

Evaluation of a novel colonoscope offering flexibility adjuster – a retrospective observational study

Christian Gerges^{ID}, Helmut Neumann Sr, Sauid Ishaq, Visvakanth Sivanathan, Peter R. Galle, Horst Neuhaus and Helmut Neumann

Abstract

Background: Although colonoscopy is the gold standard for colorectal cancer screening, colonic looping may make complete colonoscopy challenging. Commonly available stiffening device colonoscopy has been described as helpful but not effective enough to prevent looping. In this context the effect on cecal intubation time and rate was described differently in various studies and in some studies had no impact on cecal intubation time at all. The aim of this study was to evaluate whether a novel colonoscope with gradual stiffness (Fujifilm EC760R-V/I-flexibility adjuster, Tokyo, Japan) using four significantly different grades of stiffness can be an alternative to established devices in terms of loop prevention, cecal intubation rate and time, adverse events, and patient/examiner satisfaction.

Methods: Consecutive patients without previous colorectal surgery were analyzed retrospectively. Colonoscopy was performed with the new colonoscope and performance characteristics, including time to cecum, withdrawal time, total examination time, and patient and endoscopist satisfaction were recorded.

Results: Among 180 consecutive procedures, 98.3% of examinations were complete to the cecum. The endoscopic flexibility adjuster was used in 150 of 180 cases (83.3%). Overall, the device was scored by the examiner as helpful to prevent looping in 146 of the 150 cases (97.7%). Mean cecal intubation time was 6.5 min, with 35% of examination performed in under 5 min with a mean withdrawal time of 7 min. Mean total examination time was 18 min. Patient satisfaction was rated as high in all examinations performed.

Conclusion: The new flexibility adjuster colonoscope was shown to be helpful in loop prevention, allowed for fast and successful cecal intubation, and led to a high rate of patients satisfaction.

Keywords: colon cancer, colonoscopy, endoscopic imaging, endoscopy

Received: 17 January 2021; revised manuscript accepted: 7 April 2021.

Introduction

One of the most important quality criteria for colonoscopy is a cecal intubation rate greater than 90%.^{1–6} However, achieving complete colonoscopy can be challenging due to loops preventing advancement of the endoscope to the cecum. In order to overcome loop formation, several maneuvers and principles have been established, including the push and retract-technique, minimal use of CO₂/air-insufflation, or external abdominal

pressure. In selected cases, a more flexible and smaller diameter pediatric colonoscope can be used successfully to facilitate the passage of a tortuous and/or narrowed sigmoid colon.^{7,8} However, the advantage of the flexible and thinner endoscope can become a drawback once the sigmoid colon is passed, resulting in more frequent looping, making a cecal intubation even more difficult. In this context, variable stiffness colonoscopes allow for passage of the rectosigmoid colon in a

Ther Adv Gastroenterol

2021, Vol. 14: 1–5

DOI: 10.1177/
17562848211013494

© The Author(s), 2021.
Article reuse guidelines:
sagepub.com/journals-
permissions

Correspondence to:

Helmut Neumann
Interdisciplinary
Endoscopy, First Medical
Department, University
Medical Center Mainz,
Mainz, Germany
helmut.neumann@unimedizin-mainz.de

Christian Gerges
Department of
Gastroenterology,
Evangelisches
Krankenhaus Düsseldorf,
Düsseldorf, Germany

Helmut Neumann Sr
GastroZentrum Lippe,
Germany

Sauid Ishaq
Department of
Gastroenterology, Dudley
Group NHS, Foundation
Trust and Birmingham City
University, Birmingham,
UK

Visvakanth Sivanathan
Peter R. Galle
Department of
Interdisciplinary
Endoscopy, I. Medizinische
Klinik und Poliklinik,
University Hospital, Mainz,
Germany

Horst Neuhaus
Department of
Gastroenterology,
Evangelisches
Krankenhaus Düsseldorf,
Düsseldorf, Germany



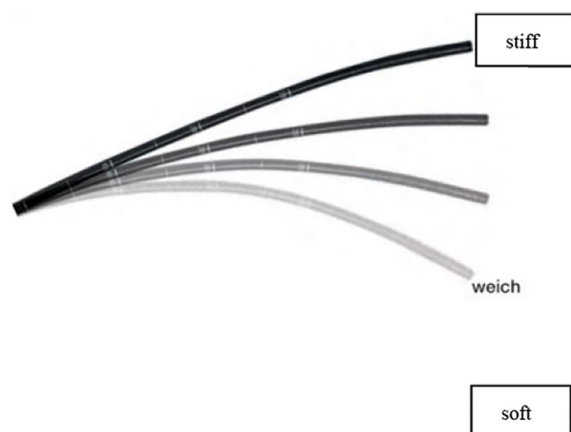


Figure 1. Flexibility adjuster.

flexible mode followed by stiffening of the device to prevent looping, thus potentially accelerating the endoscopic procedure. The idea of a variable stiffening has been evaluated in the past, mainly using a variable stiffening device with three grades of stiffness.^{9–12} Even though the stiffening device has been judged as “helpful” by examiners, and despite being ranked highest of the three available settings, it was, however, not stiff enough to prevent looping.^{9–12} In this context, the range of the three settings was identified as not wide enough to prevent looping and may also be the reason why contrary effects on cecal intubation time and rate have been described in various studies, with some studies illustrating no impact on cecal intubation time at all.^{9,12,13} A novel colonoscope with gradual stiffness has been developed by Fujifilm (EC760R-V/I Tokyo, Japan) using four significantly different grades of stiffness (Figure 1). Gradual stiffness means that the stiffness is changing over the length of the scope, being softest at the distal end and hardest at the proximal end.¹⁴ It remains unclear if this new colonoscope can be an alternative to the established devices in terms of loop prevention, cecal intubation rate and time, adverse events, and patient and examiners satisfaction.¹⁴

The aim of this study was to evaluate the above mentioned performance characteristics of a novel colonoscope offering a new type of gradual stiffness (flexibility adjuster).

Materials and methods

A retrospective observational study of prospectively collected data was performed. The retrospective



Figure 2. Fully integrated stiffing device allowing for manual adjustment.

design was chosen in order to collect statistically valid data as a basis for a prospective randomized trial. The study population included patients aged >18 years with an indication for screening or surveillance colonoscopy and without previous colorectal surgery. All patient data since 2016 were consecutively included in the study, if they were eligible, based on inclusion and exclusion criteria. Written informed consent was obtained from all patients. Patients were unaware whether the flexibility adjuster was applied for their procedure. High-definition video endoscopes with a fully integrated stiffing device allowing for manual adjustment of the stiffening in four different grades were used (EC760R-V/I, Fujifilm, Tokyo, Japan) (Figure 2). The gradual stiffness insertion section is designed to optimize force and torque transmission during colonoscope insertion, and thereby enhance insertion capability without the need for an external imaging device. The colonoscopes have a multi LED-Technology with a 170° field view, a 12-mm diameter and a 3.8-mm working channel. The stiffness can be adjusted by turning a dedicated wheel at the shaft of the colonoscope (Figure 1). All colonoscopies were performed under conscious sedation.

Outcome measures

The following outcome measures were assessed: (1) successful cecum intubation; (2) time to intubate cecum; (3) withdrawal time; (4) endoscopist

use and satisfaction of the stiffening device; (5) patients satisfaction; (6) adverse events.

Procedure

The colonoscopies were performed by an expert endoscopist with more than 10 years experience in screening and interventional colonoscopy to avoid bias. The insertion protocol was based on previous described standards in evaluating a variable stiffness colonoscope.⁹ The sigmoid colon was passed using the most flexible mode of the colonoscope. Advancement was then continued in the flexible mode until any looping started, at which point the colonoscope was straightened and immediately placed in the maximal stiffness mode, followed by additional attempts at reinsertion. Successful cecal intubation was documented by the endoscopist for each examination in the report. The time to intubate the cecum was measured by the endoscopy technician using a stopwatch. The stopwatch was started when the first endoscopic view of rectal mucosa was attained and stopped when the scope fully entered the base of the caecum. The stopwatch was not stopped while the patient was being rotated, while abdominal pressure was initiated, or while the flexibility adjuster device was being activated or deactivated. As instrument advancement progressed, insertion was at times facilitated by changing back to the flexible mode. The endoscopist scored the value of the stiffening device as helpful or not helpful, depending on the extent to which it appeared to counter the tendency to form loops or whether they used the stiffening option at all. This was documented in a questionnaire at the end of each procedure.⁹ Patients satisfaction was assessed before discharge and documented in simple questionnaire ranging from not satisfied to highly satisfied.

Results

A total of 180 patients were included; 81 of the patients were male and 99 female. The mean age of patients was 59.9 years.

Colonoscopy was completed to the cecum in 177 of 180 cases (98.3%). Of the three incomplete colonoscopies, one case was due to incomplete bowel preparation with hard, lumen filling stool. In one case, a malignant stricture in the hepatic flexure could not be passed, and in one case, in a patient with a history of hysterectomy and

Table 1. Results obtained with Fujifilm EC760R-V/I colonoscope.

Total procedures (N)	180
Completed procedures (N)	177
Mean cecal intubation time (min)	6.5 [2–15]
Mean withdrawal time (min)	7 [6–25]
Mean total exam time (min)	18 [8–32]
Patients satisfactory	
Highly satisfied	100%
Examiner score	
Helpful	97.7%
Not helpful	2.3%
Adverse events	0%

stenosing diverticulosis, the endoscope could not be passed past over the sigmoid colon. Mean cecal intubation time was 6.5 min (range 2–15 min) and mean withdrawal time was 7 min (range 6–25 min). In 63 (35%) of the procedures intubation time was under 5 min. The mean total examination time was 18 min (range 8–32 min) and patient satisfaction was rated high in all examinations (100%). The endoscopic flexibility adjuster was used in 150 of 180 cases (83.3%). Overall, the device was scored by the examiner as helpful to prevent looping in 146 of the 150 cases (97.7%). In 4 of the 11 first cases, the device was scored as not helpful. After the 11 first cases the device was always scored as helpful. No adverse events occurred (0%) (Table 1).

Discussion

The cecal intubation rate in this study evaluating a Fuji colonoscope with a novel stiffening device was 98.3% and therefore much higher than the generally recommended threshold of 90% and at the upper end of previously described results.^{2,4,5} Previous studies evaluating stiffening devices, mainly in Olympus endoscopes, showed a cecal intubation rate of 87–99.2% and examiners judged these variable stiffness colonoscopes frequently as useful.^{9–11} Time to reach the cecum in this study was below 5 min in about one-third of procedures, which is an additional quality indicator for this device as there have been differing previous reports on whether a stiffening device

reduces the time to cecum.^{9,12} However, this result might be affected by the experience of the endoscopist. Short cecal insertion time below 6 min has been associated with increased rates of detection of small adenomas, and a prolonged cecal insertion time leads to a reduced adenoma detection rate.^{15,16} The stiffening was used in 83.3% of procedures and the endoscopist described the stiffening option as “helpful” in almost 98% of the cases. While previous studies described the range of the stiffness as not wide enough to have an impact on preventing looping and cecal intubation time, this four-grade gradual stiffening technique seems to assist loop prevention and a faster cecal intubation time. However, all studies mentioned, including ours, were performed by experienced examiners, which might reduce the generalizability of the results; further evaluation in a randomized controlled trial is required. The results obtained here indicate that this novel stiffening device is at least equally effective as the former evaluated devices.⁹

The fact that the endoscopist did not score the device as “helpful” only within the first couple of procedures suggests a distinct learning curve. It remains unclear if unexperienced endoscopists who usually have more difficulties in passing the sigmoid would derive greater benefit from using this device.

Patient comfort is a key parameter in screening and surveillance colonoscopy as it helps increase screening rates and prevent recurrence of adenomas. It is unclear if a stiffening device can help increase patient comfort. In this study, patients consistently described a high satisfaction rate after the procedure, which is very likely the result of reduced looping during colonoscopy. However, the stiffening device could not be used in all cases as, in some cases, the endoscopist felt the tension on the colon would become too strong or simply because it was not needed. There are natural concerns regarding whether a stiffening device might increase the perforation rate. This large cohort, as well as previous studies with other devices, observed no adverse events as the endoscopist feels how much tension is applied during pushing.^{9,10,12} The study had a few limitations. The lack of a control group and the retrospective design may have introduced a bias. Strengths of this study were a standardized evaluation of the endoscopist and patients, number of cases, and

patients being blinded as to whether the stiffening option was used or not.

In conclusion, the new flexibility adjuster colonoscope allowed for fast and successful cecal intubation within a short period of time, was frequently judged as helpful by the examiner in loop prevention, and led to a high rate of patient satisfaction. These findings still have to be reproduced in a randomized, controlled trial and future studies should now also focus on the effect of the new colonoscope in unsedated patients and for endoscopy trainees.

Author contributions

Study concept and design: all authors. Acquisition of data: Helmut Neumann Sr, Sauid Ishaq, Visvakanth Sivanathan, Helmut Neumann. Study coordination: Helmut Neumann. Statistical analysis: Christian Gerges, Helmut Neumann. Interpretation of data: All authors. Drafting of the manuscript: Christian Gerges, Helmut Neumann. Critical revision of the manuscript for important intellectual content: All Authors. Accountability for all aspects of the work: All authors

Conflict of interest statement

The authors declare that there is no conflict of interest.

Funding

The authors received no financial support for the research, authorship, and/or publication of this article.

Ethics statement

The study was conducted ethically in accordance with the World Medical Association Declaration of Helsinki. The Authors gained approval on 28 May 2020 from the Ethics Committee “International Medical & Dental Ethics Commission.”

ORCID iD

Christian Gerges  <https://orcid.org/0000-0001-8271-1102>

References

1. de Haan MC, van Gelder RE, Graser A, *et al.* Diagnostic value of CT-colonography as compared to colonoscopy in an asymptomatic

- screening population: a meta-analysis. *Eur Radiol* 2011; 21: 1747–1763.
2. Denzer U, Beilenhoff U, Eickhoff A, *et al.* S2k guideline: quality requirements for gastrointestinal endoscopy, AWMF registry no. 021-022. *Z Gastroenterol* 2015; 53: 1496–1530.
 3. Corley DA, Jensen CD, Marks AR, *et al.* Adenoma detection rate and risk of colorectal cancer and death. *N Engl J Med* 2014; 370: 1298–1306.
 4. Kaminski MF, Regula J, Kraszewska E, *et al.* Quality indicators for colonoscopy and the risk of interval cancer. *N Engl J Med* 2010; 362: 1795–1803.
 5. Rembacken B, Hassan C, Riemann JF, *et al.* Quality in screening colonoscopy: position statement of the European Society of Gastrointestinal Endoscopy (ESGE). *Endoscopy* 2012; 44: 957–968.
 6. Rees CJ, Thomas Gibson S, Rutter MD, *et al.* UK key performance indicators and quality assurance standards for colonoscopy. *Gut* 2016; 65: 1923–1929.
 7. Saifuddin T, Trivedi M, King PD, *et al.* Usefulness of a pediatric colonoscope for colonoscopy in adults. *Gastrointest Endosc* 2000; 51: 314–317.
 8. Marshall JB, Perez RA and Madsen RW. Usefulness of a pediatric colonoscope for routine colonoscopy in women who have undergone hysterectomy. *Gastrointest Endosc* 2002; 55: 838–841.
 9. Rex DK. Effect of variable stiffness colonoscopes on cecal intubation times for routine colonoscopy by an experienced examiner in sedated patients. *Endoscopy* 2001; 33: 60–64.
 10. Shah SG, Brooker JC, Williams CB, *et al.* The variable stiffness colonoscope: assessment of efficacy by magnetic endoscope imaging. *Gastrointest Endosc* 2002; 56: 195–201.
 11. Shah SG and Saunders BP. Aids to insertion: magnetic imaging, variable stiffness, and overtubes. *Gastrointest Endosc Clin N Am* 2005; 15: 673–686.
 12. Brooker JC, Saunders BP, Shah SG, *et al.* A new variable stiffness colonoscope makes colonoscopy easier: a randomised controlled trial. *Gut* 2000; 46: 801–805.
 13. Othman MO, Bradley AG, Choudhary A, *et al.* Variable stiffness colonoscope versus regular adult colonoscope: meta-analysis of randomized controlled trials. *Endoscopy* 2009; 41: 17–24.
 14. Garborg K, Wiig H, Hasund A, *et al.* Gradual stiffness versus magnetic imaging-guided variable stiffness colonoscopes: a randomized noninferiority trial. *United European Gastroenterol J* 2017; 5: 128–133.
 15. Yang MH, Cho J, Rampal S, *et al.* The association between cecal insertion time and colorectal neoplasm detection. *BMC Gastroenterol* 2013; 13: 124.
 16. von Renteln D, Robertson DJ, Bensen S, *et al.* Prolonged cecal insertion time is associated with decreased adenoma detection. *Gastrointest Endosc* 2017; 85: 574–580.

Visit SAGE journals online
[journals.sagepub.com/
home/tag](http://journals.sagepub.com/home/tag)

 SAGE journals