 13 participants who handled the GP version 2.1 showed equivocal levels of agreement to statements regarding the handling and maneuverability of the device as sufficient for visualizing anatomy in the stomach including the retroflexion view (M = 2.69, SD =1.25) (►**Fig. 6**).

Discussion

Because organized screening for gastric cancer began in the 1980s in Japan and the 1990s in South Korea, retrospective studies have shown a lower relative risk of death in patients who received early screening, forming the basis of current guidelines.[1,17–21] As endoscopic methods have become more

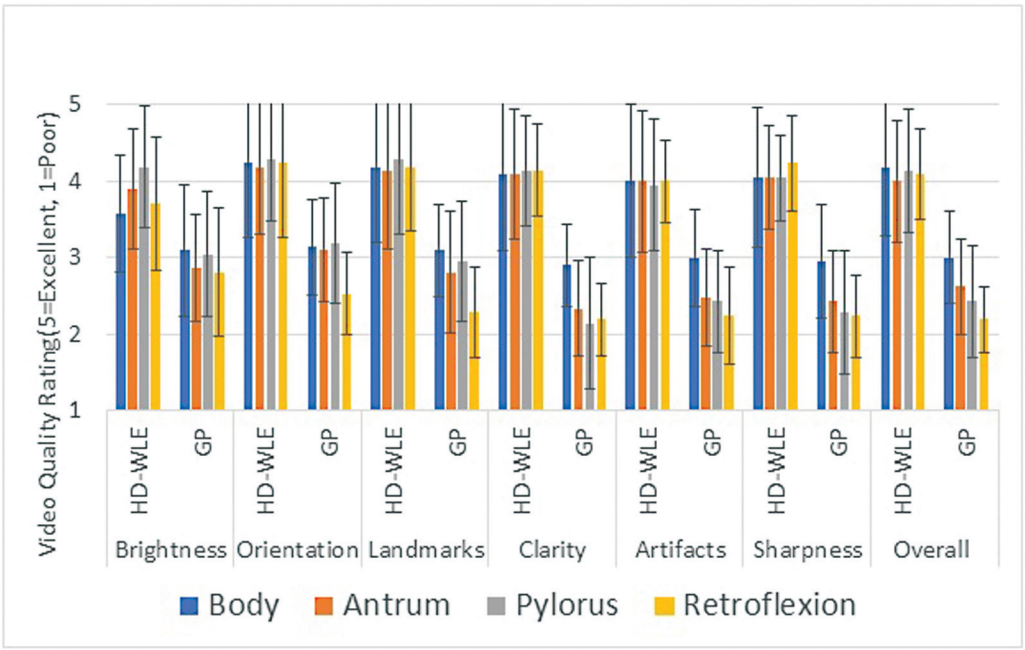

Fig. 4 ACR video quality ratings for HD-WLE and GP Version 1; On 5-point Likert scale participants rated the following video quality metrics: illumination/brightness, ability to identify orientation, ability to identify important structures/landmarks, picture clarity/texture, artefacts/background noise, contrast/border/sharpness, and overall satisfaction with video quality from 1 (poor) to 5 (excellent). Data from four different anatomic locations: body, antrum, pylorus and retroflex are shown here. Error bars are reflective of standard deviations.

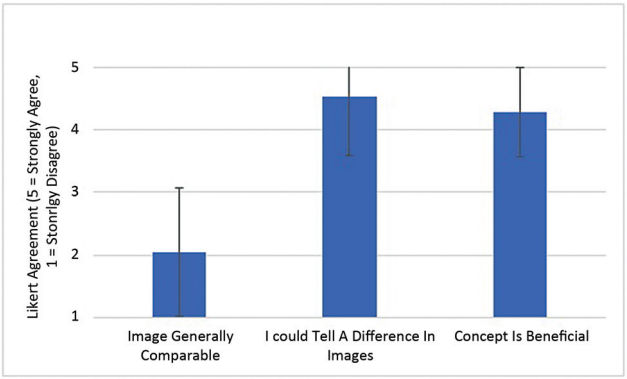

Fig. 5 Likert scale ratings for GP Version 1: 5-point Likert agreement scale from 1 (strongly disagree) to 5 (strongly agree). Error bars are reflective of standard deviations.

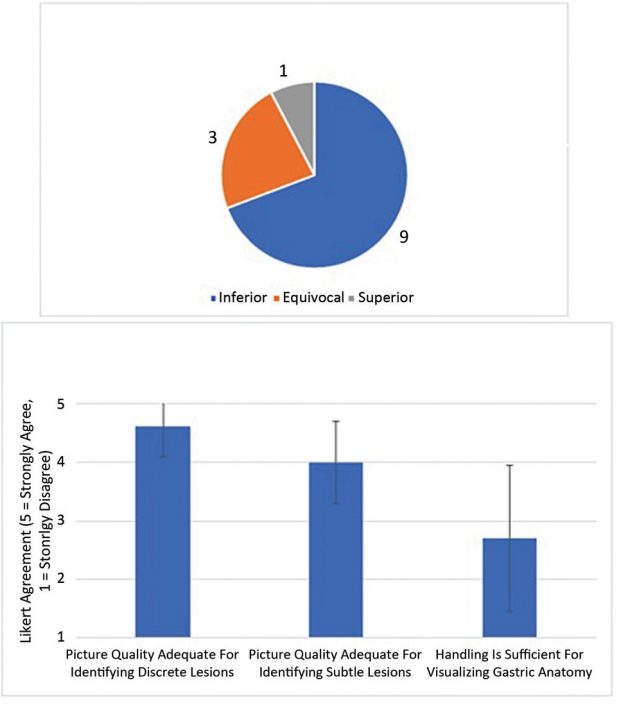

Fig. 6 Likert scale ratings for GP Version 2.1: 5-point Likert agreement scale from 1 (strongly disagree) to 5 (strongly agree). Error bars are reflective of standard deviations. Pie graph shows direct subjective video quality comparison of GPVersion 2.1 to HD WLE endoscopy.

popular, research has focused on the continued development of these technologies including methods to lower costs such as the use of trans-nasal endoscopy.[8,9] Cost-effectiveness analysis is an important consideration for countries without current organized screening that are considering adopting policies such as Singapore, where modeling has identified that cost of screening endoscopy was a key determinate in deciding cost-effectiveness.[7] There are many costs associated with endoscopic screening including device costs, procedure-related costs, physician and support staff fees, adverse event costs, and indirect costs. Not all these costs can be easily addressed. Designing a smaller endoscopic device with greater comfort could and reduce the need for procedural sedation and some ancillary clinical staff as seen in trans nasal endoscopy. Designing an endoscope specifically for gastric cancer screening but with reduced capability for other clinical tasks may also reduce overall device costs. Together, these changes may be a means of first-line screening in a tiered approach before use of more traditional

standard diagnostic devices. We set out to develop such a device and assess its potential for clinical screening.

GP Development and Device

As typical of medical device development, an iterative process of creating prototypes, collecting expert user feedback, and then refining the design was utilized during our GP development.[22] Our GP prototype is designed to be order of magnitudes lower in cost to manufacture compared to HD-WLE, given the use of low-cost and mass-produced imaging sensors, and a semi-custom design of adding maneuverability via a compression spring head and 3D printed handle to an existing commercial endoscopic device. The mechanism used for retroflexion, and maneuverability is anticipated to be much simpler and more cost-effective. Features anticipated to lower cost in clinical operation include its small cross-sectional size that approaches transnasal endoscopy to facilitate possible procedures without anesthesia, and its integration of WIFI and bluetooth smartphone functionality to minimize need for other video playback and recording equipment and infrastructure. The prototype material and production costs for our GP 1.0 and 2.0 were estimated to be roughly 100 US dollars. The exact production and final sales price of a commercial GP device would be hard to estimate and would depend on overall production numbers. We anticipate our final GP device will have the right feature/price value proposition to succeed in gastric cancer screening compared to other low-cost endoscopy competitors such as E.G II from South Korea and aScope from Denmark as examples.[23] Moreover, the other low-cost upper disposable endoscopes have limited view of esophagus only for Barrett's screening or limited view of the stomach. In addition, there is a significant cost of non-disposable parts with range estimated from $US 11,000–$15,000 compared to our device, which can be connected via a Wi-fi interface to smart tablet or phone or standard computer monitor. Similar to these lower cost devices, we also anticipate our final GP would be orders of magnitude lower than current conventional upper endoscopes used in the United States that cost roughly 20,000 USD to acquire.[23]

In addition to lower anticipated costs, our design criteria also set out to create a device with adequate optical and handling characteristics for the intended goal of screening by complementing but not replacing HD-WLE. It is not surprising that compared to HD WLE, in both ACR evaluation of the initial GP and subsequent expert surveys, most participants felt the GP had inferior video quality. The clinical significance of this remains unanswered; however, in surveys, most endoscopists felt that video quality was satisfactory for identification of discrete and subtle lesions. Ultimately, we set out to design and create a device to fulfill the unmet clinical need of gastric cancer screening in developing countries with high prevalence and to achieve this a device was proposed with certain cost, imaging, and handling metrics not yet available on the market. While, further iterative design and research is needed before clinical testing and use, we believe our initial design and results show promise.

Other Considerations for Gastric Cancer Screening and Diagnosis

Even with a clinically proven device with good video quality and maneuverability, an endoscopist must still clinically interpret findings. Despite using conventional gold-standard HD-WLE endoscopes, early gastric cancer lesions are known to be difficult to grossly identified due to their size and appearance.[6,24] In retrospective studies of patients diagnosed with gastric cancer, roughly 11% had an endoscopy within the last 1 to 3 years of their diagnosis, suggesting the possibility of missed lesions.[25] In some centers, it has been reported that roughly 73% of missed diagnoses may be attributed to endoscopist error in either not recognizing lesions or not taking biopsies.[26] The clinical challenge of visual identification of early gastric cancer may be exacerbated in an approach that relies on lowering the cost of and expanding access to endoscopic screening in low-resource countries that also lack access to well-trained endoscopists.

To address this challenge, we anticipate future features such as telemedicine, possible with cell phone compatible capabilities of the GP version 2, as well as future directions in technical development such as real-time computational algorithmic and deep learning methods to aid in the identification lesions. For example, the GP with its WIFI and smart device integration could be easily adapted for transmitting recordings via telehealth to centers with more experience. Use of real-time computational methods and AI, although less tested in clinical settings, has already been demonstrated with HD-WLE to be more accurate, sensitive, and specific than experienced endoscopists in identifying early gastric cancer on test videos.[27] How such algorithms would fare using lower cost devices such as the GP is unclear. While some image recognition algorithms have been shown to be negatively affected by lower quality image, this was most pronounced in situations of lower resolution.[28] Of note, the GP captures at 1080p HD resolution, just like HD-WLE, suggesting possible similar effectiveness. If a future low-cost device such as the GP could leverage telemedicine and computation methods together, this could negate the disparities and difficulties in diagnosis of early cancer lesions as well as manage the workload burden of more experienced endoscopists.

Limitations

Here we describe both the development and assessment of a GP. The device assessment was non-randomized and without control group. While lack of randomization may have biased device assessment, we felt at the current early stage of GP development, the benefits of having all participants assess and provide feedback for the GP to aid in the iterative design process of continual prototype development and clinician feedback would outweigh potential cons. Future prototypes would benefit from double-blinded, randomized, and controlled assessments. Other possible sources of bias during ACR video quality surveys may include the possible early identification of each system even though participants were blinded to each system as the video from HD-WLE included a circular aspect ratio versus a square aspect ratio from GP

which may have been noticed by participants. To mitigate bias, similar video dimensions/resolutions were used for each system. Even with these potential flaws, overall participants felt that HD-WLE had better video quality as expected. Other limitations include the use of a phantom upper GI training model instead of physiologic patient or animal videos. Future reiterations of GP device would need to undergo pre-clinical trials in animal (e.g., porcine-swine) models and subsequently in human subject trials and comparing with standard high-definition gastroscopes perhaps in tandem and/or randomized controlled fashion.

Future GP Development and Use Case

In addition to the research questions not addressed by this study, further work includes refinement of the GP device by enhancing video quality, ergonomics, and handling. In the future other imaging features such as digital spectral imaging color enhancement could also be implemented. Such features may provide additional benefit in identification of pathology but may possibly add to the cost of the final device. Finally, the addition of a modular, disposable exterior channel for both insufflation and aspiration of liquid biopsy could have future value if gastric liquid biopsy can be extended to have a role in screening. We anticipate a device with both reusable and nonreusable single use components as described above. Studies will need to be conducted to determine safe procedures for reuse and safe levels of reuse for reusable components. Eventually, such a device may fulfill a role in a tiered endoscopic screening approach to identify patients with concerning features and pipelining them to receive traditional EGD for biopsy and treatment. This development could complement developments in noninvasive tests such as serologic pepsinogen assays and *Helicopylori pylori* testing in ABC type algorithm or transabdominal ultrasounds with oral contrast.[1,29] *H. pylori* testing and eradication have been touted by various international consensus committees as a focus for cost-effective gastric cancer prevention, given its involvement in the pathogenesis of gastric cancer.[30] As noninvasive or less-invasive testing develops, we anticipate that a low-cost endoscopic system may still have value to confirm disease in the case of positive results.

Ultimately, cost is just one major factor amongst many other key criteria such as complication rate, and acceptance by both endoscopists and patients that will affect widespread adoption by a country for medical use. In this proof-of-concept study, we have just begun to address the potential of technological developments to lower the cost of endoscopic devices for screening. Further research and development are needed before clinical use. Any expansion of an endoscopic first screening approach to countries with high need and less resources may necessitate the adoption of new technologies that can leverage lower cost devices and use advancements such as telemedicine and AI. In this study, we tried to develop such a tool in the form of a low-cost gastroscope, and based on our clinician survey results, we believe this approach is promising. Ideally, such tools can identify high-risk individuals and direct them to standard of care techniques with more experienced endoscopists. This would hopefully expand the access to screening and potentially benefit global health by lowering the overall disease burden of gastric cancer.

Conflict of Interest
None declared.

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