Recent Data for novoGI
Compression Anastomosis Superior to Staplers for Low Anterior Resection (LAR) Procedures
Background

Despite several decades of improvements in surgical technique devices routinely employed to facilitate low anterior resection anastomotic devices have not significantly changed. Therefore unfortunately the problem and high incidence of anastomotic leak following low anterior resection remain. Accordingly alternative methods of anastomosis following low anterior resection are needed to improve upon this highly problematic morbidity. Preclinical studies have suggested that the Nitinol–based compression anastomosis might be a viable solution.

Purpose

To evaluate the performance of the nitinol compression anastomosis device in creation of a circular anastomosis in colorectal procedures.

Hypothesis

The performance of the compression anastomosis device will be comparable to or better than the performance of circular staplers as reported in the literature.

Methods

The study was designed as a prospective, multicenter, open-label, non-randomized post-marketing study using the ColonRing (NiTi Surgical Solutions Ltd). Thirteen medical centers participated in the study. Screening was performed among adult subjects who were electively scheduled for an open or laparoscopic colorectal procedure with the creation of an anastomosis. Follow-up evaluations were performed daily during hospitalization. One postoperative follow-up was done at 1 month. Enrollment was blocked by gender (with expected allocation ratio of 1:1). Complications in which the study device did not have any obvious effect on clinical outcome were defined as not related.

Results

Between September 2009 to September 2011, 266 patients completed the study per protocol.

Primary endpoint - leak rate

Primary endpoint of up to 7% leak rates was achieved.

Additionally, in LAR (n=98) leak rates were:

- 4% (95% C.I. 0.0% - 8.0%) overall
- 1% (95% C.I. 0.0% - 3.0%) device-related

Secondary endpoints:

- Hospitalization parameters were unremarkable
- Mean excretion time 12.0 days; majority of patients (79%) did not notice excretion
- 49/50 patients underwent 1 month follow-up endoscopy with no strictures; 1 narrowing did not require dilatation
- Device was rated very easy (216/266) and easy (43/266) in 97.4% of all cases

Conclusions

The study showed that the nitinol compression anastomosis device is safe, effective, and easy to use in a clinical surgical setting and may offer an advantage for low anterior resection with distal anastomosis.

References


Histopathological Advantages of Compression Ring Anastomosis Healing Compared to Stapled Anastomosis in a Porcine Model: A Blinded Comparative Study

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Background
Mechanical stapling devices have been widely used for bowel anastomosis. During the past decade, compression devices containing nitinol super elastic materials have been shown to safely and efficiently facilitate intestinal anastomoses in animal and clinical studies. Previous studies have compared the performance of compression and stapled devices in porcine colorectal anastomosis. Compression anastomoses (CA) was recently associated with elevated bursting strength and anastomotic patency in this model compared to stapled anastomosis (SA).

Purpose
To compare the histopathological features related to the healing process between compression and stapled colorectal anastomoses in a porcine model.

Methods
Fifty crossbred pigs underwent rectal transection 20 cm from the anal verge followed by end-to-end CA (ColonRing 27 mm; NiTi Surgical Solutions Ltd) or SA (CDH 29 mm, Ethicon Endo-Surgery Inc). Anastomotic tissues were harvested at intervals of 3, 7, 30, and 90 days postop (n=5-6 per group). Histopathological parameters associated with wound healing were analyzed at the different time points using image analysis: morpheometry (Metamorph) and included semiquantitation of inflammatory cells and measurement of the area of fibrosis at the anastomotic site. Samples were evaluated by a single expert gastrointestinal pathologist, blinded to both anastomotic techniques and time of tissue harvest.

Results
Histological comparison of the healing process over time (Figure 1) illustrates the differences between CA and SA. Long-term scarring in the area of anastomosis (90 days) (Figure 2) was significantly reduced in the CA group compared to the SA group (P=0.016). CA samples showed lower (P<0.001) numbers of mononuclear, polymorphonuclear cells, and lymphocytes at 30 and 90 days (Figure 3). Additionally, the anastomotic lining (Figure 1) was narrower (P=0.003) at 90 days in CA samples (0.77 ± 0.20 mm) compared to SA (1.86 ± 0.19 mm). Foreign body response was significantly reduced in the CA model (P<0.001). Interestingly, the anastomotic line values were shown to inversely correlate (r=0.51; P=0.004) with the anastomoses internal circumference, which may be a basis for further research.

Conclusions
Compression anastomotic healing was associated with less inflammation, scarring, and foreign body reactions compared to stapled anastomoses.

References
### novoGI Compression Anastomosis Superior to Staples for LAR

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<tr>
<th>Study</th>
<th>LAR Patients</th>
<th>No of Leaks</th>
<th>leak %</th>
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**novoGI CA Summary** 608 19 3.1%

### Staplers

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**Staplers Summary** 5234 762 14.6%

### novoGI Compression Anastomosis

2% 3% 4% 14% 15% 16%
novoGI compression anastomosis


Staplers


There are over 50 peer-reviewed publications on novoGi’s clinically proven compression anastomosis technology.
See Peer-review Library at www.novoGi.com and learn more.