

Compression anastomosis ring device in colorectal anastomosis: a review of 1,180 patients

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Abstract

BACKGROUND: The nickel-titanium compression anastomosis ring device (ColonRing, NiTi Surgical Solutions, Netanya, Israel) has been cleared by the Food and Drug Administration in 2006 to construct gastrointestinal anastomoses. We evaluated the anastomotic leak rate after end-to-end anastomosis using the ColonRing device.

METHODS: Using a multinational (16 countries), multicenter (178 centers) data registry provided by NiTi Surgical Solutions, Netanya, Israel, we retrospectively examined clinical data of patients who underwent elective laparoscopic or open left-sided colectomy and anterior resection from January 2008 to June 2010.

RESULTS: A total of 1,180 patients underwent end-to-end anastomosis using the ColonRing device during the study period. The overall anastomotic leak rate was 3.22% (38 patients). The median length of hospital stay was 6 days (range 2 to 21 days). The median ring expulsion time was 8 days. The earliest ring expulsion time was 6 days; however, in 1 patient, the ring did not expel. In 4 patients, the anastomosis had to be immediately recreated because of 1 misfiring and 3 incomplete anastomoses.

CONCLUSIONS: The use of the ColonRing device is feasible and safe and could be considered an alternative technology for end-to-end colorectal anastomosis.

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The classic surgical procedure for various colorectal diseases is resection and anastomosis. Anastomotic complications include bleeding, leakage, and stricture, all of which may result in considerable morbidity or even mortality after

colorectal surgery.¹ A consistently safe method of anastomosis is still ideal. Currently, there are 3 available techniques for anastomosis: hand sewn, stapling, and compression.^{2,3} Techniques involving sutures and staples are the most popular techniques for achieving bowel anastomosis with no significant advantage proven for any of them.² Another approach to bowel anastomosis is the use of a compression device. The evolution of compression anastomosis began with Denan in 1826⁴ followed by a simpler metallic “Murphy’s button” in 1892,⁵ the AKA-2 device in 1984,⁶ the Valtrac biofragmentable anastomotic ring in 1985,⁷ and most recently the Food and Drug Administration–approved nickel-titanium (NiTi) shape memory ColonRing device in 2006.³

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The compression anastomosis principle consists of a device that forms an inverted anastomosis between 2 portions of the gastrointestinal tract. The device must provide for sufficient pressure for the proximal and distal tissue over a timeframe that allows for successful tissue adherence and healing. The device must create a zone of tissue necrosis internal to the apposed and healed tissue to allow expulsion of the ring into the lumen of the bowel followed by natural passage of the device from the body.³ Obviously, the device must respond to tissue dynamics to safely and consistently provide for tissue healing before ring separation. Despite its technical safety, compression anastomosis has not been widely accepted⁸ because of concerns regarding the reproducibility of creating tissue apposition without the use of mechanical staplers or sutures. Additionally, the idea of leaving a metallic or other foreign body inside the lumen of the bowel for several days to create a safe anastomosis and then letting it be spontaneously discharged from the body is another difficult process for many surgeons to accept.⁹

The NiTi ColonRing device has been cleared by the Food and Drug Administration since 2006 for use in the colon and rectum for the creation of end-to-end and end-to-side anastomoses in both open and laparoscopic colorectal surgeries. Studies have shown that the NiTi ColonRing device may overcome many limitations of the previous compression devices^{10,11} such as retained foreign material within the tissue, narrowing of the lumen, necrosis at the anastomotic site, and problems with passage of the deployment device.¹² The use of the ColonRing device in animal models has suggested that it creates safe and effective anastomosis when compared with staplers and hand-sewn sutures.^{10,13} However, experience in humans is very limited.^{3,11,14}

In this study, we used a multinational, multicenter data registry of NiTi Surgical Solutions and included a total of 1,180 patients who underwent elective laparoscopic or open left-sided colectomy (LSC) and anterior resection (AR) using the ColonRing device. The aims of this study were (1) to evaluate the safety and feasibility of the ColonRing device in colorectal anastomoses; (2) to compare the anastomotic leak rate of the ColonRing device with other conventional methods of colorectal anastomoses (ie, hand sewn and stapled); and (3) to compare the anastomotic leak rates of LSC versus AR.

Methods

Design and study population

We evaluated the data registry of NiTi Surgical Solutions. These data were collected from a multicenter, multinational database (16 countries and 175 centers) over a 2.5-year period from January 2008 to June 2010 (Table 1). The database includes consecutive procedures being reported by a paper or electronic reference. The

Table 1 Participating countries in the NiTi study

Country	No. of cases
United States	536
Germany	220
Belgium	73
Holland	64
Israel	63
Greece	58
Austria	36
Turkey	32
Italy	30
China	23
South Korea	18
Taiwan	10
Portugal	8
England	4
Canada	3
Switzerland	2
Total	1,180

data were entered by a double data entry method and were validated.

A total of 1,180 patients who underwent elective laparoscopic or open colon and rectal resection (LSC or AR) using the ColonRing for an end-to-end anastomosis were reviewed. An LSC was defined by the creation of a colocolonic or high colorectal anastomosis, whereas an AR was defined by the creation of anastomosis to the extraperitoneal rectum. Indications for colorectal resection in this population included both benign and malignant diseases of the colon and rectum. These were clinical leaks with radiologic or other (operative) confirmation. Specifically, because an anastomotic leak was an important factor in our study, all the patients who had clinical suspicion for an anastomotic leak were carefully evaluated with a radiographic study (either a computed tomography scan and/or gastrografin enema) to confirm the anastomotic leak. Patients with a clinical suspicion for a leak with negative radiographic findings who resolved their clinical symptoms without intervention were not considered to have an anastomotic leak. All anastomoses were checked with insufflation and/or endoscopy before exiting the operating room to document an airtight anastomosis/leak or bleeding.

Permission was obtained from the NiTi Medical Technologies Corporation for use of the database; however, no support, financial or otherwise, was externally received for this study. In addition, approval for the conduct of this retrospective review was obtained from the Institutional Review Board of the University of California, Irvine Medical Center.

Device description and function

The ColonRing device is remarkably similar to a regular circular stapler (Fig. 1). It is comprised of 2 main parts: an applier and an implanted compression element. The

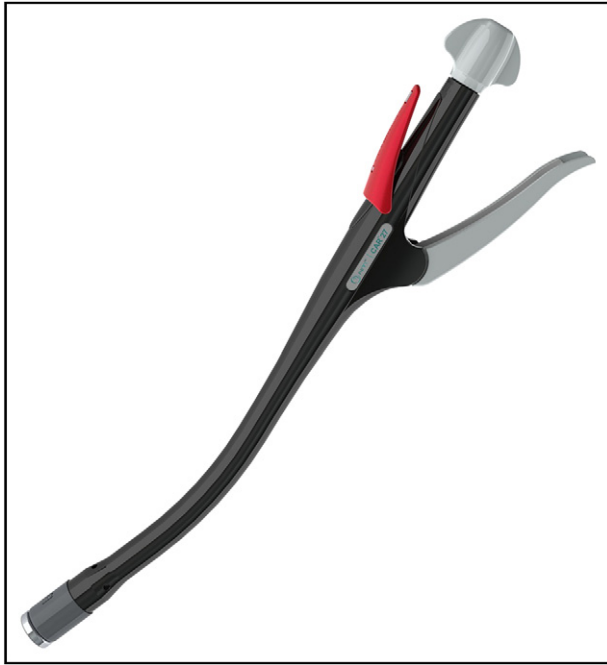


Figure 1 NiTi Coloring (NiTi Surgical Solutions, Netanya, Israel) 27 compression anastomosis device.

compression element is composed of a plastic anvil ring and a metal ring including shape memory NiTi alloy (nitinol) leaf springs (Fig. 2). The purse-string technique or any closed lumen technique (stapling technique) may be used to place anvil into the organs to be anastomosed based on surgeon experience or judgment. When “fired,” the device holds the 2 ends of tissue together with circumferentially placed barbed points, which penetrate through the tissue, holding it to the plastic ring. The NiTi ring is released, creating equal compression both radially and longitudinally around the ring. The device has a circular blade that cuts the tissue within the ring, creating patent anastomosis. The tissue heals around the circular edges that are held within the ring, and the device along with the compressed tissue is intended to slough off over the following 8 to 10 days, at which point the ring is expelled



Figure 2 The compression anastomosis ring.

from the body with a later bowel movement. The result is a full circumferential, hemostatic-sealed anastomosis without any retained foreign material. The use of the ColonRing is contraindicated in patients with any known allergy to nickel, and magnetic resonance imaging should not be used until the ring has been expelled.

Results

A total of 1,180 patients underwent elective LSC (69.3%) and AR (30.7%) during this period (Table 2). The majority of procedures were performed in the United States (45.4%) and Germany (18.6%). The mean age at operation was 64 years (range 14 to 91 years, median = 64 years). A majority of patients were female (57%); 54.7% of procedures were performed laparoscopically in this patient population. Overall, 7.9 % of patients underwent fecal diversion (LSC [2.5%] vs LAR [20.6%], $P < .01$). The mean length of hospital stay was 6.4 days (median = 6 days, range 2 to 21 days).

The overall anastomotic leak rate was 3.22% (38 patients). There was no significant difference observed in the leak rate between laparoscopic and open procedures (3.25% vs 3.18%, respectively, $P = .94$). Although the leak rate in LSC (3.79%) was almost twice that of AR (1.93%), the difference was not statistically significant ($P = .10$). Most patients did not recognize ring expulsion, but 110 patients did report the time of ring expulsion, with a median time of 8 days and the earliest time of 6 days. In 1 patient, the ring did not expel spontaneously. Misfiring was reported in 1 patient. Also, in 3 cases, tissue “doughnuts” were not completely intact, and reanastomosis was performed for these patients. No perioperative mortality was observed in this patient population. Other reported complications included 2 early bowel obstructions, 2 respiratory failures, 2 transient ischemic attacks, 1 wound infection, 1 delirium tremens, 1 reoperation for toxic colitis, and 1 readmission for abdominal pain.

Comments

The data showed that the NiTi ColonRing device was used in LSC more than AR (69.3% vs 30.7%), possibly because most surgeons were concerned about efficacy in low/ultralow rectal anastomosis in which serosa was not present

Table 2 Patient and procedure characteristics

Total number of patients	1,180
Mean age (y)	64
Female (%)	57
Laparoscopic rate (%)	54.7
LSC (%)	69.03
AR (%)	30.7
Overall anastomotic leak rate (%)	3.22

on both the proximal and distal limbs of the anastomosis.¹⁵ The device was associated with a nominal learning curve and was ergonomically easy to apply,³ and surgeons found the device equally useful in both open and laparoscopic surgeries (open: 43.45% vs laparoscopic: 56.6%). Our findings are in agreement with earlier observations that surgeons find this technique easy to learn and adopt.^{14,15}

Anastomotic leakage is one of the most serious early complications of any intestinal anastomosis, with a reported incidence rate of 1.3% to 21%.^{16,17} The incidence rate of anastomotic leakage is variable depending on the type of procedure, technique, level of anastomosis, and patient characteristics. A laparoscopic colorectal approach is not associated with a higher risk of clinical anastomotic leak^{17,18}; however, colocolonic anastomosis is associated with a higher rate of leakage compared with iliocolonic anastomosis.^{17,19} By evaluating stapled versus hand-sewn methods for colorectal anastomosis, Neutzling et al²⁰ in a recent systemic review study showed that the evidence was insufficient to show any superiority of stapled over hand-sewn techniques in colorectal surgery requiring anastomosis regardless of the level of anastomosis. Low anastomosis, male sex, and preoperative concomitant chemoradiotherapy have been shown to be independent risk factors for anastomotic leakage in rectal surgery.^{21–23} Other preoperative risk factors included malnutrition, weight loss, hypoalbuminemia, cardiovascular disease, 2 or more underlying diseases, and alcohol abuse.¹⁹ The surgery-related risk factors included an American Society of Anesthesiologists physical status ≥ 3 , an operation time greater than 2 hours, multiple blood transfusions, and intraoperative contamination of the operative field.²⁴ Our study showed that the overall anastomotic leak rate using the NiTi ColonRing device was 3.22%, which is within the expected range for this level of anastomosis (ie, 3% to 5%).^{25,26} This result compared favorably with a large prospective series from the Cleveland Clinic, which reported a 2.9% clinically apparent anastomotic leak in 1,014 patients with stapled colorectal anastomoses.²⁷ Our study found that the anastomotic leak rate was comparable between laparoscopic and open procedures (3.25% vs 3.18%, $P = .940$). Hence, the NiTi ColonRing device can be considered safe in both laparoscopy and open surgery.

Low anastomoses are associated with a higher leak rate compared with high colorectal anastomosis.^{21,27} Interestingly, our study showed that the leak rate of LSC was almost twice that of AR operation (3.79% vs 1.93%) although there was no statistically significant difference ($P = .10$). Similar to other human and animal studies,^{3,11,14,15,28–30} we observed that compression anastomosis with the NiTi ColonRing device is associated with a low leak rate for patients at high risk for leak. It is unclear why the leak rate is lower for these theoretically higher-risk applications. It could be related to the device or alternatively to differences in patient characteristics, comorbidities, or neoadjuvant chemoradiation between these groups.

With regard to ring expulsion, we found that the median time of ring expulsion was 8 days, and the earliest time was 6 days. This result was comparable with those in animal studies.^{11,13} The NiTi ColonRing device has a tapered anatomic design; therefore, the rings will expel easily in the healing process. This makes retention of a foreign material an unlikely issue. On the rare occasion that the ring is not expelled spontaneously (which typically only happens with patients who are proximally diverted), the ring can easily be extracted under sedation. We were unable to precisely confirm the time to ring expulsion because over 90% of patients failed to record the time of ring expulsion; however, only 1 patient experienced confirmed ring retention. The failure of spontaneous ring expulsion has been reported in a few patients after low rectal anastomosis with proximal diversion.³ The data also showed that technical intraoperative failure was rare in this series of 1,180 cases; only 4 patients (0.34%) needed immediate reanastomosis (1 stapler misfire leading to failure of ring deployment and 3 with incompletely intact doughnuts and air leaks). The quality of a colorectal anastomosis is a major factor in determining the rates of morbidity and mortality of colorectal bowel resections. Our results showed that the use of the ColonRing device in colorectal surgery led to a low incidence of anastomotic-related complications including leakage, bleeding, and stricture. This may contribute to the nil mortality rate in this patient population.

Although we do not have data supporting the nominal learning curve, this device functions almost identically to the current circular staplers in widespread use, facilitating the minimal learning curve. Overall, the operating surgeons felt that the device was easy to use.¹⁴ Based on current animal and clinical studies assessing compression anastomosis with the ColonRing device, there appears to be several potential benefits associated with its use. First, this technology delivers a constant stress plateau, which makes the ring detach from the anastomotic site at an appropriate and predictable time allowing for apposition of the bowel ends.³¹ Second, the absence of foreign bodies at the anastomotic site may decrease inflammatory stimuli and formation of fibrous tissue as shown in animal studies, which may lower the risk for developing anastomotic stenosis.³² Third, the absence of a raw surface at the interface of the proximal and distal ends of the anastomosis with the ColonRing device may decrease the possibility of stricture and create a smooth and intact healing line.¹³

However, there are limitations of our study. Similar to other retrospective studies using an administrative database, our study has selection, and potentially reporting, bias. For example, it is possible that patients that have a higher risk of anastomotic complications such as a history of chemoradiation were excluded from using this device. Additionally, our study lacked a long-term follow-up of patients, which makes it difficult to draw a conclusion on some important colorectal anastomosis-related complications, such as bowel stricture and obstruction. We did not have the ring expulsion time for all the patients; therefore, the

reported ring expulsion time may not be accurate. Finally, our results report only on elective end-to-end colorectal anastomosis, and it could be different from the results of urgent surgery and/or other type of anastomoses (ie, end-to-side and side-to-side anastomosis).

In conclusion, our study involved the largest number of end-to-end colorectal anastomoses with the ColonRing device to date. The rate of anastomotic leak is relatively low with the use of the ColonRing for both open and laparoscopic colorectal anastomoses. The device failure rate is very low, and problems with ring expulsion are not significant. End-to-end colorectal anastomosis with the ColonRing is feasible and safe and may lead to decreased anastomotic complications in low anastomoses and, subsequently, lower morbidity and lower mortality. Further prospective studies including a head-to-head comparison between the ColonRing device and conventional staplers evaluating long-term anastomotic complications (ie, leak or stricture) are needed to evaluate the benefits and limitations of this device.

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