World Academy of Science, Engineering and Technology
International Journal of Biomedical and Biological Engineering
Vol:16, No:06, 2022

A Single-Use Endoscopy System for Identification of Abnormalities in the Distal Oesophagus of Individuals with Chronic Reflux

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Abstract : The dramatic global rise in acid reflux has also led to oesophageal adenocarcinoma (OAC) becoming the fastest-growing cancer in developed countries. While gastroscopy with biopsy is used to diagnose OAC patients, this labour-intensive and expensive process is not suitable for population screening. This study aims to design, develop, and implement a minimally invasive system to capture optical data of the distal oesophagus for rapid screening of potential abnormalities. To develop the system and understand user requirements, a user-centric approach was employed by utilising co-design strategies. Target users' segments were identified, and 38 patients and 14 health providers were interviewed. Next, the technical requirements were developed based on consultations with the industry. A minimally invasive optical system was designed and developed considering patient comfort. This system consists of the sensing catheter, controller unit, and analysis program. Its procedure only takes 10 minutes to perform and does not require cleaning afterward since it has a single-use catheter. A prototype system was evaluated for safety and efficacy for both laboratory and clinical performance. This prototype performed successfully when submerged in simulated gastric fluid without showing evidence of erosion after 24 hours. The system effectively recorded a video of the mid-distal oesophagus of a healthy volunteer (34-year-old male). The recorded images were used to develop an automated program to identify abnormalities in the distal oesophagus. Further data from a larger clinical study will be used to train the automated program. This system allows for quick visual assessment of the lower oesophagus in primary care settings and can serve as a screening tool for oesophageal adenocarcinoma. In addition, this system is able to be coupled with 24hr ambulatory pH monitoring to better correlate oesophageal physiological changes with reflux symptoms. It also can provide additional information on lower oesophageal sphincter functions such as opening times and bolus retention.

Keywords : endoscopy, MedTech, oesophageal adenocarcinoma, optical system, screening tool
Conference Title : ICBDDE 2022 : International Conference on Biomedical Devices and Diagnostic Engineering
Conference Location : Paris, France
Conference Dates : June 23-24, 2022