

Research Article

Clinical Experience with the Use of the Contour Curved Cutter Stapler in Colorectal Surgical Procedures: A Systematic Literature Review

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Abstract

Objectives: There exist multiple choices of surgical staplers for the resection of low rectum. The objective of this study was to assess clinical experience with the use of the market leading CONTOUR® Curved Cutter Stapler in colorectal procedures by reviewing relevant clinical studies published in peer-reviewed journals.

Methods: A systematic search of the literature was conducted through the Pubmed biomedical database to identify publications between January 1, 2005 and August 1, 2017 that described the use of Contour in open or laparoscopic colorectal surgery. Key search terms including “Contour,” “Curved,” “Staplers,” and “Surgery,” and their variations were used to identify relevant articles. Studies of non-colorectal surgical procedures, reviews or concept study designs, studies that used only hand-sewn technique or linear staplers, and studies involving stapled trans-anal rectal resections were excluded. Non-English language studies were included, with subsequent translation, if their abstracts were available in English.

Results: Four studies were identified in which Contour staplers were used along with another type of stapler, and eight in which no comparison was made, for a total of 12 papers. The comparative papers indicated superiority over or equivalence of Contour over conventional linear staplers, including higher rates of anus and sphincter preservation, and less contamination. In non-comparative papers, Contour was noted as highly efficient based on excellent maneuverability in the deep pelvis.

Conclusions: This review of the literature concludes that Contour provides complete cutting and safe closure, while simplifying the resection process and avoiding potential complications. Contour continues to be a safe, effective, and reliable cutting and stapling device for use in open and laparoscopic colorectal procedures.

Introduction

Historically, open surgery has been the standard approach for colorectal procedures [1]. More recently, the laparoscopic approach has also gained in popularity owing to advantages in smaller incision length, less blood loss and pain, and quicker recovery compared to open surgeries [2,3]. However, laparoscopic surgery may become problematic if the surgery involves large and heavy tumors, due to the lack of tactile feedback and adequate exposure [2,4]. The benefits of laparoscopic surgery are generally harder to realize in the resection of rectal cancers because of technical difficulties in working around the complex anatomy near the rectum - especially in a deep male pelvis. There also are some

patient types, including obese patients, and those with prohibitive lesions, thickened bowels, locally advanced disease or difficult anatomy, for whom open surgery may be the only viable option [5]. In addition, the longer learning curve for laparoscopic surgery may require a surgeon to perform a sufficient number of procedures each year to attain a high level of competence in such procedures as an alternative to open surgery [5,6]. Increasing experience in laparoscopy has also been associated with improved economic outcomes [7]. It is understandable, therefore, that the majority of data demonstrating the benefits of laparoscopic surgery have been generated in high-volume institutions or clinical trials, where surgeons are generally more experienced in laparoscopic techniques

[8]. As such, it is possible that the benefits of laparoscopic surgery are potentially less pronounced at low-volume institutions - thus strengthening the value of open procedures at such centers [9,10].

As a more recent attempt at finding a more universally viable option, hybrid surgical approaches consisting of laparoscopic splenic flexure takedown (with or without partial rectal mobilization and devascularization) followed by completion of the procedure via infra-umbilical midline laparotomy, have also been attempted with surgical staplers resulting in shorter incision and hospital stay [11]. Irrespective of the surgical approach, however, the choice of tools, including surgical staplers, is critical to optimizing outcomes of colorectal surgery. For example, the use of mechanical surgical stapling devices rather than hand-sewing with sutures for anastomosis formation has been linked to improved outcomes and reduced costs of open colorectal surgery [12]. The CONTOUR® Curved Cutter Stapler (Ethicon, Cincinnati, OH, (Figure 1) has been utilized for the last several years as a versatile stapling device, offering optimal anatomic access and a secure staple line in both open and hybrid surgical procedures.



Figure 1: The Ethicon Contour Curved Cutter Stapler.

With its unique curved head, Contour is designed to provide a more precise transection and less tissue slippage compared to other similar stapling devices currently available. The curved head allows for placement of a 40 mm cutline in the width of a 30mm space and low pelvic access without handle obstruction - thus enabling transection perpendicular to the rectum (Figure 2).

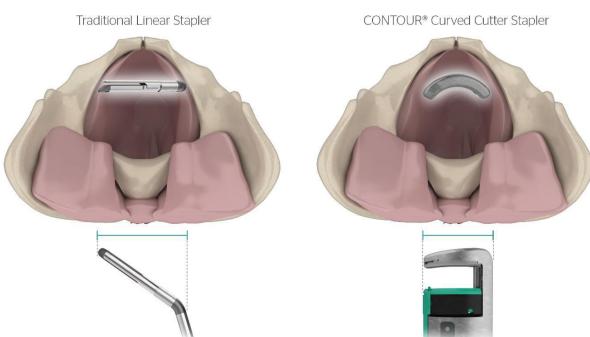


Figure 2: Comparison of a traditional laparoscopic linear stapler and Contour Curved Cutter Stapler for deep pelvic access.

The tissue retaining pin with manual closure option holds tissue in place during compression and firing, allowing for a more precise transection. This enables the Contour stapler to experience less tissue slippage during firing and may, as a result, eliminate the need for one extra reload per procedure compared to other similar staplers. Contour is also designed to be reloaded when needed to complete a single transection with multiple firings. In addition, with the stapling and cutting functions combined in one device, the need and cost for a bowel clamp and scalpel are eliminated. However, despite its obvious potential advantages as a cutter-stapler, the evidence of clinical value of Contour is not well documented. The goal of this study was to review research published in peer-reviewed journals, and report an assessment of the clinical value of the market leading Contour device in colorectal procedures.

Methods

A systematic search of the PubMed database was conducted for clinical studies published between January 1, 2005 and August 1, 2017 on the use of Contour in colorectal surgical procedures. The search terms included "Contour," "Curved," "Staplers," and "Surgery" and their variations like "Surgical procedures", "Operative" and "General surgery." Studies were excluded if they did not involve colorectal surgical procedures, used only hand-sewn technique or linear tapers, involved stapled trans-anal rectal resections, were concept design only, or if they were in a language other than English. Non-English articles that provided an English abstract were also additionally reviewed for relevance and those identified through that process were subsequently translated in to English. The review was conducted by two independent reviewers to ensure suitability and appropriateness of the selected articles. From the search, 51 articles were retrieved with potentially relevant information (Table 1). After the exclusion criteria were applied to the 51 retrieved articles, two comparative studies and six non-comparative studies were identified in which Contour was used in colorectal surgical procedures not involving prolapse or endometrial surgery. Additionally, four Chinese language articles were identified through the manual review of their English abstracts, and their translated versions were added subsequent to the initial search. Thus, a total of 12 articles with relevant information were identified: four comparative studies (including two translated from Chinese), and eight non-comparative studies (including two translated from Chinese).

Systematic Search: Curved, Contour Staplers	N
Total studies retrieved from systematic search	51
Excluded surgical procedures other than colorectal	10
Excluded studies that were reviews or concept design	2
Excluded articles not in English	4
Excluded articles with only hand sewn or linear stapler	2
Excluded for redundant with another study	2
Total studies with curved/Contour stapler use in colorectal surgery	31
Excluded articles of Contour Transtar (prolapse surgery)	18
Excluded articles of endometrial surgery	5
Total studies with curved/Contour stapler use in colorectal surgery, not involving prolapse or endometrial surgery	8
Manually identified papers	4
Systematic Search: Curved, Contour Staplers	N
Group 1: Stapler comparison studies with Contour	4
Group 2. Non-comparative studies with Contour	8

Table 1: Attrition table.

Results

Comparative Studies

As stated above, there were four studies identified that presented comparisons of outcomes based on the use of Contour or another device or transection modality. A study in China evaluated 309 patients undergoing low rectal cancer surgery and found that the Contour stapler group had a statistically higher rate (57.8%) of anus preservation compared to a locally manufactured linear stapler group (44.7%, $p<0.05$), while other complication rates were similar for both groups [13]. In another prospective randomized study comparing the use of Contour staplers with linear staplers among 60 patients undergoing mid to low rectal cancer surgery, there were no statistical differences in the incidence of postoperative complications (such as anastomosis site bleeding, anastomosis leak, wound complication or removal of Foley catheter) between Contour and a conventional linear stapler. However, the pelvic contamination rate was significantly higher in the linear stapler group (20.0%) than in the Contour group (3.3%, $p=0.044$). In addition, although it did not reach statistical significance, the Contour group had a longer distal resection margin than the linear stapler group [14].

In a similar study of 120 lower anterior resection patients comparing a double stapling anastomosis (Contour stapler) group

to a single stapling anastomosis group (purse-string suture) - the double anastomosis group had a higher sphincter preserving rate compared to the single anastomosis group (98% vs 82.9%, $p<0.05$). It was concluded that Contour with double stapling technique can potentially simplify and shorten the procedure compared to single stapling technique [15]. Finally, a study of 333 patients with ulcerative colitis who underwent Ileal Pouch-Anal Anastomosis (IPAA) surgery, the use of either Contour staplers or another commercially-available anastomotic stapler with a double-stapling technique was associated with a lower risk for cuffitis than a single-stapling technique. It was concluded that the incidence of cuffitis after stapled IPAA could be minimized by performing the anastomosis as low as possible, a procedure that can be accomplished with a modern stapler device such as Contour. Incidence of cuffitis was significantly higher in the single-stapling technique than in the double-stapling procedures (31.6% vs 14.4%, $p<0.05$) [16].

Non-Comparative Studies

A total of eight studies were identified through this systematic review that provided some assessment of the clinical effect of the use of Contour, without comparing that with another relevant device. About half of these studies primarily reported on the ease of use of the Contour device in anatomy that was harder to access and operate in. A study in Japan, applying Contour in laparoscopic rectal cancer resection, reported that this stapler reduces misfiring that could result from incomplete cutting. With Contour, the transected rectum is thoroughly stapled to the lateral tissue edge, which cannot be accomplished with conventional staplers, as the retaining pin is located within the staple line [17]. In another study of 26 laparoscopic rectal transections, surgeons reported that in all cases but one, the placement of Contour was feasible without the level of difficulty typically experienced with a traditional device [18]. Similarly, using a double stapling technique with Contour in low anterior resection of rectal cancer, anastomoses were highly successful (120/122, 98%) and the stapler was assessed as having exceptional maneuverability and ease of use [19]. Yet another study reported that laparoscopic rectal cancer transections were performed with Contour in 34 subjects, and successful transections were accomplished for all cases [20].

Along with the relative ease of use, the remaining non-comparative studies also reported on potential clinical benefits of low rates of surgical complications that were observed in association with the use of the Contour device. In a study of 65 patients undergoing ultra-low anterior resections for low rectal cancer, Contour showed the advantage of complete cutting, safe closure and low anastomotic leak rate (2/65, 3.65%) [21]. In another study, when used in 40 subjects with rectal cancer undergoing ultra-low anterior resection, Contour was successful in limiting bleeding of the anastomotic stoma, stenosis and anal incontinence [22].

Using a combination of an endo-Satinsky clamp rectal transection method and Contour for 12 rectal cancer patients, resection of the lower rectum was possible in another study, in adverse anatomical conditions through a small incision. The combination technique in all cases could accomplish complete rectal transection with only one firing using one cartridge and with no major complications [23]. Finally, in a review of 45 laparoscopic lower rectal resections, Contour was used to successfully perform a lower section of the rectum in all cases, with low rates of intraoperative and postoperative staple line bleeding [24].

Discussion

The curved linear staplers along with conventional linear staplers have been a standard of care in colorectal cancer surgery. This study reviewed clinical trials, cohort studies and case reports that were published in peer-reviewed journals globally with an aim to provide an up-to-date assessment of the effectiveness of the Contour Curved Cutter Stapler in colorectal cancer surgery performed either laparoscopically or by using an open surgical approach. In general, effectiveness of a surgical stapling device is dependent upon multiple factors: heights and sizes of staples, thickness and compressibility of tissues in the body, device-tissue interactions, inherent patient differences and the surgeon's familiarity with device and understanding of optimal stapler-tissue interaction [25]. In gastrointestinal tract surgery, different types of anastomotic methods are regarded as one of the major risk factors to influence complications including anastomotic leak. Anastomotic leak after colorectal surgery is the most serious complication that can increase morbidity and mortality rates significantly, and result in greater healthcare utilization. A retrospective cohort study using the US hospital administrative data reported anastomotic leaks was associated with additional hospital stay of 7.3 days and additional hospital costs of \$24,129 [26].

When compared with hand-suturing, a safe and effective mechanical stapling device like Contour could offer sizable clinical and economic benefits. A recent literature review and meta-analysis involving eight randomized clinical trials with a total of 1,172 patients with ileocolic anastomoses found that the mechanical stapling group had lower (2.4%) anastomotic leaks compared to the hand-sewn group (6.1%). The researchers reported that mechanical stapling instead of hand-sewn suturing could result in approximately \$11,000 of cost saving per patient for a hospital through a value analysis model considering OR time cost, reoperation cost, readmission cost, etc. [12]. Among different stapling techniques, double stapling using a conventional linear stapler or Contour has shown better outcomes compared to single stapling technique with use of purse-string forceps [16]. However, anastomosis following rectal resection presents additional challenges to surgeons. It is difficult to place the conventional straight, linear staplers at right angles to the rectum in the deep and

narrow pelvis especially in males, or in the presence of a voluminous tumor. These technical constraints often result in additional stapler firings and 'dog ear' formation that may cause anastomotic leak [24].

The Contour stapler was developed to cut and staple deep in the pelvis perpendicular to the rectum. The availability of 45-mm linear staplers should theoretically enable placement further down the pelvis; however, due to the narrowness of the pelvis, a conventional 45-mm stapler is unable to properly secure the distal rectum. The design of Contour conforms to a patient's natural anatomy, thereby allowing access deeper in the pelvis during a low anterior resection without handle obstruction. The Contour device is reloadable and may be fired up to 6 times in a single procedure [14]. Our review of 4 comparative studies and 8 non-comparative studies demonstrate that Contour performed at minimum on a par with conventional linear staplers in major postoperative complications such as anastomosis leak, anastomosis site bleeding or wound complications, and showed significantly better outcomes in inflammation at the anal transition zone or anus preserving compared to single-stapling technique. For example, Lee et al. [14] in their prospective randomized trial for rectal cancer surgery showed that the patients treated with Contour had significantly lower pelvic contamination rate compared to the patients with the linear stapler. Similarly, Wenqi and colleagues [13] determined that the Contour patient group was associated with higher anus preservation rate as compared with the linear stapler patient group. These results may be owing to several features of the Contour device. Contour with parallel jaw closure is designed to help compress tissue evenly within the jaws of the instrument for consistent staple formation, which can produce less tissue movement along the cut line. Thus, Contour can capture the rectum in a single firing when tissue fits comfortably within the jaws of the device. In addition, Contour with its unique curved head design enables surgeons to fit deeper in the pelvis and delivers a 17% longer cut line compared to the conventional 45 mm linear stapler.

Although stapling devices and techniques for colorectal or coloanal anastomoses have been improved, laparoscopic anastomosis is still technically difficult, and the rate of leakage is high [17]. Colorectal surgeons express that with presently available laparoscopic devices, resection of the low rectum in selected patients (males and mid-third rectal tumors) is often difficult [18]. Contour has shown to be an effective and reliable alternative instrument when rectal resection with the current laparoscopic stapler may be difficult. Of the 12 studies reviewed, five studies investigated use of Contour in laparoscopic surgery, and demonstrated the device performed successful resections without major complications. In a study of laparoscopic lower rectal resections, it was noted that Contour has characteristics to reduce misfiring risk resulting from incomplete cutting or an overlapping staple line and the formation of dog ears, and concluded that the curved stapler enables resection of the lower rectum to be easily performed without giving up the

benefits of laparoscopic access [24]. Two studies in Japan reported that the authors encountered no issues with using Contour for laparoscopic rectal resection and found no morbidity related to anastomosis or no major complications including anastomotic leak [17,23]. Similarly, Targarona et al., [18] reported that Contour provides an ideal closure and division of the rectal stump, not only in open, but also in laparoscopic procedures. They stated that Contour was effective particularly for those patients whose lower pelvis was too small in diameter to achieve a safe distal margin or who require a restorative proctocolectomy and an ileoanal J-pouch anastomosis.

While this review of the literature generally finds the use of Contour in colorectal surgery to be both clinically and potentially economically beneficial, there are a few potential limitations that need to be taken into account while using it for decision making. First, this study undertook a systematic literature review methodology to cover existing studies in peer-reviewed journals at a global level, but owing to the high specificity of inclusion criteria, a total of only 12 articles were identified and included in the study. Second, most of the selected studies were single centered and had small sample sizes. And finally, a few selected articles also primarily presented commentary based on the authors' previous anecdotal experiences with the Contour device, rather than the actual findings from their study. As such, assessment of effectiveness and safety of the device was made from a relatively small evidence base and the findings should be interpreted with these limitations in mind.

Conclusion

The Contour Curved Cutter Stapler along with conventional linear stapler has now been used as standard of care in open colorectal surgery over the last decade. This systematic review of the literature suggests that Contour continues to be a safe, effective, and reliable cutting and stapling device for use in open and laparoscopic colorectal procedures. It provides complete cutting and safe closure while potentially simplifying the resection process and avoiding surgical complications.

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