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USABILITY OF A NOVEL DISPOSABLE ENDOSCOPE FOR GASTRIC CANCER SCREENING IN LOW-RESOURCE SETTINGS: RESULTS FROM RURAL INDIA

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Background: Gastric cancer prevalence is highly dependent on geographic location, with over 70% of cases occurring in developing nations. Although screening for stomach cancer through upper endoscopy (EGD) can significantly reduce mortality, implementation of screening programs in many disease-burdened regions is too expensive. Our academic lab has developed a novel pneumatically driven disposable endoscope that may facilitate ultra-low-cost visual screening for many of these areas. With a revised device design, the usability of the system in-the-field is unknown.

Methods: *Platform:* As shown in Figure 1, pivoting of the novel endoscope handle against the user's abdomen mechanically actuates internal syringes that in turn vary the pressure on bellow chambers at the tip. With three parallel bellows, bending may be achieved in 360° around the central axis of the scope. Improvements were implemented into the latest endoscope design; namely: reducing the tip diameter (OD: 8 mm); increasing the maximum bending angle to 160°; and utilizing a 120° field of view (FOV) camera with 400x400 pixels. The inclusive cost for fabrication is 32 USD.

Task: To assess the device performance, 5 medical practitioners from rural India with previous experience performing EGDs with conventional flexible endoscopes (FEs) but without experience with the novel endoscope were tasked with performing an EGD procedure on a bespoke gastric simulator. Participants were asked to visualize 6 key landmarks in the simulator (Figure 2). Outcomes included successful landmark identification, time-to-landmark visualization, NASA task load index mental and physical demand, and user feedback.

Results: All participants were able to successfully visualize the 6 landmarks in under 5 minutes (median time: 127 s). Mental and physical demand were low; 33 [29, 38] and 38 [33, 57] respectively. All participants expressed satisfaction with image quality, lighting, stiffness, and range of motion. Use of the pivoting handle was deemed easy to use/useful (n=2), good/satisfactory but not optimum (n=2), a little cumbersome (n=1).

Conclusions: The novel endoscope was intuitive to use without prior training or experience as all users were able to successfully visualize all landmarks. The novel endoscope is comparable in size and range of motion to a conventional FE. The low-cost, portable and disposable nature of the device make it an ideal tool for potentially enabling cost-effective gastric cancer screening programs in at risk rural communities.

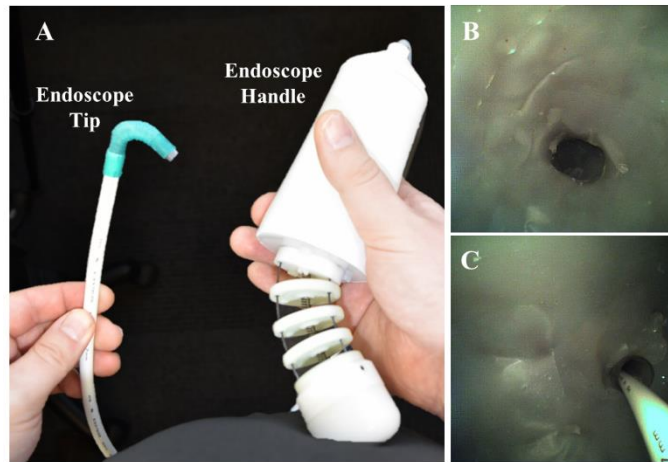


Figure 1: Novel endoscope design during operation, showing: A) endoscopic handle under actuation and corresponding tip motion; two of the visually identified regions from the stomach simulator trial – the antrum B) and fundus C).

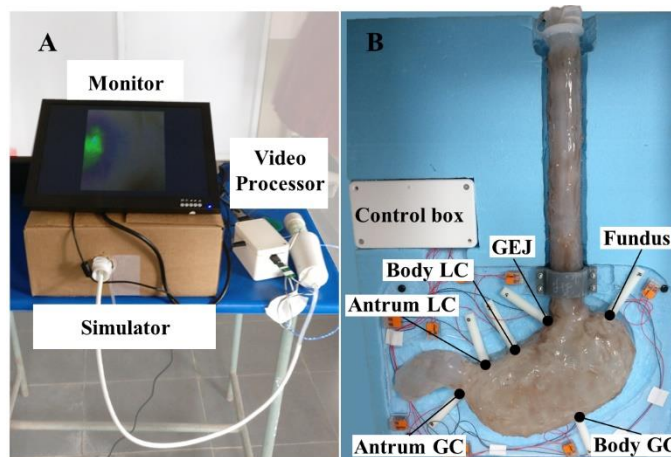


Figure 2: Human stomach and esophagus simulator; arranged for user trail A), internal configuration of location markers, identifying: gastroesophageal junction (GEJ), fundus, body greater curvature (GC), body lesser curvature (LC), antrum GC, and antrum LC.