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ORIGINAL ARTICLE

# Protection of colorectal anastomosis with an intraluminal bypass device for patients undergoing an elective anterior resection: a pilot study

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## Abstract

**Background** Currently, the only clinically valid method to prevent morbidity and mortality related to colorectal anastomotic leaks is by construction of a protective ileostomy. Intraluminal bypass might also be a possible way to proctect the anastomosis. The aim of the present study was to evaluate the CG-100 intraluminal bypass device for the reduction of anastomosis-related morbidity and stoma creation in cases of rectal resection.

**Methods** A prospective study was conducted on patients having sphincter-preserving rectal resection who were treated with the CG-100 device at Soroka University Medical Center, Beer Sheva, Israel between May 2015 and February 2017. The device was implanted during surgery and removed after $10 \pm 1$ days. All patients underwent a radiologic leak test with water-soluble contrast prior to removal of the device. Patients were followed for 30 days. Information about adverse events, anastomotic leaks, device usability and tolerance were collected.

**Results** Forty-seven patients participated in the study. Most patients were operated on due to cancer 44 (93.6%). Four (9%) patients received a primary protective stoma on top of the CG-100 device as part of the learning curve of the surgical team and none required a stoma after device removal. Five (9%) serious adverse events were reported, but only 2 (4%) were classified as related to the device. One was a transient enterocutaneous fistula after removal of the device. The second was an asymptomatic radiologic leak in 1 (2.1%) patient which was treated by keeping the device in place and antibiotic treatment for another 10 days without creation of diverting ileostomy.

**Conclusions** CG-100 may provide a safe method for fecal diversion over a newly created anastomosis without the complications related to stoma creation and closure. A larger prospective randomized study in patients originally scheduled to receive diverting stoma is needed to confirm these findings.

**Keywords** Anastomotic leakage · Colorectal surgery · Complication · Rectum · Device

## Introduction

Recent decades have brought significant advancements in the field of rectal surgery. Improved surgical techniques made sphincter preservation surgery available to most patients undergoing rectal surgery [1]. However, the incidence rate of anastomotic complications remains high [2, 3] and the struggle to reduce the incidence of symptomatic anastomotic leakage has not been fruitful [4–6].

The etiology of anastomotic leak is known to be multifactorial and have serious consequences.

There is an increasing interest in the role of microbiome in AL. Shogan et al. demonstrated high collagen-degrading activity from microbes in leaking anastomosis in rats [7]. Leaking anastomoses were noted to have been colonized by *Enterococcus faecalis*, a commensal in gut, with high collagen-degrading activity and ability to activate host intestinal matrix metalloproteinase 9 (MMP9). A study by van Praagh et al. found that there was a lower microbial diversity and higher gut concentration of Lachnospiraceae in patients with AL [8]. These studies provided a possible explanation of the effect on AL of gut decontamination.

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Fluorescence imaging has been recently applied to assess microperfusion of the bowel before and after fashioning of the anastomosis. It involves intravenous injection of indocyanine green (ICG). ICG binds to plasma proteins and stays in the intravascular compartment. It absorbs near infra-red light at 800 nm and emits fluorescence. The presence of fluorescence, therefore, indicates perfusion. Surgeons can transect where bowel is well-perfused and fashion an anastomosis using this bowel. In one multicenter study, using fluorescence imaging led to a change in surgical decision in 8% of the cases [5]. The overall leakage rate was 1.3%. In another similar study, the AL rate was only 0.9% out of a total of 107 patients [9].

Multiple attempts including sealants [10], adhesives [11] and buttressing materials [4] designed to reinforce the anastomosis have failed to demonstrate clinical efficacy. The only clinically valid method to alleviate the clinical symptoms of AL is to create a fecal diversion through a primary protective ileostomy [12]. Unfortunately, this solution exposes the patient to a new set of complications related to the ileostomy and the additional surgery required to remove the ileostomy after the anastomosis has healed [13].

To maintain the benefits of fecal diversion without the complications of a primary ileostomy, we studied a new concept for an intraluminal bypass device designed to protect the anastomosis from meeting large amounts of fecal material [14]. The Colospan device is a soft hollow silicone tube with three inflatable balloons at its distal edge. After creating and testing the intestinal anastomosis, the Colospan intraluminal bypass device is placed proximal to the newly formed anastomosis. Once in place the three balloons are inflated, fixing the device in place above the anastomosis. Fecal material is diverted through the internal lumen of the silicone sheath, having no contact with the anastomotic site, and there is no distention of anastomosis.

The CG-100 device was previously studied in a preclinical study [14] evaluating the safety and performance of the device in a porcine model. In this study, 12 pigs had low colorectal anastomosis with insertion of the CG-100 device. Contrast material injection, abdominal X-ray, and histology studies were used to evaluate sealing quality, device positioning, and tissue damage, respectively. Absolute sealing was observed in tested animals, there were no device-related adverse events, and no critical histological abnormalities were noted in the bowel area that was compressed by the device. The device was found to be easy to insert, position, and extract. The authors concluded that the CG-100 device efficiently reduced contact between fecal content and low colorectal anastomosis in a porcine model, is easily deployed and extracted, and it holds promise for clinical use.

## Materials and methods

### Study population

Between May 2015 and February 2017, all eligible subjects 18 years or older, scheduled for elective colorectal surgery (open or laparoscopic) with an anastomosis 20 cm or less from the anal verge, were screened. Subjects were excluded if they were pregnant, had an active infection at the time of surgery, an American Society of Anesthesiologists (ASA) score above 3, or took steroids on a regular basis during the 6 months prior to surgery.

### Ethics

All patients treated with CG-100 (Colospan Ltd., Kfar Saba, Israel) signed a written informed consent form to participate in the study, prior to any study-related procedures. We received Medical Ethical Board approval for this trial. The trial was sponsored by Colospan Ltd.

### Endpoints

The primary endpoint of this study was to assess the safety of the Colospan device by measuring the rate of adverse events and device-related adverse events. The secondary endpoints included the assessment of clinical anastomotic leakage while the device was in place; measurement of device position 10 days after surgery by contrast enema; and assessment of device ease of use with a questionnaire distributed to surgeons after implantation and removal. Subject comfort was assessed by a dedicated questionnaire administered to patients after device removal. Both questionnaires were designed using a 5-point Likert scale.

### The Colospan intraluminal bypass device

The CG-100 device) Colospan Ltd. Kfar-Saba, Israel) is composed of three main components (Fig. 1): an internal silicone sheath, a removable fixating ring and a delivery system.

The internal silicone sheath has three round inflatable balloons and four silicone catheters. Each catheter is connected to a single balloon to allow for gradual filling of the balloons during implantation. The fourth catheter has an opening outside from the silicon sheath into anastomosed bowel lumen area between the colon mucosa and the silicone sheath. Contrast material injected through the fourth catheter fills a space around the silicone sheath between the caudal balloon and anal sphincter, and demonstrates the integrity of the anastomosis or a possible leak before the device is removed.

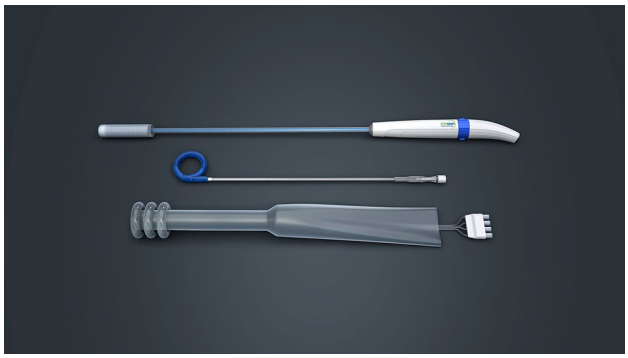

**Fig. 1** Components of the CG-100 temporary intraluminal fecal diversion system from top to bottom: the delivery system, external fixation ring and intraluminal silicone sleeve

The removable fixating ring is designed based on a straight flat silicone part which gets its round shape by the design of the locking mechanism. In this way, the ring can encircle the colon and be locked around the serosal surface of the colon about 10 cm proximal to the anastomosis and distal to the internal sheath balloons. The delivery system guides the internal silicone sheath in its deflated state through the anus until it reaches its position proximal to the anastomosis and above the external ring. Once it is positioned and the balloons are inflated, the internal sheath will direct the bowel content through its internal lumen and prevent the contact with the anastomotic area.

The application of CG-100 begins after resection of the diseased bowel segment. The external ring in its flat state is introduced through a small mesenteric window to encircle the colon, proximal and at least 10 cm from the colonic end. Next, a colorectal anastomosis is created, and the integrity of the anastomosis is verified using babble test, then the delivery system with the silicone sheath is introduced through the anus until it reaches a position proximal to the external ring. Each balloon is inflated with 12 ml of diluted contrast, which provides a radiological image of the inflated balloons above the anastomosis (Fig. 2). Once inflated, the balloons prevent passage of fecal material and gas around the device toward the anastomosis, and direct the flow of stool through the silicone sheath (Fig. 3). The external ring has a connecting tube which goes out from the abdominal cavity through one of the trocar ports or through a small abdominal wall incision just like a surgical drain. The lock mechanism is activated from the end of the connecting tube, so the ring can be opened and resume its flat state without any surgical intervention.

Ten days after the surgery, a radiological test of integrity of the anastomosis is performed. First, a contrast material is injected through the fourth catheter and the anastomosis, and a whole area between the anus and balloons is investigated for a possible leakage from different angles. If there

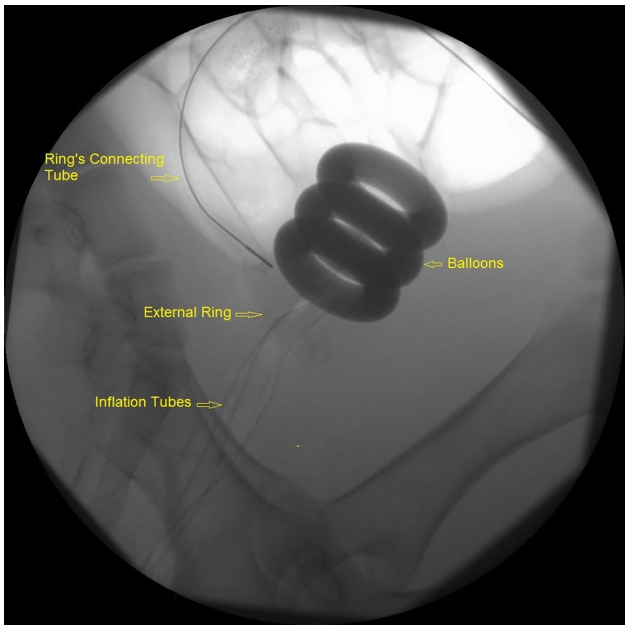


**Fig. 2** X-ray image of the CG-100 device in place, the balloons are filled with contrast material and are clearly visible. The external ring connecting wire is seen as it ascends to the abdominal wall and the inflation tubes are visible as they go down through the rectum

are any doubts, a computed tomography (CT) scan is performed. Next, the external ring lock mechanism is released, and the ring is removed by gentle traction like any other

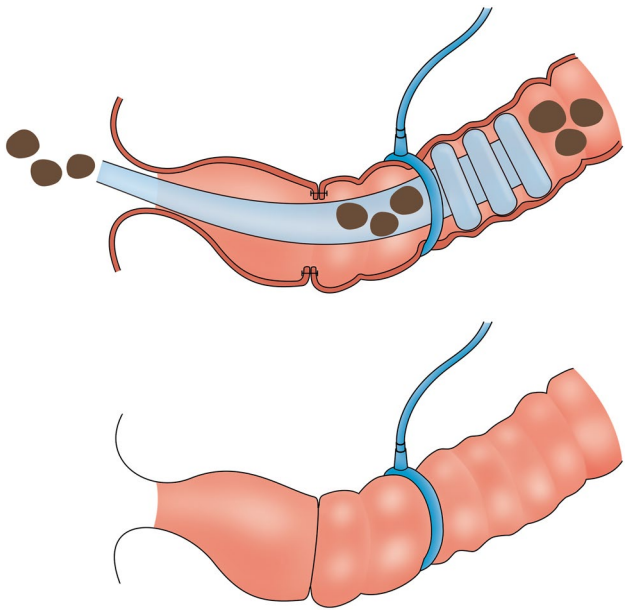

**Fig. 3** The CG-100 is placed in the rectum; at the first stage, the external fixation ring is placed above the anastomotic site, next the silicone sleeve is inserted, and the balloons are inflated. Once the balloons are inflated, the internal lumen is open and allows for diversion of fecal material to the anus without any contact with the anastomosis

intra-abdominal drain. Finally, the balloons are deflated, and the silicone sheath is removed through the anus.

The device has European conformity (CE) marking and is also regulated for marketing approval by the Israeli ministry of health.

### Perioperative care and follow-up procedures

Mechanical (picosalax in two doses) and antibiotic (neomycin and flagyl) bowel prep the day before surgery were used on routine basis. After positioning the patient in lithotomy washout of rectum was performed with povidone solution, as well as a reassessment of height of the planned anastomosis. There were no special adjustments of local treatment protocols of postsurgical recovery except that the first ten patients were kept in the hospital for 10 days for a better understanding of device comfort. Later, patients were discharged whenever they felt ready enough to go home and come back for a radiology test and for removal of the device.

On day 10 (±1), a rectal contrast enema was performed to determine device position and identify sub-clinical anastomotic leaks. After device removal, subjects were asked to complete a device comfort questionnaire (Table 4) by the follow-up visit in the outpatient clinic at 30 days for final evaluation of adverse events.

### Statistical analysis

Sample size determination is based on literature and clinical data collected on CG-100, a rate of 5% device-related serious adverse events (SAEs) (primary safety) and 95% successful device implantation (primary performance) is expected. Given these rates, a sample of $n=47$ subjects will provide 10% precision to estimate true safety and performance rates in the population. Precision is defined as the half-width of the two-sided, exact binomial 95% confidence interval.

Data archiving, although not mandated for this publication, will be made available upon reasonable request.

## Results

There were 47 patients treated with CG-100 at Soroka Medical Center Israel. Indications for surgery included colorectal cancer in 44 patients (94%), diverticular disease in 2 (4%) and one patient had Hartman reversal (2%). The mean age was 66 (range 27–86) years and the mean body mass index was 27 (15–43)kg/m$^2$. Baseline characteristics are summarized in Table 1.

Most patients were operated laparoscopically. Two patients had planned open approach because of previous low abdominal surgery. The mean distance of the anastomosis from the anal verge was 10 cm (1–19 cm) and an additional primary diverting ileostomy was created in the first 4 (8.5%) cases as part of the learning curve of the surgical team. These patients met the same inclusion and exclusion criteria as the remaining 43 patients and had the same risk profile. The mean operating time was 159 (83–281) min and the mean time dedicated to deploying CG-100 was 7 (3–26) min; additional data on surgery parameters are summarized in Table 2. Deployment of the device during surgery and removal of the device on postoperative day 10 was performed successfully in all patients except one case when the device was intentionally left in place and removed on day 18 (see below).

**Table 1** Baseline characteristics of included patients

| | $N=47$ |
|---|---|
| Gender male | 24 (51%) |
| Age (range), years | 66 (27–86) |
| BMI (range), kg/m$^2$ | 27 (15–43) |
| Neoadjuvant radiotherapy | 3 (6.4%) |
| Reason for surgery | |
| Cancer | 44 (93.6%) |
| Diverticular disease | 2 (4.3%) |
| Hartman reversal | 1 (2.1%) |

*BMI* body mass index

**Table 2** Parameters related to index surgery and device implantation

| | $N=47$ |
|---|---|
| Surgical approach | |
| Open | 1 (2.1%) |
| Laparoscopic | 45 (96%) |
| Conversion to open | 1 (2.1%) |
| Type of operation | |
| Low anterior resection | 19 (40%) |
| Anterior resection | 17 (36%) |
| Sigmoidectomy | 9 (19%) |
| Hartman reversal | 1 (2%) |
| Left colectomy | 1 (2%) |
| Anastomosis distance from anal verge (cm) | 10 (1–19) |
| Primary ileostomy created | 4 (8.5%) |
| Operating time (min) | 159 (83–281) |
| Duration of CG-100 application (min) | 7 (3–26) |

### Endpoints

Five adverse events were reported in 47 patients (9%). One patient had reoperation for early postoperative bleeding, one patient was readmitted for rectal bleeding and one was readmitted for wound infection and both patients were treated

conservatively. Two SAEs were classified by the safety board as related to the device 5% (95% CI 1–14%). In one case, an enterocutaneous fistula was identified at the external ring removal site 1 day after device removal. The fistula resolved gradually in 5 days with antibiotic treatment for 10 days and a strict low-fiber diet. In a second case, an asymptomatic radiological leak was identified prior to device removal and the device was left in place for an additional week. Intravenous antibiotic treatment was initiated, on day 18, the test was repeated and was negative for leak, and the device was successfully removed. The patient was kept in hospital for further 3 days for close observation and completion of antibiotic treatment and then was discharged safely.

## Secondary endpoints

No clinical AL was reported in our initial series of patients treated with CG-100. A single sub-clinical leak was reported. This leak was treated medically and leaving the device for additional 8 days and did not require a second surgical intervention. This case was reported as device-related SAE and is one of the two SAEs listed above.

The position of the intraluminal bypass was confirmed in all patients with a rectal contrast enema just prior to device removal. In all subjects, the balloons were located proximal to the anastomosis, in the correct anatomical position.

Investigators reported their satisfaction with device implantation and removal on a five-point Likert scale ranging between 1—must improve and 5—excellent (Table 3). For all questions, the average score ranged between 4.08 and 4.57. Overall, the investigators found the device to be simple and easy to use.

Patients were asked to report on discomfort related to the use of the device. The assessment questionnaire (Table 4) was based on a 5-point Likert scale ranging from 1 (no discomfort) to 5 (extreme discomfort). The median score on all questions ranged between no discomfort (1) and moderate discomfort (3). The main complaint was a seepage of stool; however, this is expected due to the design of the device with the intraluminal sheath passing through the anus.

**Table 3** Summary of surgeon's usability questionnaire

| | | Score | | | | |
|---|---|---|---|---|---|---|
| | | 1 | 2 | 3 | 4 | 5 |
| 1 | Learn-ability of the technique (compared to other systems) | Must improve | Training required | Same | Min. training required | Intuitive/memorable |
| 2 | Overall level of complexity of the device (general) | Must improve | Poor | Fair | Clear | Intuitive |
| 3 | Device ease of use | Very difficult | Difficult | Easy | Fairly easy | Very easy |
| 4 | Compatibility and adequacy of device design to anatomy | Must improve | Poor | Fair | Good | Excellent |
| 5 | Device external ring deployment | Must improve | Poor | Fair | Good | Excellent |
| 6 | Device internal sheath deployment (including positioning and balloons inflation) | Must improve | Poor | Fair | Good | Excellent |
| 7 | Withdrawal of the delivery system after deployment | Must improve | Poor | Fair | Good | Excellent |
| 8 | Fixation of external ring connecting tube | Must improve | Poor | Fair | Good | Excellent |
| 9 | Fixation of inflation tubes | Must improve | Poor | Fair | Good | Excellent |
| *After device removal* | | | | | | |
| 10 | Removal of external ring | Must improve | Poor | Fair | Good | Excellent |
| 11 | Removal of internal sheath | Must improve | Poor | Fair | Good | Excellent |

**Table 4** Summary of patient tolerance questionnaire

| | | Median score (range) |
|---|---|---|
| 1 | During the past 10 days did you experience any discomfort from the CG-100 device? | Moderate discomfort, 3 (1–5) |
| 1.1 | If you experienced discomfort from the CG-100 device, please estimate the prevalence? | Some of the time, 3 (1–5) |
| 1.2 | When did you experience the discomfort from the CG-100 device? | NA |
| 2 | During the past 10 days, how often did you experience incontinence of gas? | Never, 1 (1–5) |
| 3 | During the past 10 days, how often did you experience incontinence of liquid stool? | 1–2 times, 2 (1–5) |
| 4 | During the past 10 days, how often did you experience incontinence of solid stool? | Never, 1 (1–4) |
| 5 | During the past 10 days, how often did you have to wear a pad? | 4–5 times, 3 (1–5) |

## Discussion

Fecal diversion is widely accepted as the method of choice to reduce morbidity and mortality related to possible AL of colorectal and coloanal anastomoses [15]. Unfortunately, a diverting stoma requires additional surgery of closure and introduces responsible for additional morbidity [16–18] such as acute kidney injury due to high stoma output, a parastomal and internal hernias, stoma-handling difficulties during the time until closure or complications at the time of ostomy reversal. These disadvantages introduce a surgical dilemma between the risks and benefits of constructing a stoma and the dire consequences of an AL. Recent studies have evaluated early closure of a temporary ileostomy [19–21] (8–13 days after stoma creation); compared to late closure (> 12 weeks) and found that the early closure approach is safe and has some benefits, but still adds a significant burden and may be difficult to implement in many surgical settings.

This study is not powered to explore the effectiveness of the device in reducing the use of diverting stoma but evaluates the incidence of complications and reinterventions in patients treated with CG-100 and provides important feasibility data to be used in future studies.

Prior attempts to create an intraluminal fecal bypass emphasize the clinical challenges in creating an efficient tool that will protect the anastomosis without introducing new complications. The concept of an intraluminal bypass technique to avoid the use of a temporary deviating stoma after a low colorectal anastomosis was introduced by Ger and Ravo [22] during the 1980s. Their procedure consisted of suturing a soft pliable latex tube (Coloshield; Deknatel, Inc, Fall River, MA, USA) to the mucosa and submucosa proximal to the anastomotic site using biodegradable suturing material. Clinical and experimental data have shown that the concept of an intraluminal bypass is safe with only a few complications [23, 24]. Others have modified this concept using a latex condom as an intraluminal bypass [25], or a soft thin Vicryl tube that is attached to a biodegradable anastomosis ring [26]. The most recent attempt involved a biodegradable intraluminal sheath (C-seal) that was tested in a randomized study and failed to show any benefit with a 10% AL rate [27]. To explain these results, the authors suggest that manipulation on the afferent bowel loop to introduce the C-seal may have caused injury to the bowel, rendering it more prone to development of leakage. In addition, the authors mention that traction on the anastomosis through the C-seal during or after the operation could have been a factor in the development of a leak. In contrast to C-seal, the current device is not introduced during stapling and is not anchored to the anastomotic staple line. Even more significant is the fact that the device is not biodegradable and is removed based on surgical considerations after radiological testing of anastomotic integrity. In one case, we decided to keep the device in place for 10 more days due to a sub-clinical leak, resulting in spontaneous healing. This approach resembles current clinical practice when a stoma is used but can be removed in an outpatient setting without a second surgery.

CG-100 has multiple advantages when compared to previous devices: implantation of the device is simple; it only adds several minutes to surgery and does not change the construction of the anastomosis. There is minimal and acceptable inconvenience for patients after surgery, and this is preferred to dealing with ileostomy. It is designed to allow radiological testing of the anastomosis, to make no rush decisions when there is a radiological leak discovered in an asymptomatic patient and can be removed in an outpatient setting with no major complications.

Additional clinical data are required to further establish the benefit of CG-100 and its ability to delay the decision to create a diverting stoma, thereby significantly reducing the number of unnecessary stomas fashioned.

This pilot study was conducted in a single center with a small cohort of patients and without randomization. Further multicenter studies should be conducted to explore the potential benefits of this device in a multicenter randomized setting.

## Conclusions

Our first experience with the CG-100 intraluminal bypass device suggests that it may provide a safe alternative to a primary diverting stoma in patients undergoing sphincter-preserving surgery. Additional clinical data are needed to further establish this potential benefit and a larger prospective randomized study in patients originally scheduled to receive a diverting stoma is needed to confirm these findings.

**Author contributions** All authors were involved in study design, patient recruitment, data collection and writing or reviewing the manuscript.

### Compliance with ethical standards

**Conflict of interest and funding** Study was sponsored by Colospan Ltd.; none of the authors have any direct involvement with the company. Data collection was done by the company, but the analysis was done independent of any company involvement.

**Ethical approval** All procedures performed in the study involving human participants were in accordance with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

**Informed consent** Informed consent was obtained from all individual participants included in the study.

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