

Development and Validation of a Virtual Bariatric Endoscopic (ViBE) simulator

Abstract

Obesity is associated with significantly increased risk of morbidity and mortality and is a growing national epidemic with more than two-thirds of Americans considered overweight or obese. Bariatric (weight loss) surgery remains the most effective and durable treatment of obesity, **though less than 1% of morbidly obese patients actually undergo the procedure** due to cost, access, and patient concerns regarding adverse events and re-operation. Thus, the majority of the overweight and obese patients are left without a viable and durable option. Novel **endoscopic bariatric therapies (EBT)**, using only flexible gastrointestinal endoscopes, are providing new hope to these patients due to their cost effectiveness, low invasiveness, reversibility, lower complication rates and significant improvements in co-morbidities. **Endoscopic Sleeve Gastroplasty (ESG)** is a trans-oral EBT which significantly reduces the volume of the stomach by suturing it from within the gastric lumen. It is associated with significant durable weight loss and reduction of co-morbidities associated with obesity. However, learning to **perform ESG is technically demanding with a minimum of 35 cases** necessary to attain basic proficiency. This is because ESG requires complex maneuvers to apply full-thickness sutures using flexible endoscopic tools from within a floppy hollow organ like the stomach.

With no formal curriculum or competency standards in place for ESG outside the patient-centric apprenticeship model of medical and procedural education, it is anticipated that a **virtual reality (VR)**-based trainer, with visual and haptic (touch) feedback, will be invaluable for training in ESG, allowing trainees to attain competence in a controlled environment with no risk to patients; to enable customized learning; and to offer real time feedback, mentoring and objective assessment. **The goal of the present proposal is to design, develop and validate a Virtual Bariatric Endoscopic (ViBE) simulator that can be used to train endoscopic bariatric procedures such as ESG.** A multidisciplinary team has been assembled to achieve the following Specific Aims: **(SA 1) Design and develop a Virtual Bariatric Endoscopic (ViBE) simulator platform for endoscopic modification of gastric anatomy.** Specifically, we will develop (i) physics-based computational models of human anatomy based upon *in vivo* experimental studies; and (ii) haptic hardware interface. **(SA 2) Develop training scenarios for endoscopic sleeve gastroplasty (ESG) within ViBE with instructional feedback.** Specifically, we will (i) integrate the computational models and *in vivo* experimental data from SA1 to develop a hands-on skill training environment for ESG which will allow the trainee to perform alternative approaches and encounter consequences of typical pitfalls, (ii) develop metrics of task performance and goal scores which will serve as end points of learning and (iii) develop a cognitive feedback module. **(SA 3) Establish the validity of the ViBE as a training tool** by conducting experiments at Indiana University (IU) School of Medicine with voluntarily enrolled participants to ensure that appropriate skills are being learned on the ViBE and performance measured on the ViBE reflect the technical skills they intend to measure.