

# Technical Review

Peri-Strips Dry® #1

## Buttressing Considerations



FIGURE 1: Peri-Strips Dry

## Buttress strength and staple line integrity: a comparison between Peri-Strips Dry® and SEAMGUARD® Bioabsorbable staple line reinforcement materials

*Synovis Life Technologies, Inc.  
Department of Research and Development*

### INTRODUCTION

Peri-Strips® Staple Line Reinforcement was introduced in 1994 by Synovis Surgical Innovations (Saint Paul, Minn.) as the first product for staple line reinforcement and quickly established a record of success in reducing the risk of bleeding, leaking and rupture at the surgical staple line. Peri-Strips Dry® (Figure 1), introduced in 1997 as the next generation of staple line reinforcement, has extended that record of success by providing simplified preparation and one-step application.

Peri-Strips Dry is derived from bovine pericardium and enhanced with Apex Processing®, Synovis' unique tissue manufacturing technique, to retain the intrinsic strength of bovine pericardium while providing excellent biocompatibility, performance and safety. Nearly 40 peer-reviewed publications have demonstrated the efficacy of Peri-Strips products. Peri-Strips Dry remains the gold standard for staple line buttress materials.

Recently W.L. Gore & Associates introduced SEAMGUARD® Bioabsorbable Staple Line Reinforcement Material for use in bariatric surgery.

Synovis conducted testing to compare the performance of Gore's product to that of Peri-Strips Dry. The tensile strength, leak resistance and burst resistance of staple lines buttressed with SEAMGUARD Bioabsorbable or Peri-Strips Dry reinforcement materials were measured in side-by-side comparisons. The leak

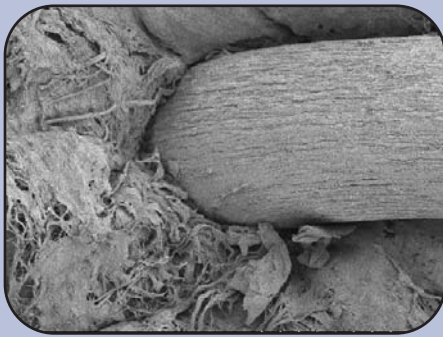


FIGURE 2A: Peri-Strips Dry

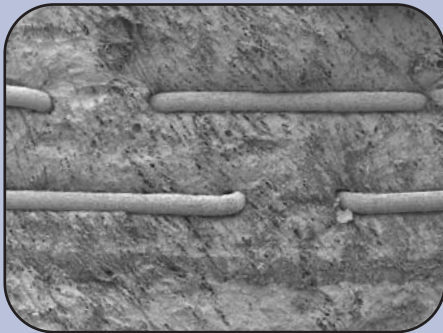


FIGURE 2B: Peri-Strips Dry

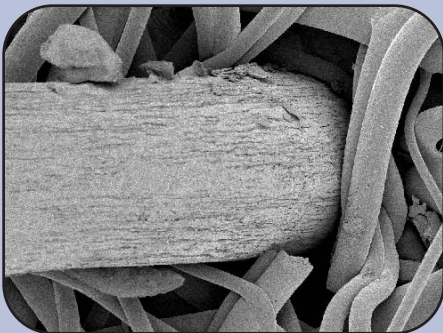


FIGURE 2C: SEAMGUARD Bioabsorbable

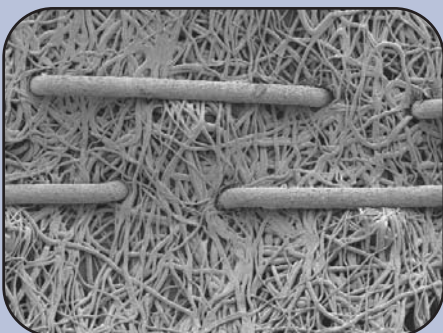


FIGURE 2D: SEAMGUARD Bioabsorbable

pressure and burst pressure of staple lines buttressed with SEAMGUARD Bioabsorbable or Peri-Strips Dry were also compared to those of non-buttressed intestinal staple lines.

## MATERIAL STRUCTURE AND STAPLE LINE REAPPROXIMATION

Under scanning electron microscopy, Peri-Strips Dry, a type I collagen, is observed to be a smooth, dense membrane which readily reapproximates around individual staples of a buttressed intestinal staple line (Figure 2, A and B). This reapproximation is believed to be responsible for the hemostatic properties of Peri-Strips products. In contrast, the SEAMGUARD Bioabsorbable material, a polymer, is highly porous (Figure 2, C and D). The hemostatic properties of this material are presently unknown.

## TENSILE STRENGTH

The pre-implant tensile strength of Peri-Strips Dry and SEAMGUARD Bioabsorbable was measured using an MTS Q5 uniaxial tensile tester. The SEAMGUARD Bioabsorbable material was significantly weaker than Peri-Strips Dry (Figure 3). The peak load of Peri-Strips Dry was  $5,142.0 \pm 1,591$  g at failure while that of the SEAMGUARD Bioabsorbable material was  $1,223.6 \pm 493$  g; **Peri-Strips Dry is nearly five times as strong as SEAMGUARD Bioabsorbable.** Importantly, given its absorbable nature, the strength of SEAMGUARD Bioabsorbable would be expected to decline following implantation. In contrast, the strength of Peri-Strips Dry, which is designed to resist degradation *in vivo*, is maintained following implantation.

## IN VITRO STAPLE-LINE INTEGRITY TESTING

To assess the *in vitro* performance of both buttresses, pig small intestines were obtained and transected using Ethicon ETS 45 staplers equipped with blue cartridges (3.5 mm staple length). An equal number of anastomoses were buttressed with Peri-Strips Dry or SEAMGUARD Bioabsorbable. Non-buttressed anastomoses were also created and served as a control. Blue dye was introduced into the anastomosed intestines at a constant rate. Leak and burst pressure at the staple line were assessed as described by Arnold et al.<sup>1</sup>

## LEAK PRESSURE

The staple lines in the Peri-Strips Dry, SEAMGUARD Bioabsorbable and non-buttressed groups were monitored until leaking was observed. The leak pressure was then recorded (Figure 4).

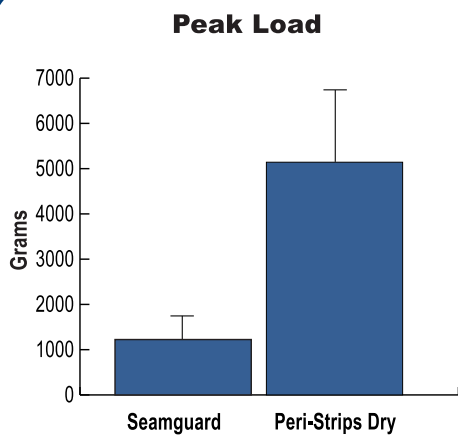


FIGURE 3

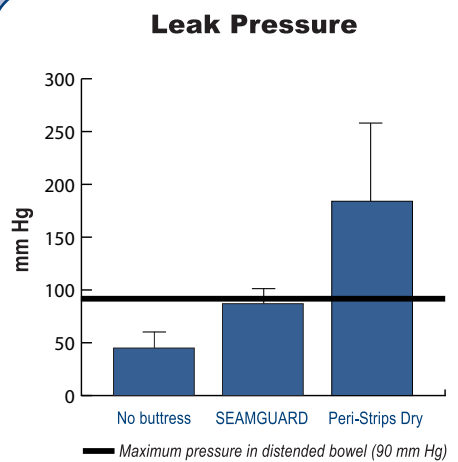


FIGURE 4

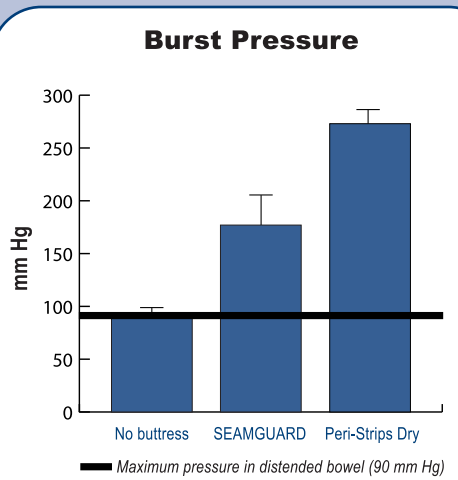


FIGURE 5

Intestinal staple lines buttressed with Peri-Strips Dry were approximately four times more leak resistant ( $184 \pm 74$  mm Hg) than non-buttressed staple lines ( $45 \pm 15$  mm Hg). This difference was statistically significant ( $p < 0.001$ , student t-test) and consistent with data reported by Arnold et al.<sup>1</sup> Importantly, intestinal staple lines buttressed with Peri-Strips Dry were also two times more leak resistant than staple lines buttressed with the SEAMGUARD Bioabsorbable material ( $87 \pm 14$  mm Hg). This difference was also statistically significant ( $p < 0.01$ , student t-test).

## BURST PRESSURE

The staple lines in the three groups were also evaluated to assess burst pressure levels. This was accomplished by introducing blue dye into the intestines until pressure reached a plateau or dropped abruptly as the intestines burst. The burst pressure was then recorded (Figure 5).

Intestinal staple lines buttressed with Peri-Strips Dry were approximately 2.5 times more burst resistant ( $273 \pm 13$  mm Hg) than non-buttressed staple lines ( $89 \pm 10$  mm Hg), consistent with results reported by Arnold et al.<sup>1</sup> This difference was statistically significant ( $p < 0.001$ , student t-test). Intestinal staple lines buttressed with Peri-Strips Dry were also 50% more burst resistant than staple lines buttressed with the SEAMGUARD Bioabsorbable material ( $177 \pm 28$  mm Hg). This difference was also statistically significant ( $p < 0.001$ , student t-test).

## MAXIMUM PHYSIOLOGIC PRESSURES

It is important to note that published reports document the creation of pressures of up to 90 mm Hg in distended bowel.<sup>2,3</sup> The data thus suggest that the non-buttressed intestinal staple line is at risk for leakage and rupture in the event of bowel obstruction or other phenomena leading to elevated bowel pressures (see maximum pressure line in Figure 4 and Figure 5). As previously noted, only the staple lines buttressed with Peri-Strips Dry provided resistance to both leakage and rupture at pressures significantly exceeding 90 mm Hg.

## STAPLE LINE SUPPORT DURING HEALING

In addition, Gore reports that SEAMGUARD Bioabsorbable maintains measurable strength for 4 - 5 weeks as a result of its time-dependent absorption.<sup>4</sup> The impact of this decrease in mechanical strength on SEAMGUARD Bioabsorbable's ability to provide the necessary margin post-operatively is unclear. While bowel healing and restoration of bowel strength may be accomplished in the normal patient in this time-frame, healing is often delayed in the obese patient with co-morbidities such as type II diabetes.<sup>5</sup>

## SUMMARY

These results demonstrate the superiority of Peri-Strips Dry over the SEAMGUARD Bioabsorbable material with respect to tensile strength, leak resistance and burst resistance. The strength of SEAMGUARD Bioabsorbable is further undermined by its progressive loss of strength during the critical 4-week post-operative period when healing is underway. In contrast, Peri-Strips Dry provides a significantly greater initial tensile strength, higher leak and burst resistance. And, because it does not undergo degradation *in vivo*, it provides enduring staple line strength.

In addition, the performance of Peri-Strips Dry is backed by a history of over a half million Peri-Strips implants and an adverse event rate of less than 0.01%. With superior tensile strength, superior leak and burst resistance, Peri-Strips Dry is still the gold standard for staple line buttressing in bariatric surgery.

## REFERENCES

1. Arnold W et al. Comparing seam burst pressure: buttressed versus non-buttressed linear cutting staple devices in a porcine model. Presented at the 19th Annual Meeting of the American Society for Bariatric Surgery, June 24 - 29, 2002.
2. Bramson RT et al. Intraluminal colon pressure dynamics with Valsalva maneuver during air enema study. *Radiology* 1997; 202: 825.
3. Schwab R et al. Early bursting strength of human colon anastomoses - an *in vitro* study comparing current anastomotic techniques. *Lagenbeck's Arch Surg* 2002; 386: 507 - 11.
4. Reinforcement enters a whole new phase. W.L. Gore and Associates 2003. AG4842-EN1.
5. King L. Impaired wound healing in patients with diabetes. *Nursing Standard* 2001; 15(38): 39 - 45.

Provided as an educational service by:

# Synovis®

Surgical Innovations

A Division of Synovis Life Technologies, Inc.

2575 University Ave. W.  
St. Paul, MN 55114-1024 USA  
651.796.7300 800.255.4018  
651.642.9018 (fax)  
synovissurgical.com

Peri-Strips, Peri-Strips Dry and Apex Processing are registered trademarks of Synovis Life Technologies.

SEAMGUARD is a registered trademark of W.L. Gore & Associates.

97204B 2/04 © 2004 Synovis Surgical Innovations. All rights reserved. Printed in the U.S.A.

CE  
0086