Robotic-assisted flexible colonoscopy: preliminary safety and efficiency in humans

Esther D. Rozeboom, MSc,[1] Barbara A. Bastiaansen, MD,[2] Elsemieke S. de Vries, MD,[2] Prof. dr. Evelien Dekker, MD,[2] Prof. dr. Paul A. Fockens, MD,[2] Prof. dr. Ivo A. M. J. Broeders, MD[1,3]

Enschede, Amsterdam, Amersfoot, The Netherlands

Background and Aims: The flexible endoscope is used as a platform for minimally invasive interventions. However, control of the conventional endoscope and multiple instruments is difficult. Robotic assistance could provide a solution and better control for a single operator. A novel platform should also enable interventions in areas that are currently difficult to reach. This study evaluates the safety and efficacy of a robotic platform that guides a conventional endoscope through the large bowel.

Methods: Adult patients scheduled for routine diagnostic colonoscopy were included in this feasibility study. The endoscope was introduced using a robotic add-on to provide tip bending and air/water actuation. The endoscopist directly controlled the endoscope shaft. Upon cecal intubation, the add-on was detached and the procedure continued using conventional control. Primary evaluation parameters were the number of serious adverse events and the percentage of successful cecal intubations.

Results: The procedure was performed on 22 consecutive patients who all gave informed consent. There were no serious adverse events. Cecal intubation was successful in 15 patients (68%) using the robotic add-on. Six cases were completed after conversion to conventional control: 3 cases were converted to pass sharp angulation in the flexures and 3 cases were converted after technical difficulties. One case was not successful with either technique because of severe diverticulosis.

Conclusions: The robotic add-on steering module allows safe endoscope intubation to reach intervention sites throughout the large bowel. The next step is to clinically evaluate complementary instrument and shaft-guiding modules in therapeutic procedures.

INTRODUCTION

Over the past decade, the flexible endoscope has evolved from a diagnostic tool to a platform for intraluminal and transluminal interventions.[1-3] Controlling the conventional endoscope for these advanced procedures requires a long learning trajectory[4] and single-person control is not always possible. Robotics are expected to aid in controlling the endoscope and its instruments.[5] Previously introduced robotic designs provide single-person control of multiple steerable instruments.[6-10] However, none of these systems have the essential versatility to arrive at intervention sites that are difficult to reach in humans.

Ruiter et al[11] introduced a robotic add-on steering module for complex interventions. The system consists of 3 modules to control a conventional endoscope tip, its shaft, and multiple instruments (Fig. 1). The first module for tip steering is used to introduce the endoscope to the intervention site. After introduction, the shaft and instrument modules are attached to provide single-person control of the endoscope and the instruments. Previous studies performed on simulators showed that the tip-steering module is effective, increases efficiency, and raises satisfaction in a simulated environment for both novice and expert endoscopists.[12,13] Although the use of simulators is a good method for training and evaluating technical skills, they lack the complexity and fidelity to be useful beyond the novice level.[14] In addition, the

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Current affiliations: Department of Robotics and Mechatronics, University of Twente, Enschede, The Netherlands (1), Department of Gastroenterology and Hepatology, Academic Medical Centre, University of Amsterdam, Amsterdam, The Netherlands (2), Department of Surgery, Meander Medical Center, Amersfoort, The Netherlands (3).

Reprint requests: Esther D. Rozeboom, Robotics and Mechatronics, Faculty of Electrical Engineering, University of Twente, PO Box 217, 7500 AE Enschede, The Netherlands.

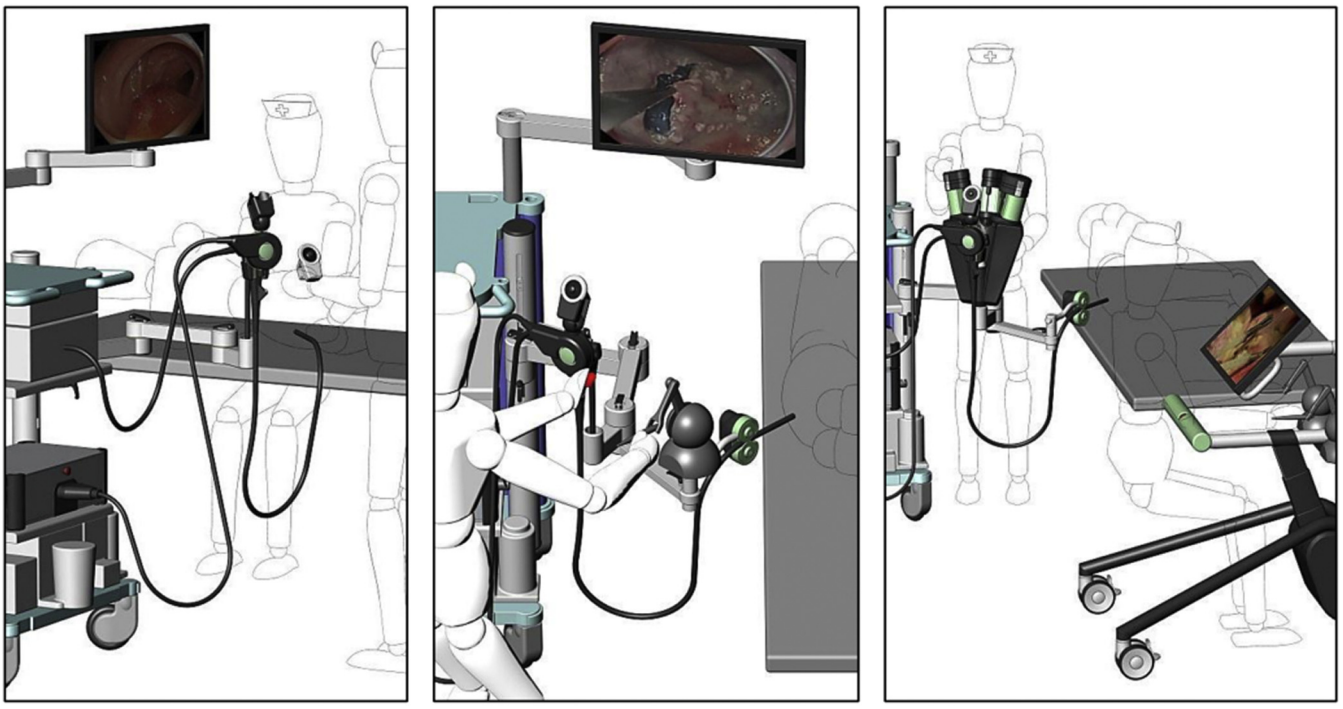

Figure 1. Robotic modules: (left) steering; (middle) shaft manipulation; (right) instrument manipulation. Reprinted from Ruiter JG, Van Der Voort MC, Bonnema GM. User-centred system design approach applied on a robotic flexible endoscope. Procedia Comput Sci 2013;16:581-90; with permission from Elsevier.

unpredictability of the human bowel may mean that additional steering options such as patient repositioning and application of bowel pressure are required.[15,16]

This is the first study on human patients in which colonoscopy is performed using a conventional endoscope with add-on robotic control. The aim of this study is to determine the safety and efficacy of cecal intubation using the add-on steering module in a clinical setting.

METHODS

Patients

Consecutive patients scheduled for a diagnostic colonoscopy examination at the Academic Medical Centre, Amsterdam, were asked to participate in the study. Exclusion criteria were previous abdominal surgery, American Society of Anesthesiologists physical status classification 3, 4, or 5, and patients with hereditary polyposis syndromes. Patients received verbal and written information on the study 2 to 3 weeks and 5 days before the procedure. They signed informed consent before the start of the procedure. Approval of the medical ethical committee of the Academic Medical Center was obtained before the start of this study.

Procedure

Two endoscopists (B.A.B., P.F.), with experience of >1000 and >5000 colonoscopies, respectively, performed a diagnostic colonoscopy according to the standard protocol. They used a robotic add-on steering module to control the endoscope during the intubation phase. Upon cecal intubation, the robotic add-on was disconnected while the endoscope remained in the same position in the patient. The procedure (withdrawal and if necessary interventions) was continued using the conventional system. Patients were consciously sedated using midazolam and fentanyl following standard sedation and recovery protocols. Ten days after the procedure, patients were contacted for follow-up on their experience and possible adverse events.

Robotic add-on system

The robotic add-on system actuates the navigation wheels on a conventional endoscope.[12] The system consists of a remote controller with which the user controls a motor drive unit and valves for air inflation, water injection, and suction (Fig. 2).[17] Two motors in the drive unit manipulate bending cables that run through a flexible transmission to a mobile drive unit. The mobile drive unit is connected to the colonoscope console by means of a single plug, providing immediate conversion to the conventional system if needed (Fig. 3). Plastic drapes (Microtek Medical, Inc., Zutphen, The Netherlands) covering the remote controller and remote drive unit were replaced for each case. The user is provided with visual feedback on the direction and extent of tip bending.