

# Use of the circular compression stapler and circular mechanical stapler in the end-to-side transanal colorectal anastomosis after left colon and rectal resections

## A single center experience



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### Use of the circular compression stapler and circular mechanical stapler in the end-to-side transanal colorectal anastomosis after left colon and rectal resections. A single center experience

**AIM:** *The aim of our study was to compare the efficacy of the circular compression stapler and the circular mechanical stapler in transanal colorectal anastomosis after left colectomy or anterior rectal resection.*

**MATERIALS AND METHODS:** *We performed a retrospective analysis of 10 patients with disease of the, sigmoid colon or rectum (carcinoma or diverticular disease) who underwent left colectomy or anterior rectal resection with end-to-side transanal colorectal anastomosis. A follow-up was planned for all patients at 1, 3 and 6 months after surgery and the anastomosis was evaluated by colonoscopy at 1 year.*

**RESULTS:** *In all patients an end-to-side transanal colorectal anastomosis was performed using a circular compression stapler (CCS group) or circular mechanical staplers with titanium staples (CMS group). The mean distance of the anastomosis from the anal margin was  $6.4 \pm 1.5$  cm in the CCS group and  $18.2 \pm 11.2$  cm in the CMS group. All patients in the CCS group expelled the ring after a mean time of 8.2 postoperative days. At 12 months colonoscopy revealed that all CCS patients had a satisfactory anastomosis with mean size of the colic lumen at the level of anastomotic line of 26.3 mm.*

**CONCLUSIONS:** *In our experience the circular compression stapler a valuable alternative to the circular mechanical stapler for the creation of transanal colorectal anastomosis, in line with the relevant literature.*

**KEY WORDS:** Anastomotic leakage, Anastomotic stenosis, Circular compression stapler, Circular mechanical stapler, Transanal colorectal anastomosis.

## Introduction

The success of an anastomosis mostly depends on technical factors and on the patient's general and the local blood supply. A reliable anastomosis requires an accurate

union of the two bowel ends, provided they have same lumen size, must be tension free and must have an adequate blood supply <sup>1</sup>.

Anastomotic leak and stenosis are the most serious complications after colorectal resection. Anastomotic leak rates range from 2.9% to 15.3% and leaks are more common in case of subperitoneal anastomosis <sup>2,3</sup>. This complication prolongs the patient's hospital stay and is associated with an increased rate of postoperative mortality as well as with a reduction of long-term survival in case of interventions performed for malignant disease <sup>4,5-7</sup>.

The incidence of stenosis after colorectal anastomosis ranges from 3% to 30% <sup>8</sup>.

Possible conditions giving rise to anastomotic stenosis are: preoperative radiotherapy, diverticular disease, anas-

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tomotic leaks, defunctionalization of the anastomosis determined by a long-term protective ileostomy and/or colostomy<sup>9,10</sup>.

One of the most important factors that may cause anastomotic stenosis is the inflammatory reaction to foreign bodies, such as suture threads or metal staples inserted by the mechanical devices often used for bowel anastomosis<sup>11</sup>.

All these factors have fostered the investigation of novel methods to perform anastomosis. For this purpose, a device, based on the concept of "compression anastomosis", has been developed in order to avoid the use of the traditional materials, which can produce local inflammatory reactions. Compression anastomosis involves the use of a device that traps the cut ends of the transected bowel, thus bringing them into apposition. The two bowel ends are compressed towards each other at a constant pressure, until the process of natural healing of the anastomosis is completed by first intention<sup>1</sup>. At this point, the trapped ischemic segments of bowel are expelled together with the device into the fecal stream<sup>12-19</sup>.

In this study, we analyzed data collected from cases in which we used a compression circular stapler (CCS group) and a circular mechanical stapler (CMS group). The aim of our study was to determine whether CCS is associated with a lower complication rate than CMS after trans-anal colorectal anastomosis in patients undergoing left colectomy or anterior rectal resection for malignant or inflammatory disease, through the analysis of statistical data based on parameters such as rate of leakage and of stenosis, operative time and length of hospital stay.

## Materials and Methods

We conducted a retrospective study on 10 patients with disease of the descending colon, sigmoid colon or rectum (carcinoma or diverticular disease), who underwent left colectomy or anterior rectal resection in the Department of Surgical Sciences, "Sapienza" University of Rome between November 2012 and July 2014.

In 5 out of 10 patients, the colorectal anastomosis was performed using a CCS (CCS group). This device, NiTi CAR27™ (NiTi Surgical Solutions, Netanyu, Israel) consisting of a 27 mm ring made of nitinol, a temperature-dependent shape memory alloy<sup>20</sup>.

In the remaining 5 patients, the anastomosis was performed with 29 mm CMS that fire titanium staples (CMS group).

All patients underwent preoperative assessment by colonoscopy with biopsy and histological examination. In 6 patients, the diagnosis was adenocarcinoma of the descending colon (n=1), sigmoid colon (n=3) or rectum (n=2), whereas, the other 4 had diverticular disease.

All patients underwent preoperative staging of the neoplasm or diverticular disease by means of abdominal and pelvic computed tomography scan, and then had routine blood tests (complete blood count, electrolytes, liver and kidney function tests and coagulation tests), a examination by a cardiologist and spirometry.

Inclusion criteria: only adult patients (>19 years old), diagnosed with left side colon or rectum carcinoma (T2, T3, N+) and/or diverticular disease (Hinchey I and II a,b). Exclusion criteria: patients reporting nickel allergy, pregnancy, emergency surgery, an American Society of Anesthesiologists (ASA) score greater than III, complicated diverticulitis (Hinchey III and IV), advanced colorectal cancer (T4 a,b, M+), colon perforation, bowel obstruction and chronic pelvic inflammatory disease.

Table I illustrates the patient characteristics. The mean age of the patients of the CCS group (3 males and 2 females) was 73.2 ± 6.53 years; that of the CMS group (3 males and 2 females) was 68.2 ± 13.5 years.

In the CCS group the histological grade of the tumor was G1 in 1 patient (20%) and G2 in 2 patients (40%). The other 2 patients had diverticular disease (1 was Hinchey I and the other Hinchey II).

In the CMS group, among the 3 patients with adenocarcinoma of the descending, sigmoid colon or rectum, the histological grade of the tumor was G1 in 1 (20%) and G2 in 2 (40%). The other 2 (40%) patients underwent surgery for diverticular disease (Hinchey II). In the CCS group the pT tumor classification was pT2

TABLE I - Patient characteristics

	Circular compression stapler	Circular mechanical stapler
Sex male/female (%)	3 (60) / 2 (40)	3 (60) / 2 (40)
Age (years) mean ± SD	73.2 ± 6.53	68.2 ± 13.5
median tumor level from anal verge (cm)	16.2 ± 1.30	28.6 ± 11.3
tumor size >= 5 cm (n)	2	3
tumor stage 0 / 1 / 2 / 3 / 4 (%)	0 / 1(20) / 1 (20) / 1 (20) / 0	0 / 0 / 2(40) / 1(20) / 0
histological grade Gx/G1/G2/G3/G4 (%)	0 / 1(20) / 2(40) / 0 / 0	0 / 1(20) / 2(40) / 0 / 0
diverticular disease		
Hinchey classification I/II/III/IV (%)	1(20) / 1(20) / 0 / 0	0 / 2(40) / 0 / 0

SD: Standard deviation

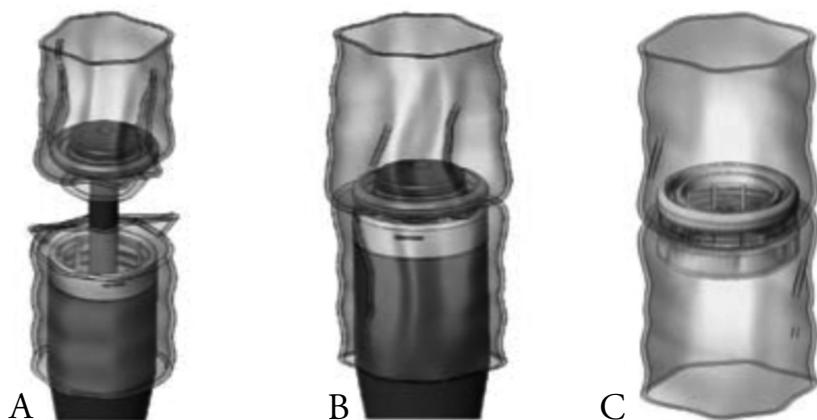


Fig. 1: The anvil of the ColonRing 27™ is fixed to the stump proximal colon (A), Once the compression is completed (B), the ring is disconnected from the device and left in place (C).

in 1 patients (20%) and pT3 in 2 patients (40%). Only 1 patient had positive lymph node metastasis pN1a. Among the 3 patients with adenocarcinoma of the descending, sigmoid colon or rectum in the control group (CMS), the pT tumor classification was pT2 in 1 (20%) and pT3 in 2 (40%); 2 of these (40%) had lymph node infiltration, respectively pN2a and pN2b.

#### SURGICAL PROCEDURE

The day before the operation, the patients took glycol solution for bowel preparation. All patients received perioperative prophylaxis with intravenous third-generation cephalosporins and metronidazole. Antibiotic prophylaxis was maintained until postoperative day 4.

In all patients bowel resection was performed with a reloadable linear stapler after the mobilization of the sigmoid, descending colon, left colic flexure, midpoint transverse colon and, if necessary, rectum and after ligation of the inferior mesenteric artery at its origin and of the inferior mesenteric vein at the lower margin of pancreas.

In the end-to-side transanal colorectal anastomosis the base of the device is inserted through the anus up to the end of the rectal stump. A central spur is advanced from the base by turning a handle to perforate the anterior wall of the rectum (Fig. 1A).

The anvil pin is wedged in the spur of the base and the device is closed. A safety lever prevents the firing of the device before complete closure (Fig. 1B). When we use the CCS and the instrument is completely closed, some nails fix the base of the ring to the plastic disk of the anvil. Once the compression is completed, the ring is disconnected from the device and left in place (Fig. 1C). When we use the CMS and the instrument is completely closed, some titanium staples are released in two staggered circular rows.

In both techniques, at the moment of firing, a knife with a circular blade cuts the tissue in the middle sep-

arating the anvil from the anastomotic tissue. This makes it possible to recreate the integrity of the intestinal lumen for the transit of feces and gas. The rings of intestinal anastomotic tissue are brought out from the anvil and their integrity is checked.

#### POST-OPERATIVE FOLLOW-UP

In the postoperative period all patients were given stool softeners. During follow-up, all patients were examined at 1, 3 and 6 months after surgery to record any complications related to the procedure or the presence of symptoms due to anastomosis.

In addition, the anastomosis was evaluated by endoscopy at 1 year (Fig. 3). Endoscopy was performed using a flexible video endoscope 12.3 mm (CF-Q1651®, Olympus, Hamburg, Germany). Stenosis was defined as the inability to overcome the anastomosis with the endoscope, as suggested by most authors.

#### Results

Operative data are shown in Table II. Four patients in the CCS group (80%) underwent left colectomy and 1 (20%) underwent anterior resection of the rectum.

Three patients (60%) in the CMS group underwent: left colectomy and 2 (40%) anterior resection of the rectum. The mean distance of the anastomosis from the anal margin was  $6.4 \pm 1.5$  cm in the CCS group and  $17.8 \pm 11.6$  cm in the CMS group.

In all patients a drainage tube was placed in the left pelvis. The mean operative time was  $154 \pm 28.80$  minutes, in the CCS group and  $230 \pm 41.7$  minutes in the CMS group.

Table III shows the postoperative recovery data and surgery-related complications.

The length of hospital stay was  $9 \pm 1.22$  days in the CCS group and  $11.6 \pm 2.4$  days in the CMS group.

TABLE II - Operative data

	Circular compression stapler	Circular mechanical stapler	<i>p</i> value
primary operative procedure (n)			
left colectomy (%)	4 (80)	3 (60)	
anterior rectal resection (%)	1 (20)	2 (40)	
approach (n)			
laparotomy	5	5	
stapler			
compression circular stapler	5	0	
29mm mechanical circular stapler, (titanium staples)	0	5	
type of anastomosis			
end-to-side (%)	5 (100)	5 (100)	
anastomotic level (cm), mean $\pm$ SD	6.4 $\pm$ 1.5	18.2 $\pm$ 11.2	0.05
operation time (minutes) mean $\pm$ SD	154 $\pm$ 28.80	230 $\pm$ 41.7	0.01

SD: Standard deviation

TABLE III - Postoperative recovery data and surgery-related complications

	Circular compression stapler	Circular mechanical stapler	<i>p</i> value
hospital stay (days)	9 $\pm$ 1.22	11.6 $\pm$ 2.4	0.06
ring expulsion (days)	8.2 $\pm$ 1.3	0	
early postoperative complications ( $\leq$ 30 days)			
anastomotic leakage (%)	0	1 (20)	0.5
late postoperative complications ( $>$ 30 days)			
anastomotics stenosis (%)	0	1 (20)	0.5

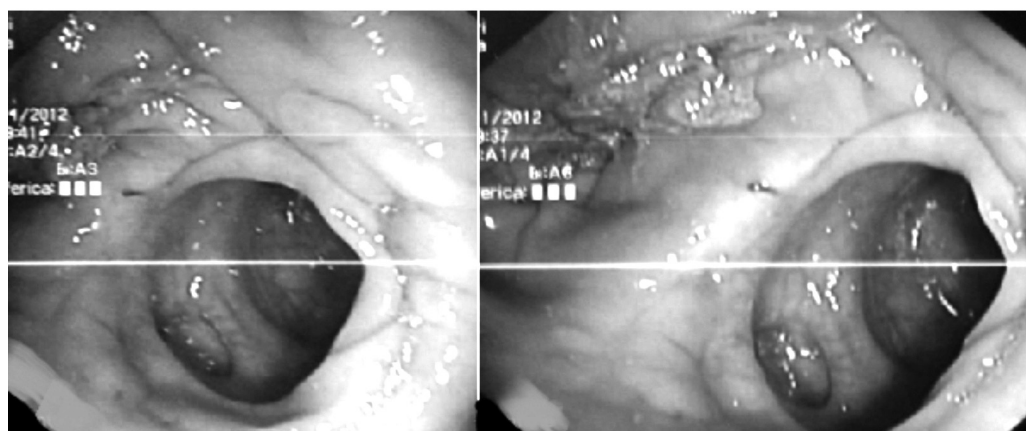


Fig. 2: Follow-up after 6 months endoscopic evaluation.

All patients of the CCS group expelled the ring after a mean time of 8.2 postoperative days. None of the 10 patients needed a protective artificial anus. Early postoperative complications ( $\leq$  30 days) occurred

in 1 patient (20%) in the CMS group: an anastomotic leak was confirmed with a barium enema. 1 patient (20%) of the CMS group had a late complication consisting of anastomotic stenosis.

## Discussion

Technological progress has led to the development of new staplers, which make it possible to perform lower intestinal anastomosis, ensuring the the preservation of the anal sphincters, and thus the preservation of continence.

In particular, in the case of left colectomy, the anastomosis can be hand-sewn or mechanical: the primer can be end-to-end or side-to-end, whereas the latter can be end-to-end (Knight-Griffen) or end-to-side and linear and circular staplers can be used. A new devices has also been designed to substitute the purse-string in the very low resections, in alternative with the Knight-Griffen procedure<sup>47</sup>. The staplers either are compression staplers or staplers that fire titanium staples<sup>21</sup>.

The first end-to-end anastomosis was performed in a canine model by Denans in 1826, using a metallic (silver or zinc) ring<sup>22</sup>. In 1881 Billroth performed the first successful manual bowel anastomosis<sup>22</sup>. New compression anastomosis devices were developed by Bonnier in 1885 and Murphy in 1892, but did not produce good results<sup>22-28</sup>. Anastomotic leaks occurred due to the different thickness of the tissues included in the compression device, to the different sizes of bowel lumen and to other anatomic features, which did not guarantee an uniform tissue necrosis<sup>25,26,29</sup>.

A device consisting of two magnetic rings was introduced in 1980<sup>30</sup>.

In 1984 Kenshin et al. developed the AKA2, a compression ring for transanal anastomosis of the proximal rectum<sup>18</sup>.

In 1985, Hardy et al. introduced the Valtrac, a biofragmentable anastomotic ring (BAR)<sup>23, 26-28,31,32</sup>. However, these devices were replaced by mechanical circular staplers using mechanical staples.

Many researchers demonstrated that intestinal anastomosis can be performed by the compression of the bowel serosa included in a circular device and the ring is subsequently ejected<sup>27,28,31,33-35</sup>. In order to facilitate the natural healing process, the intensity of the compression needs to be carefully calibrated<sup>27,33</sup>. This process can be obtained with the use of shape memory alloys (SMA), that are able to recover their original shape after being deformed<sup>25,26,31,34-36</sup>. Nitinol, a nickel-titanium SMA, had already been successfully used in medical devices because of its super-elasticity<sup>25-27,33</sup>. In fact, it can be stretched up to 6%, far beyond the limits of other metals such as steel<sup>24,26,29,37</sup>. The properties of Nitinol depend on the temperature. When it is -quenched in water (temperatures < 0°C), it enters the Martensite metastable phase (open and flexible), characterized by a decreased stiffness and increased elasticity before application<sup>26-28</sup>. In the colon, instead, at a higher temperature, the Nitinol is heated and completely returns to its original shape, corresponding to the Austenite phase (closed configuration). In this way, the Nitinol ring com-

presses the two ends of the colon and exerts a uniform and constant pressure, regardless of the thickness of the tissue<sup>26,27,29</sup>. A new compression anastomosis device using Nitinol leaf springs is available both as in clip for side-to-side anastomosis and as ring mostly for end-to-end anastomosis<sup>25,27,33,35,37-41</sup>.

Regardless of the degree of strain, the Nitinol leaf springs provide a compressive circular, constant and uniform force (7.5 Newtons or 0.75 Kg), which makes it possible to control the compression process. In particular, the constant pressure determines a double synchronous process, necrosis and healing of the tissue included in the anastomosis, thus avoiding early necrosis which can lead to consequent anastomotic leaks. The anastomosis is immediately sealed without sutures.

In left colectomy and anterior resection of the rectum, the most important complications are stenosis and dehiscence of the anastomosis. No matter what the reconstruction modality of intestinal continuity is and regardless of whether the resection is performed for benign or malignant disease, the surgeon must always respect the vascularization of the stump and pay attention to the caliber/size uniformity of the two bowel ends. The vascularization is guaranteed by a correct surgical procedure, which involves resection of the rectum right below the sigmoid-rectal junction at about 2 cm from the peritoneal reflection. In this way, the vascularization of the colic stump is achieved by the marginal artery of Drummond. The possible discrepancy in intestinal caliber can be overcome by performing an end-to-side anastomosis, that is, end for the colon stump and side for the rectal stump, on its front wall. The risk of postoperative dehiscence and stenosis, in fact, seems to be higher in the case of an end-to-end anastomosis, because the staples of the circular suture fall on the previous linear suture of the rectal stump (Knight-Griffen procedure).

In 2012, Kang et al. conducted a study to evaluate the effectiveness of the use of the CCS in end-to-end anastomosis, reporting an anastomotic leak rate of 5%, that is 1 out of 20 patients<sup>42</sup>. This result turns out to be better than the result obtained with circular staplers with titanium staples, which are associated with an anastomotic leak rate ranging from 2.9% to 15.3%, as shown by Brisinda et al<sup>4</sup>. In our study, we did not find any dehiscence in the CCS group. In the CMS group instead, we observed 1 case of dehiscence (20%). This was documented radiologically by a barium enema, performed because the patient had fever for 4 days. This case was successfully treated conservatively with antibiotic therapy.

The anastomosis performed using a CMS with metal staples has a bigger risk of postoperative stenosis because of the local inflammatory reaction to the staples. This risk increases in patients treated for diverticular disease or chronic inflammatory disease. According to the relevant literature, in particular in the study of Kang et al, no cases of stenosis after CCS use were observed after

a 6 month follow-up. The mean size of the colic lumen at the level of anastomotic line measured by colonoscopy was 26.3 mm, much larger if compared to the 18.2 mm of the anastomosis performed with the classical circular staplers. Anastomotic stenosis, is, in fact, more common in patients treated using a CMS, with metal staples. McKee et al, reported an anastomotic stenosis rate ranging from 3% to 30%, consistent with our study, in which there was only 1 patient (20%) with anastomotic stenosis<sup>8</sup>. Our results are in agreement with previous studies focusing on the use of the CCS in humans. The first European studies can be traced back to those made by D'Hoore et al, Dauser et al. and Herbst et al.<sup>33,43-45</sup>. They treated, respectively, 10 and 12 patients, who underwent left colectomy and in which the anastomosis was performed with circular compression stapler. They also describe only minimal postoperative complications. Similar results have been recently reported in Israel (10 patients) by Tulchinsky et al and in the United States (23 patients) by Buchberg et al.<sup>1,39</sup>. In the latter study, there were 3 postoperative complications: 1 was a anastomotic leak and 2 were stenosis.

It is important to remark that in our case series it was not necessary to switch from the use of the compression stapler to the use of mechanical stapler with staples.

The ease of use of this compression stapler has made it possible to reduce the operating time, (mean time  $154 \pm 28.8$  minutes). These results are consistent with a recent report by Kang et al. and Buchberg et al, which analyze the improvements with respect to the previous compression devices<sup>39,42</sup>.

Avgoustou claims that with a device that is so easy to handle, the Nitinol technology and the compact size of only 27 mm anastomosis can be performed lower down<sup>46</sup>. In our study, the anastomosis is, on average,  $6.4 \pm 1.5$  cm from the anal verge.

Additional relevant data in our study was the mean length of hospital stay. In the CCS group it was  $9 \pm 1.22$  days, whereas in the control group it was  $11.6 \pm 2.4$  days. These results are, on the one hand, consistent with the study by Tulchinsky et al, but remain, on the other hand, at variance with other results discussed in the literature, e.g. the study of Kang et al, who reports a length of hospital stay of about 12.6 days<sup>1,42</sup>.

## Conclusions

The good results we obtained with CCS in terms of anastomotic leakage ( $p=0.5$ ) and stenosis ( $p=0.5$ ) show that the device that is easy to use and reliable, and can be considered an alternative to CMS for end-to-side trans-anal colorectal anastomosis after left colectomy or anterior resection of the rectum.

The new technique, which seems to reduce the incidence of anastomotic leakage and stenosis, may represent a significant breakthrough if compared to the methods cur-

rently used.

Another important result achieved with the use of the CCS is the reduction of the operating time and consequently the reduction of comorbidities associated with the surgery. This paves the way to a faster recovery and shorter hospital stay and therefore a reduction of costs. Our data indicates that the CCS is just as valuable as the CMS, in line with the relevant literature.

## Riassunto

**SCOPO:** Lo scopo del nostro studio è confrontare l'efficacia della suturatrice circolare a compressione rispetto alla suturatrice circolare meccanica negli interventi di emicolectomia sinistra e resezione anteriore del retto.

**MATERIALI E METODI:** È stata effettuata un'analisi retrospettiva di 10 pazienti affetti da patologie del colon discendente, sigma o retto (carcinoma o malattia diverticolare) sottoposti a emicolectomia sinistra o resezione anteriore del retto con anastomosi coloretale transanale termino-laterale. Il follow-up è stato effettuato in tutti i pazienti a 1, 3 e 6 mesi dopo l'intervento chirurgico e l'anastomosi è stata valutata mediante endoscopia a 1 anno.

**RISULTATI:** In tutti i pazienti è stata effettuata un'anastomosi coloretale transanale termino-laterale utilizzando la suturatrice circolare a compressione (gruppo CCS) o la suturatrice meccanica circolare con clip di titanio (gruppo CMS). La distanza media dell'anastomosi dal margine anale è di  $6.4 \pm 1.5$  centimetri nel gruppo CCS e di  $18.2 \pm 11.2$  centimetri nel gruppo CMS. Tutti i pazienti del gruppo CCS hanno espulso l'anello dopo un tempo medio di 8.2 giorni postoperatori. Un'anastomosi soddisfacente è stata rilevata nei pazienti del gruppo CCS valutati endoscopicamente a 12 mesi con calibro medio del lume colico a livello della linea anastomotica di 26.3 mm.

**CONCLUSIONI:** Nella nostra esperienza il dispositivo a compressione si è rivelato valido quanto la suturatrice circolare meccanica tradizionale per il confezionamento di anastomosi coloretale transanale, in linea con gli studi presenti in letteratura.

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