

Original article

Compression anastomosis for Roux-en-Y gastric bypass: observations in a large animal model

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Abstract

Background: In the morbidly obese, laparoscopic Roux-en-Y gastric bypass (RYGB) effectively achieves weight loss with the resolution of co-morbidities. The goal is to create a small-volume gastric pouch with a narrow gastrojejunal anastomosis (GJA). The procedure is associated with a GJA stricture rate of approximately 3%. The use of a compression anastomotic device to create a sutureless gastrointestinal anastomosis, replacing sutures or staples, might reduce tissue trauma and improve the GJA patency rate. A temperature-dependent, memory-shape, Nitinol Compression Anastomosis Clip (CAC) has been successfully used in intestinal anastomoses. Compression of the entrapped bowel leads to necrosis, with device expulsion after 7–10 days.

Methods: We designed a pilot animal model study of open RYGB to examine the clip's safety in the performance of upper gastrointestinal anastomoses. Six 40-kg female pigs underwent RYGB. Group 1 (n = 3) underwent GJA with the CAC and a stapled jejunojunal anastomosis (JJA). Group 2 (n = 3) underwent GJA and JJA with the CAC. One pig from each group was euthanized at 1, 4, and 8 weeks postoperatively.

Results: Two pigs, one from each group, developed gastroparesis. At autopsy, all anastomoses were patent; the mean GJA diameter with the CAC was 1.6 cm (range 0.6–3), the mean JJA diameter with the stapler was 3.8 cm (range 3.5–4.0), and the mean JJA diameter with the CAC was 3 cm (range 3–3.2). Anastomotic burst pressures were similar between the stapled and CAC anastomoses. The device was passed per rectum by postoperative day 9 (range 8–12). Histologic examination of the CAC anastomoses demonstrated a complete mucosal lining with no evidence of stricture formation at 2 months.

Conclusion: The results of this small animal study have demonstrated the safety of sutureless compression anastomoses in an animal model of open RYGB. (*Surg Obes Relat Dis* 2008;4: 115–121.) © 2008 American Society for Metabolic and Bariatric Surgery. All rights reserved.

Keywords:

Gastrojejunal anastomosis; Jejunojunal anastomosis; Compression anastomotic ring; Roux-en-Y gastric bypass; Obesity

Morbid obesity is a significant health problem in the United States, and surgery is the most effective treatment [1]. Since its first description in 1964, Roux-en-Y gastric bypass (RYGB) has continued to gain popularity. The introduction of the laparoscopic technique has further increased patient acceptance, and it is now the most common

bariatric procedure worldwide [2,3]. The advantages of laparoscopic RYGB compared with open RYGB include a reduction in the mean operative time, operative blood loss, length of intensive care stay, postoperative pain, and in-hospital stay and faster recovery, with similar perioperative morbidity and mortality rates [3–6].

Stenosis of the gastrojejunal anastomosis (GJA) has been reported in 3–27% of patients after laparoscopic RYGB [7,8]. More recent studies have demonstrated a GJA stricture rate of approximately 3% [8]. To ensure anastomotic healing, the basic conditions of a good blood

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Table 1
Study parameters of 6 animals for both groups

Animal No.	GJA	JJA	Euthanized (wk)
1	CAC	Stapled	4
2	CAC	Stapled	1
3	CAC	Stapled	8
4	CAC	CAC	4
5	CAC	CAC	1
6	CAC	CAC	8

No. = number; GJA = gastrojejunal anastomosis; JJA = jejunojejunal anastomosis; CAC = Compression Anastomosis Clip.

supply, accurate tension-free serous apposition, a watertight seal, and an adequate nonobstructed lumen are required. Advances in stapling technology during the past decade have reduced, but not eliminated, the incidence of GJA stenosis [5,9–13].

Although stapling techniques are quick, easy to perform, and effective and create standardized anastomoses, the risk of bleeding from the staple line and subsequent stricture formation is increased [14]. Staples can act as foreign bodies within the bowel wall, potentially increasing the risk of infection, foreign body granuloma, ulceration, and stricture formation [15,16]. Another option is the construction of a sutureless atraumatic intestinal anastomosis of inverted ends of bowel and/or stomach wall using a compression anastomotic device [17]. The device consists of two rings that entrap the cut ends of the transected bowel or stomach wall, bringing them into apposition. The compressed bowel edges become ischemic and subsequently slough, releasing the rings into the bowel lumen and fecal stream, and leaving behind a healing and sutureless intestinal wound [17–19].

Since the first description of the Denans's ring in 1826 to create an end-to-end ileostomy in a dog, a number of compression anastomotic devices have been designed; however, none have fulfilled all the necessary requirements for a reproducible, safe, complication-free anastomosis [20,21]. A new device, the Nitinol Compression Anastomosis Clip (CAC; NiTi Medical Technologies, Netanya, Israel) has been developed and used successfully in intestinal anastomoses in both animal and human studies [18,19]. The technique takes advantage of the properties of nitinol, an alloy of nickel and titanium, which is a reversible, temperature-dependent, memory-shape metal. The present pilot study was designed to examine the potential role of this device in upper gastrointestinal anastomoses in the field of bariatric surgery. We evaluated the ability of the CAC to create sutureless compression anastomoses in an animal model of open RYGB in an attempt to produce standardized, easily reproducible, and automated anastomoses of adequate diameter [17].

Methods

Six 40-kg female pigs underwent open RYGB. All procedures were performed under sterile conditions with general anesthesia provided by intravenous pentitol and halothane inhalation with endotracheal intubation. The ethical committee of the Rabin Medical Center, Israel approved the study. RYGB was performed through a midline abdominal incision. The pigs were divided into two study groups (Table 1). The first group (group 1, $n = 3$) underwent a side-to-side GJA with the CAC (NiTi Medical Technologies) and a side-to-side jejunojejunal anastomosis (JJA) with a linear stapling device. The second group (group 2, $n = 3$) underwent side-to-side GJA and JJA with the CAC.

The CAC is a double-oval clip with a 3-cm diameter (Fig. 1) and a compression power of 400 g/cm². The biologically inert nickel-titanium alloy ring is shaped under high temperatures in a metallurgic oven. It loses its rigidity when cooled in ice water at 0°C for 30 seconds and can be opened to an angle of 30–40°. When warmed by body temperature, the double ring contracts to its original closed shape and configuration, which, by continued compression of the entrapped bowel wall, leads to tissue necrosis. The ring is expelled approximately 7 days later with stool, leaving behind a healing, uniform, sutureless anastomosis.

Each clip was mounted on a hand CAC (NiTi Medical Technologies), a palm-size, sterile, single-use, applicator instrument designed for both open and hand-assisted laparoscopic procedures (Fig. 2). This device is operated by open, close, slit, and withdraw steps. The “open” position allows safe introduction of the clip into the abdominal cavity and intraluminally. In the “close” position, the clip approximates the bowel ends. The “slit” step operates a protected internal blade to create an axillary slit to allow passage of flatus and feces. In the “withdraw” step, the clip is released from the applicator.

In all animals, the distal stomach was divided with a 75-mm linear gastrointestinal anastomosis (GIA) stapler

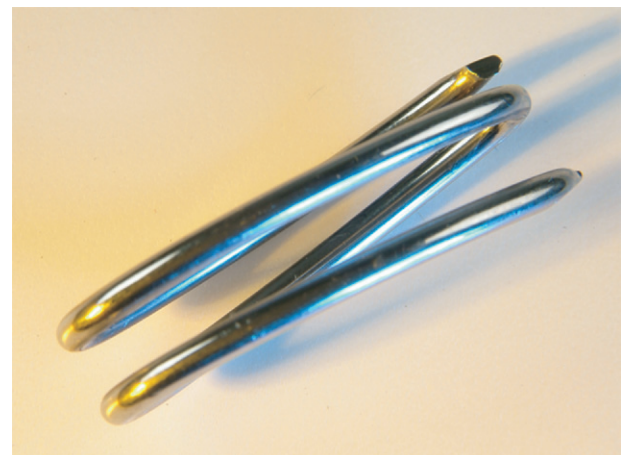


Fig. 1. CAC (NiTi Medical Technologies, Netanya, Israel).

(Ethicon Endo-Surgery, Cincinnati, OH) with 3.5-mm staples. The proximal jejunum was divided with a 60-mm linear GIA stapler with 3.5-mm staples (Ethicon Endo-Surgery) 40 cm distal to the ligament of Treitz. The proximal stomach and distal jejunal limb were placed parallel to each other, and a 5-mm anterior gastrotomy and enterotomy were created with diathermy. The CAC was placed in ice water, cooled, and introduced into the proximal stomach and jejunal lumen according to the open, close, slit, and withdraw steps. The 5-mm incisions were closed with continuous 3-0 Vicryl suture. In group 1, a side-to-side JJA was fashioned with a 60-mm linear GIA stapler with 3.5-mm staples (Ethicon Endo-Surgery). In group 2, the side-to-side JJA was created with a CAC using the described technique (Table 1).

The pigs were followed up carefully and euthanized by administration of intravenous potassium chloride after inhalational sedation at various points after RYGB (Table 1). Pro-kinetic agents or proton pump inhibitors were not administered in the postoperative period. After death, an exploratory laparotomy was performed on all the pigs for signs of generalized or localized peritonitis, indicating an anastomotic leak, hemorrhage, and gastrointestinal ischemia. All anastomoses were resected and examined for anastomotic integrity, diameter, and burst strength. Each anastomosis was subjected to a detailed histopathologic examination.

Results

All the pigs recovered uneventfully from the surgical procedure. One pig from each group was euthanized at 1, 4, and 8 weeks postoperatively. Two animals, one from each group (33%), vomited and refused oral fluids in the absence of signs of sepsis from postoperative day 3. Both were euthanized on postoperative day 7, and an autopsy was performed. Neither had signs of peritonitis. In both animals, the gastric pouch was distended (Fig. 3). The GJA was patent, with free passage of fluid and air into the alimentary limb. After excision, the patency of the anastomoses was

confirmed (Fig. 3). The histologic examination revealed a patent, healing GJA. These findings suggested gastroparesis. The remaining 4 pigs (67%) had no adverse outcomes and tolerated normal oral intake. At autopsy, all anastomoses were patent (Table 2). The mean GJA diameter with the CAC was 1.6 cm (range 0.6–3; Fig. 4). The mean JJA diameter was 3.8 cm (range 35–40) after the stapled anastomosis and 3 cm (range 3–3.2) with the CAC device. The anastomotic burst pressures were similar between the stapled and CAC anastomoses. In the animals killed at week 1, the CAC was visible at the GJA and just distal to the patent JJA in group 2. At week 4, the CAC was present in the blind-ending jejunal limb in 1 animal. In the remaining pigs, the CAC had passed without complications per rectum by postoperative day 9 (range 8–12).

The macroscopic and microscopic examinations of all nine CAC anastomoses demonstrated intact anastomoses with a complete mucosal lining and reepithelialization (Fig. 5). A moderate-to-marked diffuse lymphoplasmacytic and eosinophilic infiltrate with linear fibrosis was seen in all sections and was not associated with the method of anastomosis. Focal granulomas were evident on examination of the stapled anastomoses. No strictures were seen after the CAC anastomoses at 2 months. In contrast, in the stapled JJAs, staples were clearly seen, surrounded by macrophages, fibrocytes, and a mild-to-moderate lymphocyte infiltration, and accompanied by a diffuse lymphoplasmacytic and eosinophilic infiltrate.

Discussion

Wounds undergo several stages of healing [22,23]. During the lag phase of 0–4 days, an acute inflammatory response clears the wound of debris. This is followed by the fibroplasia phase, with fibroblast proliferation and laying down of immature collagen at 3–14 days. Finally, the maturation phase occurs at >10–80 days, with collagen remodeling. The wound is weak during the lag phase and increases in strength during fibroplasia. Traditionally, sutures and, subsequently, staples have been used to provide reinforcement, particularly during the lag phase. By the end of the second phase, wound support is no longer required. Non-absorbable sutures and staples are permanent, and even absorbable sutures have only degraded long after they are needed. The potential advantages of a sutureless anastomosis include reduced tissue trauma, improved tensile strength, reduced inflammatory response, and reduced perianastomotic sepsis [15,16,24–26]. Sutureless intestinal anastomoses have been shown to be superior to conventional anastomoses with regard to operative time, postoperative complications, and the return of bowel function [27–29]. Standardization of the performance of gastrointestinal anastomoses with the use of a sutureless device could reduce the complexity of the procedure and technical errors, and thereby improve patient outcome.



Fig. 2. CAC Hand applicator device (NiTi Medical Technologies).

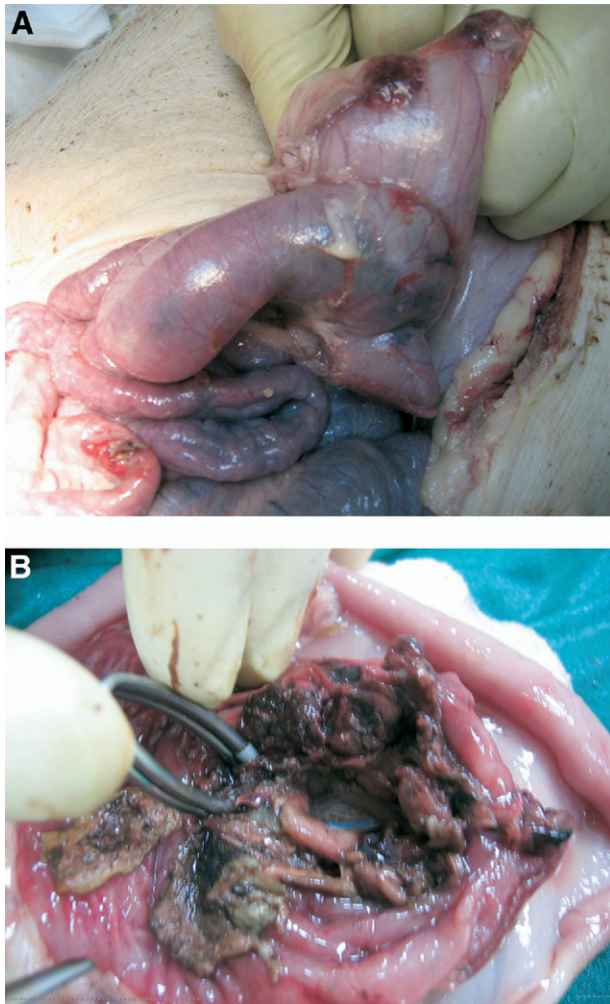


Fig. 3. Patent CAC GJA in animal with postoperative vomiting. (A) Easy passage of gastric contents into jejunum. (B) Patent anastomosis with clip in situ.

Since the first description of the compression anastomotic device, additional devices were designed by Bonnier in 1885 [21] and Murphy [30] in 1892. The Murphy button consisted of two circular metal rings, scalloped in the shape of a bowl, and held in place by a purse-string suture in either side of the open gut lumen. Although the device was widely used, problems arose because of early obstruction from the narrow lumen of the button, and later obstruction resulting from stenosis [17]. Years later, Hardy et al. [31] introduced

Table 2
Mean anastomotic diameter for both groups

Group	Mean GJA diameter (cm)	Mean JJA diameter (cm)
1	1.8 (0.6–3)	3.8 (3.6–3.7)
2	1.4 (0.6–3)	3 (3–3.2)

Abbreviations as in Table 1.
Data in parentheses are ranges.

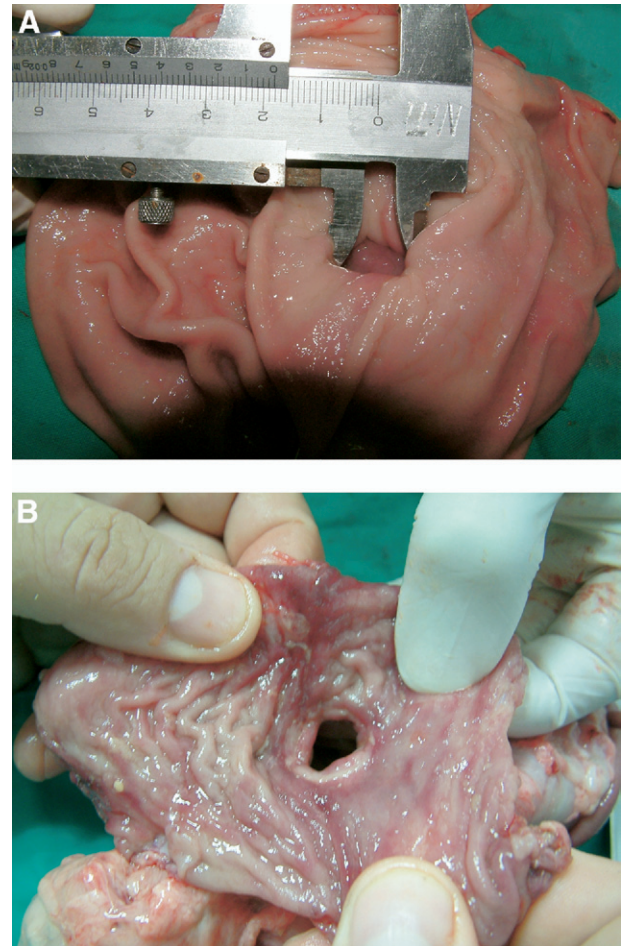


Fig. 4. Resected CAC GJA. (A) Patent anastomosis from gastric aspect. (B) Patent anastomosis from jejunal aspect.

the Valtrac biofragmentable anastomotic ring (BAR) device (Davis and Geck/Cyanamid, Danbury, CT). The BAR device is made of two identical rings composed of absorbable polyglyconate and 12.5% barium sulfate, rendering it opaque [31]. At 2–3 weeks postoperatively, the BAR rings fragment and pass in the stool. Several studies have demonstrated the advantage of the BAR device over hand-sewn or stapled anastomoses [27,31–35]. However, intraoperative difficulties in inserting and deploying the BAR device can occur in $\leq 17\%$ of cases [28,36]. The device is bulky, awkward to deploy, and expensive [37]. These problems have made the BAR device unpopular. The AKA-2 device (Seidel Medipool, Munich, Germany) was developed by Kanshin et al. [38] in 1984 for transanal application. In contrast to the BAR device, the AKA-2 rings are not resorbable and separate from the anastomosis in 4–6 days. Although early detachment and expulsion can occur, low rates of clinical and asymptomatic leaks have been reported [29].

The CAC might represent an attractive alternative option to currently available devices. Nitinol has been used effectively in vascular prosthesis, internal fixation devices, and

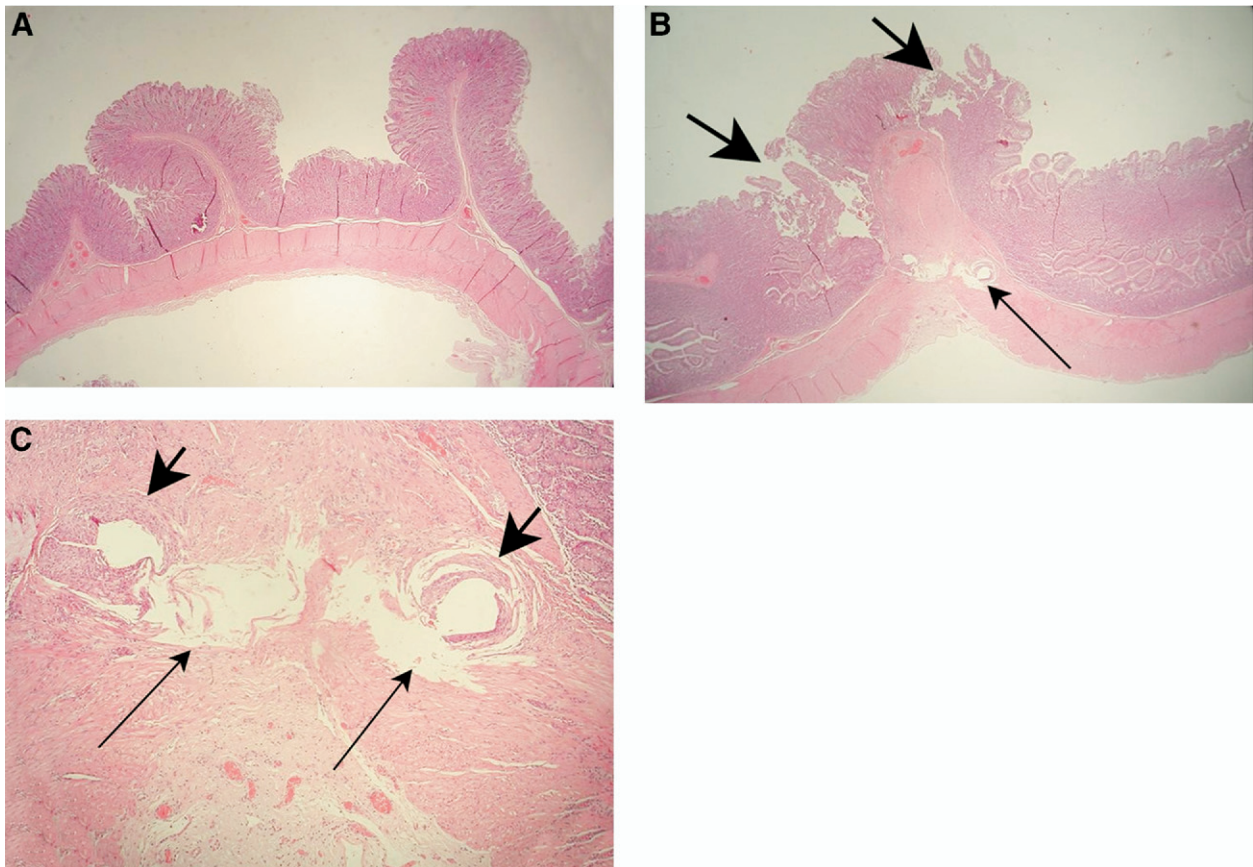


Fig. 5. Resected JJA. (A) Complete mucosal epithelial lining with reepithelization in CAC anastomosis. Hematoxylin-eosin stain, original magnification $\times 20$. (B) Staple orifices (thin arrows) and incomplete mucosal lining in stapled anastomosis (fat arrows). Hematoxylin-eosin, original magnification $\times 20$. (C) Visible staple orifices (thin arrows) with surrounding infiltrate of fibroblasts, macrophages, and lymphocytes (fat arrows). Hematoxylin-eosin, original magnification $\times 100$.

orthodontic braces, taking advantage of the alloy's property of controlled compression with a constant force. The Nitinol CAC (NiTi Medical Technologies) has been approved by the Food and Drug Administration for use in intestinal anastomoses, and both animal and human studies have demonstrated its ease of use and safety [18,19,39,40]. Unlike the BAR device, which can perform only end-to-end anastomoses, the Nitinol CAC can be used for end-to-end, side-to-side, and end-to-side procedures because of its temperature-dependent flexibility. In addition, it is easy to apply, shortens the length of the procedure, and is less cumbersome than other devices [40]. Its safety and efficacy have been demonstrated in laparoscopic-assisted colonic procedures [41]. Other advantages include its low cost and a theoretical reduction in intraoperative contamination because of its ease of introduction through small incisions and intraluminal retention compared with stapling devices. Finally, firing of a stapler cuts the intestinal wall, creating a raw surface and increasing the risk of hemorrhage and stricture formation. The NiTi device is contraindicated in the presence of a distal small or large bowel stricture. To date, no cases of device-related small bowel obstruction,

inability of the device to traverse the ileocecal valve, or device-related small or large bowel perforation have been reported.

In our study, the CAC was easy to apply and created anastomoses with burst strengths similar to those of stapled anastomoses. The mean diameter of the JJA and GJA with the CAC was 3 cm and 1.6 cm, respectively. Also, no evidence of stricture formation in the CAC anastomoses was found at 2 months postoperatively. Conversely, examination of the stapled anastomoses demonstrated peri-staple infiltration of macrophages, fibroblasts, and lymphocytes that could contribute to future stricture formation. Although 2 pigs developed gastroparesis, their GJAs were patent and healing well at the three periods examined. Delayed gastric emptying has been described after distal gastrectomy with Roux-en-Y gastrojejunostomy.

Conclusion

We have demonstrated the safety of a sutureless compression anastomotic technique in a large animal model of open RYGB. It is important to emphasize that these results



Fig. 6. Laparoscopic Hand applicator device (NiTi Medical Technologies).

are preliminary and based on a very small animal study. Extensive work is required before considering its applicability to patients in the clinical setting. In this era of minimally invasive surgery, compression anastomosis devices will only replace staplers if the devices are easy to use, safe, capable of producing competent and adequate anastomoses, and expelled without difficulty. A laparoscopic instrument, the Lap CAC has been designed to create intracorporeal anastomoses (Fig. 6). This tool will allow us to critically analyze the CAC and assess its applicability in laparoscopic bariatric surgery.

Disclosures

The authors have no commercial associations that might be a conflict of interest in relation to this article.

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