

# Bioabsorbable Staple Line Reinforcement in Restorative Proctectomy and Anterior Resection: A Randomized Study

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## ABSTRACT:

**Background:** Anastomotic complications, including leaks, strictures/stenoses, and bleeding, cause considerable mortality and morbidity after colorectal surgery.

**Objective:** The aim of this study was to assess whether the use of a synthetic, bioabsorbable staple line reinforcement material with circular staplers would reduce postoperative anastomotic leakage in patients with a colorectal, coloanal, or ileoanal anastomosis.

**Design:** This was a randomized study that compared outcomes in patients in whom the reinforcement material was used with those in patients who were not given the material.

**Settings:** This study was conducted at several centers in the United States.

**Patients:** The 258 patients (123 in the reinforcement group and 135 control subjects) underwent surgery for a variety of conditions, but most (n = 200) were treated for rectal cancer.

**Main Outcome Measures:** The main outcome measures were occurrence of anastomotic leaks and other complications according to the study protocol.

**Results:** There were no significant differences in the 2 study groups with respect to age, BMI, ASA physical status, operating time, diagnosis, previous chemoradiotherapy, surgical technique, or 30-day complications, except for a higher rate of small-bowel obstruction (p = 0.03) and anastomotic stricture (p = 0.006) in the control group. The overall anastomotic leak rate was 12% (bioabsorbable staple line reinforcement, 11.4%; no bioabsorbable staple line reinforcement, 12.6%).

**Limitations:** The study was nonblinded and was terminated at the first planned interim analysis because of insufficient power to detect an intergroup difference in anastomotic leak rate in the time allotted for the investigation.

**Conclusion:** Reinforcing the circular staple line in colorectal anastomoses with bioabsorbable material did not significantly affect the anastomotic leak rate but may have reduced anastomotic strictures. Most strictures did not require an anastomotic revision or delay in stoma closure. The bioabsorbable material may positively affect some aspects of the healing of circular stapled colorectal anastomoses; however, additional research on factors associated with anastomotic leakage is needed.

## KEY POINTS:

1. This was a multi-center, prospective, randomized study of 258 patients undergoing colorectal anastomosis with a circular stapler (<10 cm) to compare outcomes in patients in whom BSLR (GORE SEAMGUARD Bioabsorbable Staple Line Reinforcement) was used with those in patients who were not given the BSLR.
  - a. The participating sites were high-volume colorectal surgery facilities with fellowship trained surgeons.
2. Sites included:
  - a. Central Michigan University College of Medicine, Saginaw, Michigan
  - b. Kendrick Regional Center for Colon and Rectal Care, Indianapolis, Indiana
  - c. Division of General Surgery, Albany Medical Center, Albany, New York
  - d. Colorectal Surgery Department, Cleveland Clinic Foundation, Weston, Florida
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3. The overall anastomotic leak rate was 12% (31 of 258 patients). The anastomotic leak rate among the control group was 12.6% (17 of 135 patients).
4. The reported rate of anastomotic leakage after a restorative proctectomy ranges from 3% to 48%, with death occurring in 6% to 39% of patients in whom leaks occur.
  - a. Although the cause of leakage is multifactorial, performing a technically sound, tension-free anastomosis between well-vascularized segments of bowel remains important in reducing the risk of leaks, although it does not always prevent them.

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