Colonoscopy with robotic steering and automated lumen centralization…

10.1055/s-0034-1392550
Endoscopy

Colonoscopy with robotic steering and automated lumen centralization: a feasibility study in a colon model

Authors
Hendrikus J. M. Pullens[1,2], Nanda van der Stap[3,4], Esther D. Rozeboom[3], Matthijs P. Schwartz[1], Ferdi van der Heijden[3], Martijn G. H. van Oijen[2,5], Peter D. Siersema[2], Ivo A. M. J. Broeders[3,4]

Institutions
Institutions are listed at end of article.

submitted
28. December 2014
accepted after revision
29. May 2015

Bibliography
DOI http://dx.doi.org/10.1055/s-0034-1392550
Published online: 2015
Endoscopy

ISSN 0013-726X

Corresponding author
H. J. M. Pullens, MD, PhD
Meander Medical Center
PO Box 1502
3800 BM Amersfoort
The Netherlands
Fax: +31-33-8502695
hjm.pullens@meandermc.nl

Background and study aims: We introduced a new platform for performing colonoscopy with robotic steering and automated lumen centralization (RS-ALC) and evaluated its technical feasibility.
Participants and methods: Expert endoscopists (n = 8) and endoscopy-naive novices (n = 10) used conventional steering and RS-ALC to perform colonoscopy in a validated colon model with simulated polyps (n = 21). The participants were randomized to which modality they were to use first. End points were the cecal intubation time, number of detected polyps, and subjective evaluation of the platform.
Results: Novices were able to intubate the cecum faster with RS-ALC (median 8 minutes [min] 56 seconds [s], interquartile range [IQR] 6 min 46 s – 16 min 34 s vs. median 11 min 47 s, IQR 8 min 19 s – 15 min 33 s, *P* = 0.65), whereas experts were faster with conventional steering (median 2 min 9 s, IQR 1 min 13 s – 7 min 28 s vs. median 13 min 1 s, IQR 5 min 9 s – 16 min 54 s, *P* = 0.12). Novices detected more polyps with RS-ALC (median 88.1 %, IQR 79.8 % – 95.2 % vs. median 78.6 %, IQR 75.0 % – 91.7 %, *P* = 0.17), whereas experts detected more polyps with conventional steering (median 80.9 %, IQR 76.2 % – 85.7 % vs. median 69.0 %, IQR 61.0 % – 75.0 %, *P* = 0.03). Novices were more positive than experts about the new platform (*P* = 0.02), noting an easier and faster introduction of the colonoscope with RS-ALC than with conventional steering.
Conclusions: Colonoscopy with RS-ALC is technically feasible and appears to be easier and more intuitive than conventional steering for endoscopy-naive novices.

Introduction

With the initiation of population screening for colorectal cancer, there has been a steady increase in the demand for colonoscopy in many countries [1, 2]. Physicians entering colonoscopy training programs face extensive learning curves and must perform several hundred colonoscopic procedures before being able to intubate the cecum in the vast majority of patients [3, 4]. This difficulty can at least partly be attributed to the nonintuitive steering mechanism of flexible endoscopes. Furthermore, musculoskeletal complaints due to the non-ergonomic design of the colonoscopy setup have been reported to occur in up to 50 % of endoscopists [5]. Colonoscopes with a more intuitive and ergonomic steering mechanism might reduce learning curves and improve the efficiency of colonoscopic interventions, subsequently increasing colonoscopic capacity.
Robotics have the potential to overcome the challenges encountered in endoscope control. Technical studies on the use of robotic steering in gastrointestinal endoscopy have, however, yielded diverse results [6 – 8]. During both introduction and withdrawal of the colonoscope, it is important that the tip of the colonoscope be oriented in a manner that optimizes overview of the colonic anatomy. Robotic control of flexible endoscopes allows automated visual flexible endoscope navigation. This can help to keep the tip of the scope oriented in the colonic lumen.
We introduced a robotic platform with the option of automated lumen centralization (ALC) to assist the endoscopist in steering the endoscope tip and performed a randomized, crossover pilot study with a colon model to evaluate the feasibility of colonoscopy with robotic steering and ALC (RS-ALC).

Participants and methods

Study population

Both expert endoscopists and novices participated in the study. The expert endoscopists were gastroenterologists from two hospitals (Meander

Medical Center, Amersfoort, the Netherlands, and University Medical Center, Utrecht, the Netherlands), all with individual experience of more than 2000 colonoscopies. The novices were students of technical medicine at the University of Twente, Enschede, the Netherlands. All had basic knowledge of gastrointestinal anatomy and pathophysiology, and all knew the technical principles of gastrointestinal endoscopy. None of the novices had any experience in performing endoscopy.

Study design

All participants performed colonoscopies on a physical colon model with both conventional steering and RS-ALC. We used a crossover design in which participants were randomized to which of the two modalities they were to use first. Before testing, each participant received both verbal and written instructions on the goals of the study, the colon model, and RS-ALC. Novices also received instructions on conventional steering.

Expert endoscopists had 5 minutes in which to become familiar with the colon model while using the conventional steering method and 20 minutes to practice with the robotic setup before the study started. Novices were granted 10 minutes to get used to the colon model and 20 minutes to practice each modality. Participants were instructed to have the endoscope reach the cecum as fast as possible. Withdrawal time was set at 6 minutes. During testing, we allowed no additional instructions. Participants who were not able to reach the cecum with one of the steering modalities were excluded.

After completion of the tests, the participants filled out a questionnaire with dichotomous questions on their subjective evaluation of the new platform.

Colon model with simulated polyps

All procedures were performed with an Olympus Exera II CLV-180 endoscopy platform and colonoscope (Olympus, Tokyo, Japan). We used the Kyoto Kagaku Colonoscope Training Model (Kyoto Kagaku Co. Ltd, Kyoto, Japan), which is a physical colon model consisting of a life-size plastic torso with a synthetic colon inside (▶ **Supplementary Fig. 1**). The colon is threaded through rubber rings that are attached to the torso, either directly or with springs. The colon was configured into standard cases, according to the layout guides provided by the manufacturer.

Expert endoscopists used case 2 of the colon model to perform the tests, which is one of the cases that has previously been validated for assessing colonoscope insertion skills [9]. During pretesting of the platform setup for feasibility, none of the novices was able to reach the cecum with either modality while using this case. Therefore, novices performed the tests on case 1, which is easier.

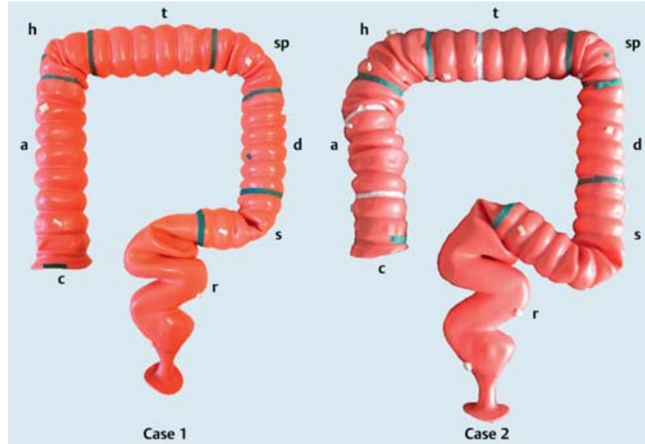


Fig. 1 The cases of the colon model with distribution of the simulated polyps: c, cecum; a, ascending colon (3 simulated polyps); h, hepatic flexure (3 polyps); t, transverse colon (2 polyps); sp, splenic flexure (3 polyps); d, descending colon (2 polyps); s, sigmoid colon (4 polyps); r, rectum (4 polyps).

We manually applied 21 foam fabric simulated polyps, varying in size, throughout the colon in a distribution similar to that reported by Gralnek et al. [10]. The novices used a shorter part of the synthetic colon for case 1, so the simulated polyps were redistributed to obtain the same distribution per colonic segment as in case 2 (▶ **Fig. 1**). The participants were blinded with regard to the number of simulated polyps and the fact that they performed both procedures on the same case of the colon model.

Robotic steering with automated lumen centralization

When RS-ALC was used, the angulation wheels of the endoscope were connected to a remote drive unit and placed in a docking station (▶ **Supplementary Fig. 2**) [11]. The user steered the tip by means of a joystick controller (▶ **Fig. 2**). To compensate for the lack of tactile feedback from the angulation wheels, a feedback circle was shown on screen to indicate to the participant in which direction and to what extent the tip of the colonoscope was bent [12].

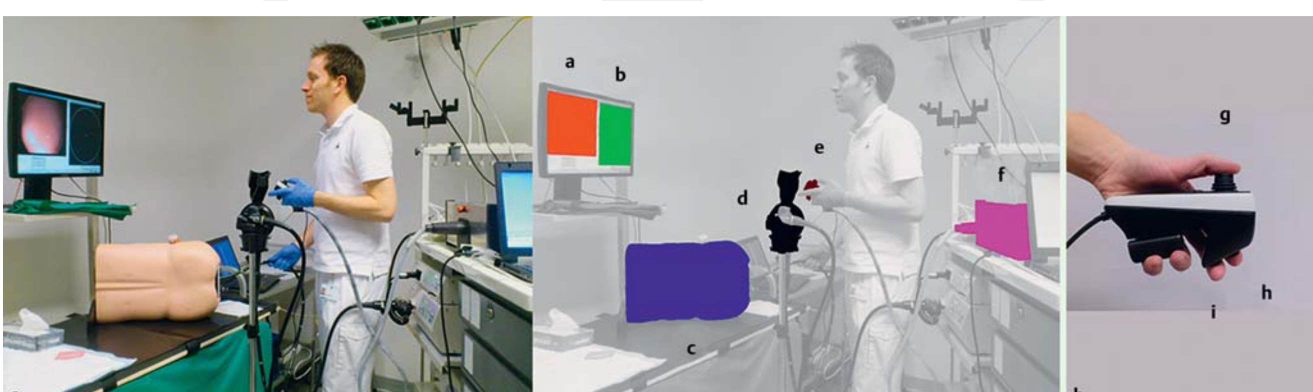


Fig. 2 **a** Setup of the experiment: a, endoscopic image; b, visual feedback circle; c, Kyoto Kagaku Colonoscope Training Model; d, docking station; e, joystick controller; f, motor unit. **b** Details of the joystick controller: g, joystick; h, button 1; i, button 2.

ALC consisted of a software algorithm that identifies the darkest pixels in the image [13]. The darkest region in the image usually corresponds to the middle of the colonic lumen, which is the target area for the colonoscope. On screen, a small circle continuously depicted the target as detected by the ALC algorithm. When the position of the circle corresponded to the actual target, the participant could actively decide to let the platform steer the scope to center this point in the endoscopic image. This was done by pressing and holding button 1 on the joystick controller. Releasing the button immediately stopped the platform from steering the tip.
All tests were performed single-handedly, with the joystick controller or conventional colonoscope steering mechanism in one hand and the shaft of the colonoscope in the other. With both modalities, the colonoscope could be torqued as usual.

Study end points

Study end points were the cecal intubation time, number of detected simulated polyps during endoscope withdrawal, and participants' subjective evaluation of the new platform.

Statistical analysis

We performed data analysis with SPSS version 22 (IBM, Armonk, New York, USA). For both participant groups, we used Wilcoxon's signed rank test to compare the median cecal intubation times and numbers of detected simulated polyps achieved with the robotic method and the conventional method. We used Fisher's exact test to compare the median "on" times of the two participant groups for the ALC option. Categorical variables were also compared with Fisher's exact test. All tests were two-tailed. We considered a *P* value of less than 0.05 to be statistically significant. Because this was a pilot study, no power calculation was performed beforehand.

Results

▼

A total of 8 expert endoscopists (7 men, median age 47 years [interquartile range (IQR) 42.25 – 56.25]) and 12 novices (3 men, median age 21.5 years [IQR 20 – 22]) participated in the study. We excluded the data for 2 novices from further analysis, one of whom failed to reach the cecum during colonoscopy with conventional steering (randomized to RS-ALC first) and one of whom failed to complete the first procedure without additional instructions (randomized to start with conventional steering).
Novices required a shorter time to intubate the cecum with RS-ALC (median 8 minutes [min] 56 seconds [s], IQR 6 min 46 s – 16 min 34 s) than with conventional steering (median 11 min 47 s, IQR 8 min 19 s – 15 min 33 s, $P = 0.65$) (**Fig. 3**). The intubation time of expert endoscopists was shorter with conventional steering (median 2 min 9 s, IQR 1 min 13 s – 7 min 28 s) than with RS-ALC (median 13 min 1 s, IQR 5 min 9 s – 16 min 54 s, $P = 0.12$). The intubation times did not differ between the randomization groups in either the experts or the novices.
Novices detected more polyps with RS-ALC than with conventional steering (median 88.1 % [18.5/21], IQR 79.8 % – 95.2 % vs. median 78.6 % [16.5/21], IQR 75.0 % – 91.7 %, $P = 0.17$), whereas expert endoscopists found significantly fewer polyps with RS-ALC than with conventional steering (median 69.0 % [14.5/21], IQR 61.0 % – 75.0 % vs. median 80.9 % [17.0/21], IQR 76.2 % – 85.7 %, $P = 0.03$) (**Fig. 4**).

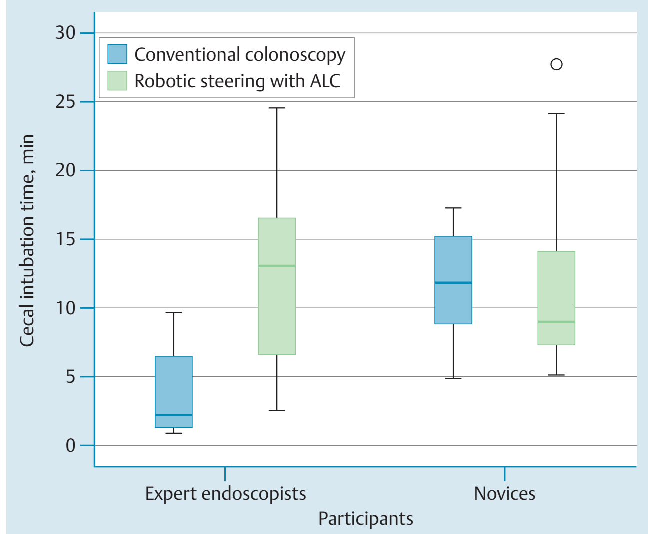


Fig. 3 Box and whisker plot with cecal intubation times for expert endoscopists and novices using conventional colonoscopy or robotic steering with automated lumen centralization (ALC).

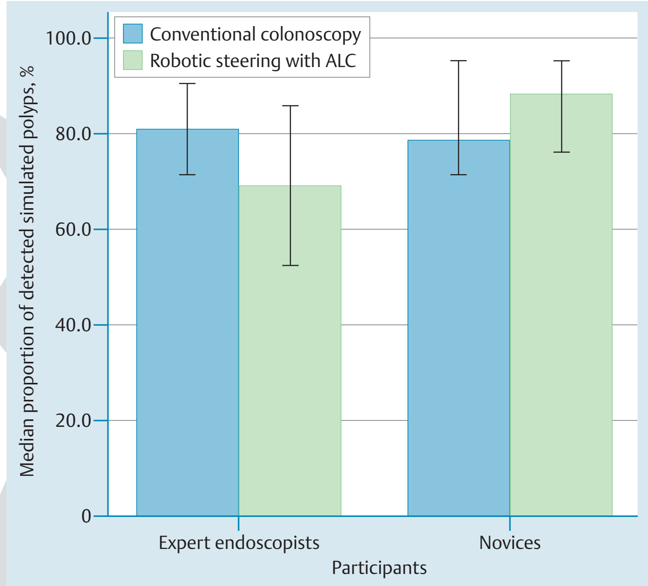


Fig. 4 Bar graph with median polyp detection rates for expert endoscopists and novices using conventional colonoscopy or robotic steering with automated lumen centralization (ALC). A rate of 100 % equals detection of 21 simulated polyps. Error bars indicate 95 % confidence interval.

During endoscopy with robotic steering, we found no significant difference in regard to the median percentage of overall time during colonoscopy that the ALC option was switched on between the expert endoscopists (7.3 %, IQR 3.3 % – 13.6 %) and the novices (2.6 %, IQR 2.4 % – 4.1 %) ($P = 0.153$).
Table 1 shows the results of the post-procedural interviews regarding RS-ALC. All novices and four experts were generally positive about RS-ALC. All participants but one agreed that RS-ALC makes performing colonoscopy easier for novices, but not for experienced endoscopists. All novices thought that RS-ALC made introducing the colonoscope easier and performing colonoscopy overall faster in comparison with conventional steering.

Table 1 Subjective evaluation of experience with and future use of robotic steering with automated lumen centralization (RS-ALC).

Statement	Agrees with statement		*P* value*
	Expert endoscopists (n = 8), n (%)	Novices (n = 10), n (%)	
Colonoscopy with RS-ALC …			
– makes introduction of the scope easier.	3 (37.5)	10 (100.0)	0.007
– makes performing endoscopy faster.	2 (25.0)	10 (100.0)	0.002
– is more intuitive than conventional colonoscopy.	4 (50.0)	9 (90.0)	0.118
– makes performing endoscopy easier for novices.	7 (87.5)	10 (100.0)	0.444
– makes performing endoscopy easier for experts.	1 (12.5)	1 (10.0)	1.00
I am positive about this platform.	4 (50.0)	10 (100.0)	0.023
I see a potential role for this platform in clinical use.	5 (62.5)	8 (80.0)	0.608

* Fisher's exact test.

Discussion

This colon model study shows that the use of RS-ALC is feasible in both expert endoscopists and novices. Post-procedure interviews indicated that RS-ALC was considered most appropriate for novices.

Overall, the proportion of simulated polyps detected by the participants in our study during colonoscopy with conventional steering was larger than the 52.9 % of simulated polyps detected by the expert endoscopists in the in vitro colonoscopy study by Gralnek et al. [10]. We based the location of the simulated polyps in our colon model on the model used by Gralnek et al., but instead of metallic beads, we used simulated polyps made of foam fabric. These may have been easier to identify.

Allemann et al. and Zhang et al. previously evaluated the performance of a motorized conventional endoscope with a joystick interface [6, 7]. Their results were somewhat disappointing, possibly owing to the fixed position of the endoscope in their experimental setup, which limited maneuverability and proprioceptive feedback. Reilink et al. reported no significant difference between cecal intubation time with conventional steering and intubation time with an intuitive interface when novices were allowed to perform simulated colonoscopy [8]. The design of our platform is different from that of previous studies as it still allowed manual handling of the shaft of the endoscope. Therefore, our platform is more comparable with normal clinical practice.

The strengths of this study are the randomized, crossover design, which prevented the influence of a learning effect with the colon model. The novices in our study were well matched and comparable with fellows starting training in gastrointestinal endoscopy. Furthermore, we used a colon model that several cases had previously validated [9].

A potential drawback of this study is that the time to practice on the colon model was short. Arguably, 20 minutes of practice is too short, especially for novices who are completely endoscopy naive. This is probably also reflected in the fact that the participants had the ALC option turned on during only a small proportion of the total colonoscopy time. Participants were asked to combine many different cognitive and motor tasks that were new to them. Pressing and holding an additional button may have been too much to ask. The current experimental setup might therefore not be the optimal way to evaluate the intuitiveness of the ALC option.

Nonetheless, considering that this was a feasibility study and as such not designed and powered to detect significant differences between the different modalities and participant groups, the results are promising. A direct comparison between RS-ALC and conventional steering in the hands of expert endoscopists was not possible because of the fact that they had already had considerable experience in conventional steering, whereas the ALC platform was entirely new to them. All expert endoscopists were, however, able to reach the cecum with RS-ALC. Finally, no conclusions can be drawn regarding the longevity of the finding that RS-ALC appears to be easier and more intuitive for endoscopy-naive novices because each participant performed only one examination with each modality.

Our study shows the potential use of RS-ALC, especially in inexperienced endoscopists. The possible additional value of the current platform would best be indicated by the learning curve of endoscopy-naive novices. For endoscopists in training, this platform might be attractive because it can be used as a click-on system with existing and readily available endoscopy equipment. Before the platform is introduced into clinical practice, however, further studies are required. The next step could be a randomized trial evaluating the learning curves of fellows in gastroenterology using either the conventional steering mechanism or RS-ALC at the start of training. The primary end point in such a study should be the cecal intubation time.

In conclusion, performing colonoscopy with RS-ALC is technically feasible. Its main advantages appear to be its intuitiveness for inexperienced endoscopists, whose evaluation in our study regarding the currently presented platform was unequivocally positive.

Competing interests: None

Institutions
[1] Department of Gastroenterology and Hepatology, Meander Medical Center, Amersfoort, the Netherlands
[2] Department of Gastroenterology and Hepatology, University Medical Center, Utrecht, the Netherlands
[3] Department of Robotics and Mechatronics, University of Twente, Enschede, the Netherlands
[4] Department of Surgery, Meander Medical Center, Amersfoort, the Netherlands
[5] Department of Medical Oncology, Academic Medical Center, University of Amsterdam, Amsterdam, the Netherlands

Acknowledgements

The authors would like to thank all the expert and novice endoscopists for their participation in this study.

References

1 *Terhaar siveDroste JS*, *Craanen ME*, *Kolkman JJ* et al. Dutch endoscopic capacity in the era of colorectal cancer screening. Neth J Med 2006; 64: 371 – 373

2 *Seeff LC*, *Richards TB*, *Shapiro JA* et al. How many endoscopies are performed for colorectal cancer screening? Results from CDC's survey of endoscopic capacity. Gastroenterology 2004; 127: 1670 – 1677

3 *Marshall JB*. Technical proficiency of trainees performing colonoscopy: a learning curve. Gastrointest Endosc 1995; 42: 287 – 291

4 *Ward ST*, *Mohammed MA*, *Walt R* et al. An analysis of the learning curve to achieve competency at colonoscopy using the JETS database. Gut 2014; 63: 1746 – 1754

5 *Ridtitid W*, *Coté GA*, *Leung W* et al. Prevalence and risk factors for musculoskeletal injuries related to endoscopy. Gastrointest Endosc 2015; 81: 294 – 302

6 *Allemann P*, *Ott L*, *Asakuma M* et al. Joystick interfaces are not suitable for robotized endoscope applied to NOTES. Surg Innov 2009; 16: 111 – 116

7 *Zhang SH*, *Wang DX*, *Zhang YR* et al. The human machine interface implementation for the robot assisted endoscopic surgery platform. Proceedings of the 11th IEEE Workshop on Robot and Human Interactive Communication. 2002: 442 – 447

8 *Reilink R*, *Stramigioli S*, *Kappers AML* et al. Evaluation of flexible endoscope steering using haptic guidance. Int J Med Robotics Comput Assisted Surg 2011; 7: 178 – 186

9 *Plooy AM*, *Hill A*, *Horswill MS* et al. Construct validation of a physical model colonoscopy simulator. Gastrointest Endosc 2012; 76: 144 – 150

10 *Gralnek IM*, *Carr-Locke DL*, *Segol O* et al. Comparison of standard forward-viewing mode versus ultrawide-viewing mode of a novel colonoscopy platform: a prospective, multicenter study in the detection of simulated polyps in an in vitro colon model. Gastrointest Endosc 2013; 77: 472 – 479

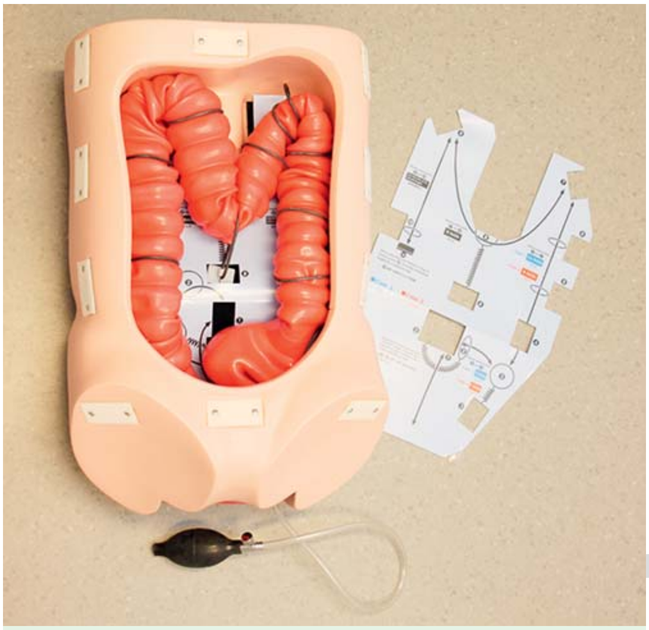
11 *Ruiter J*, *Rozeboom E*, *Van Der Voort M* et al. Design and evaluation of robotic steering of a flexible endoscope. IEEE RAS and EMBS International Conference on Biomedical Robotics and Biomechatronics (BioRob). 2012: 761 – 767

12 *Rozeboom E*, *Ruiter J*, *Franken M* et al. Intuitive user interfaces increase efficiency in endoscope tip control. Surg Endosc 2014; 28: 2600 – 2605

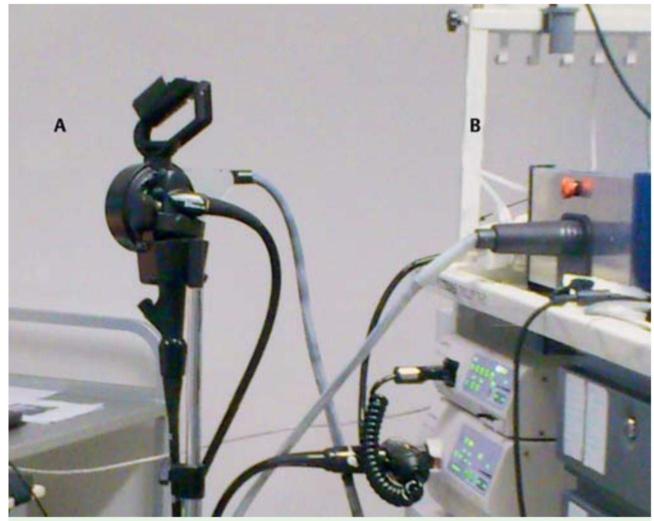
13 *Van Der Stap N*, *Slump CH*, *Broeders IAMJ* et al. Image-based navigation for a robotized flexible endoscope. Computer Assisted and Robotic Endoscopy 2014; 8899: 77 – 87

Supplementary Figures 1 and 2

online content viewable at:
http://dx.doi.org/10.1055/s-0034-1392550



Supplementary Fig. 1 The Kyoto Kagaku Colonoscope Training Model with an example of a layout guide for standard cases, as provided by the manufacturer.



Supplementary Fig. 2 Close-up view of the steering mechanism of the robotic steering with automated lumen centralization (RS-ALC) platform. The angulation wheels of the colonoscope are placed in a docking station and connected with the mobile drive unit, which is connected to the motor unit and the joystick controller. The steering wheels of the colonoscope can easily be placed in the docking station by means of a click-on system. A, mobile drive unit; B, motor unit.