

A novel endoscopic device for repeated right-side colonic access during colonoscopy (with video)

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Background: Megachannel is a newly developed colonic access system allowing rapid and multiple passes of the colonoscope to the right side of the colon.

Objective: The aim of this study was to evaluate the safety and clinical feasibility of placing a 100 cm Megachannel prototype in the right side of the colon.

Setting: Six centers, international, both surgeons and gastroenterologists performing endoscopy.

Design and Intervention: Patients scheduled for colonoscopy with suspected right-side colonic polypoid lesions were included. The prototype was loaded onto a 160 cm lower GI endoscope and introduced via colonoscopic guidance.

Main Outcome Measurement: The ability to place this device in the right side of the colon.

Results: The Megachannel prototype was introduced in 41 patients (19 female, mean age 54 years) undergoing colonoscopy. The cecum was reached in 27 cases (66%) within 18 minutes (range, 3-35 minutes) and with 73 cm (range, 40-100 cm) of the device being inserted into the colon. Mild tissue bruises and mild pain were observed in 5 and 3 patients, respectively. In 14 patients, the device assisted the removal of multiple polyps (2-12) as tissue was repeatedly retrieved through the channel. The device also allowed delivery of an endoscopic US scope or suction caps to the right side of the colon.

Limitations: Prototype performance may differ from the actual product (80 cm in length, redesigned introducer plugs). Small number of patients, difficult in diverticular disease.

Conclusions: This newly developed colonic access system can be safely placed in the right side of the colon and is useful for a variety of advanced procedures that require repeated insertion of the colonoscope or delivery of bulky instruments. (Clinical trial registration number: NCT00987896.)

We developed a new colonic access device (Megachannel) that allows rapid, multiple passes of the colonoscope to the right side of the colon and delivery of bulky devices for advanced endoscopic interventions. This device may also serve as platform for colonoscopic appendectomy, a novel endoluminal procedure that does not require access to the peritoneal cavity.¹ The aim of the present study was to evaluate the safety and clinical feasibility of placing Megachannel in the right side of the colon.

METHODS

The 6 international centers that participated included both surgeons and gastroenterologists. Five centers were considered to be high volume (>3000 colonoscopies per year) and 1 low volume (<500 colonoscopies per year: Ecuador). The study was approved by the Ethics Committee of the Medical University Vienna and by local Institutional Review Boards.

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*These authors contributed equally to the concept, design, and writing of this article and share first authorship.

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Patients scheduled for colonoscopy were screened and included after written informed consent. In the Austrian center only, patients with right-side colonic polypoid lesions were included. Patients with previous abdominal surgery, with past or currently diagnosed intra-abdominal cancer, presenting with unstable angina, who were drug abusers or pregnant women, or with known colonic strictures were excluded.

Megachannel colonic access device

The colonic access device Megachannel (Minos Medical, Irvine, Calif; 22 mm outer diameter, 100 cm length) was constructed of a wire-reinforced polyvinylchloride plastisol tube and coil spacing to achieve optimal flexibility and control. The channel has an inner diameter of 20 mm designed to resist collapse. The overtube includes a proximal handle with insufflation sealing cap that accommodates a standard colonoscope (Fig. 1A). On the distal tip a removable thermoplastic plug was integrated to facilitate the introduction of the overtube through the lower GI tract (Fig. 1B-D). The plug has a frustoconical shape with through-orifice for colonoscope passage, to enable steering capability under endoscopic guidance. The smooth solid surface between the overtube and colonoscope prevents tissue entrapment. For all studies, this device was lubricated, preloaded onto a lower GI endoscope (Pentax EC 3470LK or Olympus CF-Q160AL) before insertion, and then introduced via colonoscopic guidance (Video 1, available online at www.giejournal.org).

Patients were sedated for procedures with midazolam and/or propofol. The free 60 cm of the colonoscope was inserted using standard techniques. After passing the sigmoid, the colonoscope was straightened and the Megachannel inserted to the tip of the colonoscope. Then the colonoscope was further advanced, straightened, and followed by further insertion of the Megachannel. Time to cecum, insertion length of endoscope and Megachannel, and time to remove the endoscope with the Megachannel fixed was documented. Patients were observed for 3 hours after the end of the procedure and were discharged on the same day.

Statistics

Baseline characteristics were compared using Mann-Whitney-Wilcoxon rank sum test for parametric or chi-square test for categorical variables by SPSS for Windows. For all tests, *P* values of <.05 were considered to be statistically significant.

RESULTS

The Megachannel was tested in 41 individuals (19 female, 22 male; mean age, 54 years) undergoing colonoscopy (Table 1). Indications for colonoscopy assisted by Megachannel were suspected multiple polyps in 12 (29%)

Take-home Message

- Repeated intubation and delivery of bulky devices into the right side of the colon is associated with extra constraints and is sometimes even impossible. With the assistance of the Megachannel, a novel colonic access system, complex and time-consuming diagnostic and therapeutic colonoscopic interventions might be facilitated.

and suspected large right-side polypoid lesions in 29 patients (71%).

Overall, the cecum was reached with both the scope and the Megachannel in 27 patients (66%; Table 2). In the low-volume center, the frequency to reach the cecum was low both with and without Megachannel. In 3 patients (7%), the Megachannel could not be passed beyond the sigmoid colon owing to diverticular disease. Reaching the cecum with the endoscope was not related to body mass index (*P* = .21), gender (*P* = .68), or age (*P* = .63). When reaching the cecum, the Megachannel was inserted into the colon with a median length of 73 cm (range, 40-100 cm). In 14 patients, Megachannel assisted the removal of multiple or large polyps as tissue was repeatedly retrieved through the device (Table 2). In one patient, an endoscopic US scope was delivered for evaluation of wall infiltration by the tumor before mucosal resection. In another patient, a suction cap was placed on the tip of the colonoscope and then successfully delivered to the right flexure for removal of an incomplete-lifting polyp (due to scarring after biopsies and piecemeal polypectomy during 2 preceding procedures). In 27 patients, either none or only single small polyps in the right side of the colon were detected, which did not need repeated endoscopic insertion.

Mild intracolonic tissue bruises were observed in 5 patients (12%). No anal injury was detected, nor did patients report any postendoscopic sphincter dysfunction. Transient mild-to-moderate pain was reported by 3 patients (7%) within 1 hour after procedure without the necessity for extra pain medication. One case of a late perforation was observed at the site of polypectomy (which included the use of hot biopsy forceps for cleaning of margins), 10 days after the investigation. The site of perforation had not been in contact with the device, and therefore the endoscopist judged this complication as not related to the device.

DISCUSSION

In the present study, we evaluated the safety and clinical feasibility of placing Megachannel in the right side of the colon. Megachannel was inserted to the cecum in 66% within 18 minutes, which prolonged colonoscopy only a

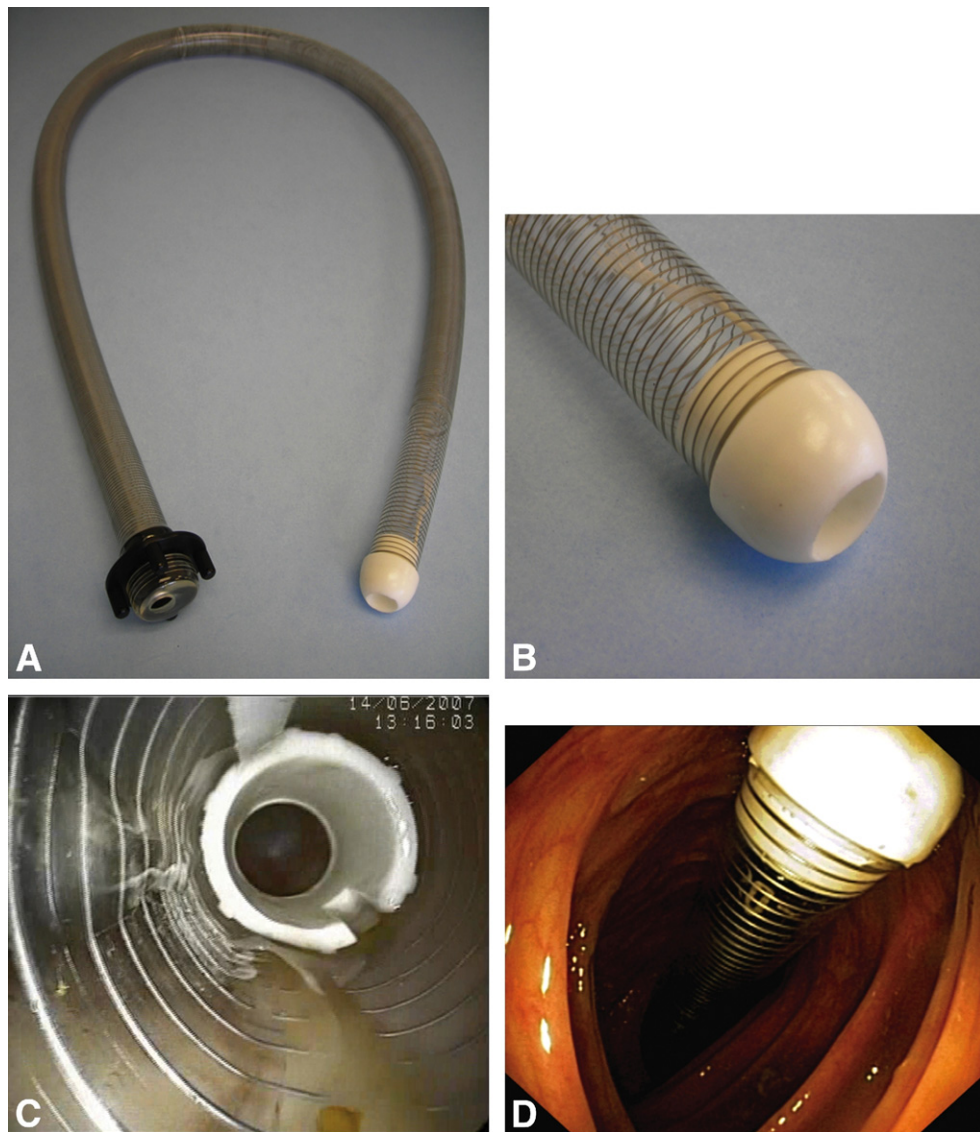


Figure 1. The Megachannel prototype. **A**, The colonic access device has a 22 mm outer diameter and 100 cm length and is constructed of a wire-reinforced polyvinylchloride plastisol tube with variable coil spacing. **B**, The introducer plug has a frustoconical shape and can be deployed by pushing from the inside with a biopsy forceps. The smooth surface between the overtube and colonoscope prevents potential tissue entrapment. **C**, Endoscopic view of introducer plug. **D**, Inversion of the scope in the cecum to document placement of the distal prototype tip.

TABLE 1. Patient demographics			
	Austria	India	Ecuador
Gender, % female	50	40	45
Age, y, mean	67	45	52
Body mass index, kg/m ² , mean	24.7	19.6	26.2

little.² A higher endoscopy frequency was associated with a greater success rate (90%). Except for mild tissue bruises and some postprocedural pain, placement of Megachannel was considered to be safe.

During the initial design and animal and cadaver testing, the diameter of the device was pushed to a maximum tolerable size. Because the cecum was reached with a median insertion length of 73 cm it was anticipated that an 80 cm commercial version is long enough and easier to handle (Video 1). The deployment of the introducer plug turned out to be unreliable, blocked the intracolonic vision, and was tedious to remove. The commercial version is equipped with a corkscrew-design plug that is pulled through the channel. Also, the proximal seal was improved to prevent air leakage and can be opened for retrieval of large tissue specimens.

Rather than a simple overtube, Megachannel represents a platform that facilitates repeated removal and insertion

TABLE 2. Megachannel performance according to endoscopic volume

	High volume	Low volume	Overall
Cecum reached (%)	18/20 (90)	9/21 (43)*	27/41 (66)
Time to cecum, min	15 (3–35)	20 (10–25)	18 (3–35)
Patients with multiple/large polyps	12/20	2/21	14/41
Tissue retrieval steps per patient	4 (2–14)	3 (2–4)	4 (2–14)
Time to remove and reinsert scope(s), min	15 (2–60)	15(10–15)	15 (2–60)
Introducer plug removal	3/5		3/5

If not otherwise indicated, data are presented as median (range).
 *P < .01 between high- and low-volume centers.

of the endoscope or other instruments. Devices with limited vision (eg, banding devices, suction caps, sideview scopes, endoscopic US) can be simply delivered to the right side of the colon. Also instruments for advanced endoluminal procedures such as endoluminal cutters or submucosal resection systems can be passed. Another example is colonoscopic appendectomy, in which Megachannel carries the appendix-inverting device as well as a ligation suture (Fig. 2).

Possible limitations for the use of Megachannel are luminal narrowing, such as diverticular disease observed



Figure 2. Colonoscopic appendectomy prototype assembly. Because of its large inner diameter, Megachannel can deliver several devices to the cecum, including the appendix-inverting device and the ligation ligature, both of which are fitted next to the colonoscope.

in 3 patients. Also, larger patient numbers will be needed to adequately assess Megachannel's safety. Although it cannot be ruled out completely, the late perforation was related to the use of hot biopsy forceps rather than to Megachannel. Also, the prototype performance likely differs from the actual product, which has been improved for length and introducer plug and seal design as a result of the present study. This redesign as well as further clinical practice will likely improve the overall success rate of placing this device for advanced endoluminal procedures.

REFERENCES

1. Silberhumer GR, Birsan T, Noda W, et al. Design and instrumentation of new devices for performing appendectomy at colonoscopy (with video). *Gastrointest Endosc* 2008;68:139-45.
2. Petrini JL, Egan JV, Hahn WV. Unsedated colonoscopy: patient characteristics and satisfaction in a community-based endoscopy unit. *Gastrointest Endosc* 2009;69:567-72.