

Technical Review

Peri-Strips Dry® #2

Buttressing Considerations



FIGURE 1: Peri-Strips Dry

Data from Peri-Strips Dry Technical Review #1:

- The pre-implant tensile strength of Peri-Strips Dry was significantly greater than that of the SEAMGUARD Bioabsorbable buttress material.¹
- In an *in vitro* model, intestinal staple lines reinforced with Peri-Strips Dry were two times more leak resistant and 1.5 times more burst resistant than staple lines reinforced with the SEAMGUARD Bioabsorbable buttress material.¹

Long-term buttress integrity: a comparison of *in vitro* degradation rates of Peri-Strips Dry® and SEAMGUARD® Bioabsorbable staple line reinforcement materials

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INTRODUCTION

Peri-Strips Dry® (Figure 1) remains the gold standard for staple line reinforcement in bariatric and thoracic surgery. Peri-Strips Dry helps control bleeding and leaks and provides lasting security at the staple line. Derived from bovine pericardium and enhanced with Synovis' unique Apex Processing® manufacturing technique, Peri-Strips Dry retains 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 in bariatric and thoracic surgery.

W.L. Gore & Associates recently introduced the SEAMGUARD® Bioabsorbable Staple Line Reinforcement Material, a product made from a copolymer of glycolide and trimethylene carbonate.

A previous Synovis Technical Review compared the tensile strength, leak resistance and burst resistance provided by Peri-Strips Dry and the SEAMGUARD Bioabsorbable material. The results from that study clearly highlight the superior strength of Peri-Strips Dry buttress when compared to SEAMGUARD Bioabsorbable buttress material:

- The pre-implant tensile strength of Peri-Strips Dry was significantly greater than that of the SEAMGUARD Bioabsorbable buttress material.¹

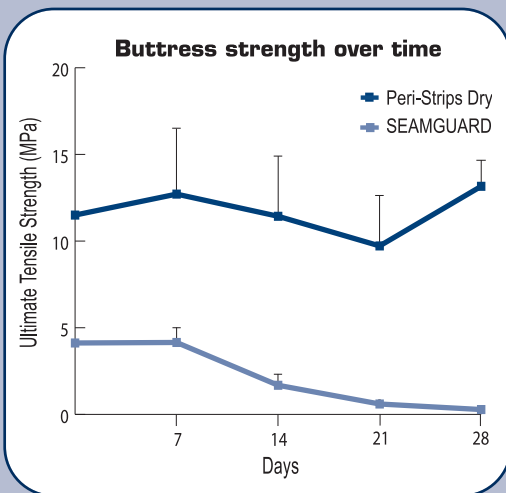


FIGURE 2

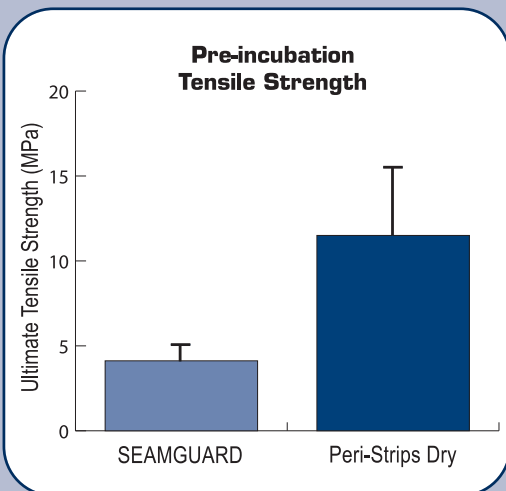


FIGURE 3

- In an *in vitro* model, intestinal staple lines reinforced with Peri-Strips Dry were two times more leak resistant and 1.5 times more burst resistant than staple lines reinforced with the SEAMGUARD Bioabsorbable buttress material.¹

A second study, designed to assess the loss of strength over time of Peri-Strips Dry and the SEAMGUARD Bioabsorbable material as a consequence of hydrolysis, has now been completed and the results are presented here.

This study was performed using methods described by Kangas J, et al.² In brief, individual samples of Peri-Strip Dry and SEAMGUARD Bioabsorbable were placed in sterile saline and incubated at 37°C. At regular intervals (e.g., 7, 14, 21 and 28 days), individual samples were removed from saline and their tensile properties were assessed using an MTS QT-5 tensile tester.

LOSS OF BUTTRESS TENSILE STRENGTH OVER TIME

As seen in Figures 2 - 3, the tensile strength of Peri-Strips Dry at time zero (e.g., before incubation in saline) was 11.5 ± 3.99 MPa ($n = 12$) while that of the SEAMGUARD Bioabsorbable material was 4.12 ± 0.96 MPa ($n = 6$). This difference is statistically significant ($p < 0.00002$) and confirms, as previously reported, that Peri-Strips Dry has nearly three times the pre-incubation tensile strength of the SEAMGUARD Bioabsorbable material.

Following 7 days in sterile saline at 37°C, both buttress materials maintained their pre-incubation tensile strength (Peri-Strips Dry = 12.71 ± 3.79 MPa; SEAMGUARD Bioabsorbable = 4.15 ± 0.84 MPa). However, after 14 days, the SEAMGUARD Bioabsorbable material had lost nearly 60% of its pre-incubation strength (1.68 ± 0.63 MPa).

Thereafter, the SEAMGUARD Bioabsorbable product continued to degrade at a rapid rate. After 21 days its strength was only 14.6% of its pre-incubation strength (0.6 ± 0.21 MPa). After 28 days in sterile saline at 37°C, the ultimate tensile strength of the SEAMGUARD Bioabsorbable product was 0.28 ± 0.08 MPa or just 6.8% of its pre-incubation tensile strength.

In contrast, the tensile strength of Peri-Strips Dry, which is designed to resist degradation *in vitro* and *in vivo*, did not decrease over time. There was no statistically significant decrease in the tensile strength of Peri-Strips Dry during the 28-day period ($p=0.101$, one way ANOVA).

A COMPARISON OF STRENGTH

Peri-Strips Dry started out significantly stronger and remained stronger throughout its incubation in saline (Figures 3 - 5). Unlike the SEAMGUARD Bioabsorbable buttress, Peri-Strips Dry undergoes little or no hydrolysis in saline. As a result, Peri-Strips Dry maintains strength while the SEAMGUARD Bioabsorbable material rapidly declines in strength. What is significant is the widening gap between the strength of the Peri-Strips Dry and SEAMGUARD Bioabsorbable materials that occurs over the duration of 28 days. Peri-Strips Dry product was nearly three times as strong as SEAMGUARD Bioabsorbable product prior to incubation (Figure 3). **After 28 days, Peri-Strips Dry was 47 times stronger than the SEAMGUARD Bioabsorbable product (Figure 5).**

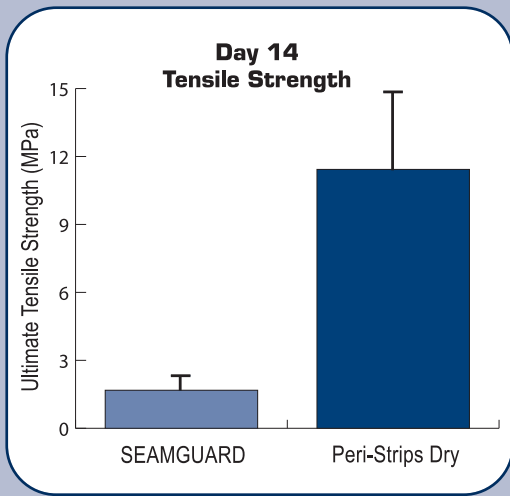


FIGURE 4

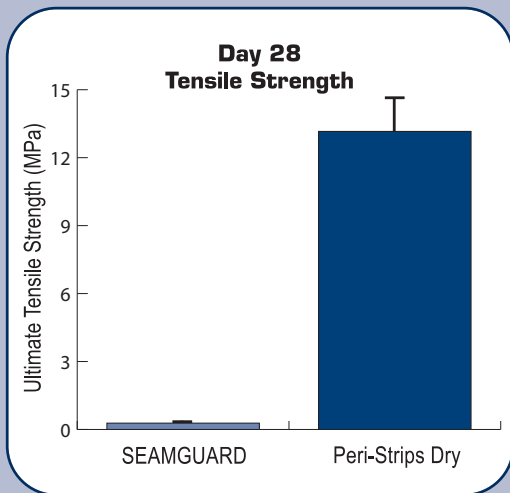


FIGURE 5

THE PHYSIOLOGY OF HEALING

The ideal buttress is one that controls staple line bleeding and provides the mechanical support necessary to reduce the probability of staple line leaks. On this basis, Peri-Strips Dry is the clear choice for staple line buttressing. Peri-Strips Dry provides superior tensile strength, superior leak resistance¹, and superior burst resistance¹ when compared to the SEAMGUARD Bioabsorbable buttress. Peri-Strips Dry has also been documented to help control staple line bleeding.³⁻⁵

Moreover, because the staple line remains at risk for leakage during the critical post-operative period,⁶ the ideal buttress is one that retains sufficient strength throughout the healing process.

Between day 7 and day 14, the SEAMGUARD Bioabsorbable buttress lost nearly 60% of its pre-incubation strength; at 14 days, the SEAMGUARD Bioabsorbable product provided just 14.6% of the strength provided by Peri-Strips Dry (Figure 4).

Importantly, while healing and restoration of strength may be accomplished in the normal patient within two weeks, healing is often delayed in the obese patient with co-morbidities such as type II diabetes.⁷ The rapid hydrolysis of SEAMGUARD Bioabsorbable buttress material and its profound loss of mechanical strength in the 14 - 28 day timeframe (SEAMGUARD Bioabsorbable provided just 6.8% of its pre-incubation strength at day 28) may cause even greater concerns about long-term staple line integrity. In contrast, Peri-Strips Dry resisted degradation *in vitro* and did not lose tensile strength during the 28-day incubation.

SUMMARY

Superior tensile strength¹, superior leak resistance¹, superior burst resistance¹ and superior resistance to degradation ensure adequate staple line protection, especially in the face of uncertain post-operative healing rates.^{6,7} These features, in combination with a documented ability to help control staple line bleeding,³⁻⁵ make Peri-Strips Dry the clear choice in staple line buttressing.

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