

Technical Review

Peri-Strips Dry® #2

Buttressing Considerations



FIGURE 1: Peri-Strips Dry® and Peri-Strips Dry with Veritas® Collagen Matrix are supplied in an easy-to-use mounting unit.

Impact of resorption on long-term buttress integrity: an *in vitro* comparison of Peri-Strips Dry®, Peri-Strips Dry with Veritas® Collagen Matrix and SEAMGUARD® Bioabsorbable

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INTRODUCTION

Since 1994, the Peri-Strips® family of products have been used for controlling leaks and bleeding at the staple line. Since then, more than 600,000 units and 40 peer-reviewed publications have demonstrated the efficacy of Peri-Strips® products.

Peri-Strips Dry® (Figure 1), the gold standard staple-line reinforcement material currently on the market, was introduced in 1997. 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.

Building on the success of Peri-Strips Dry, Synovis recently introduced Peri-Strips Dry® with Veritas® Collagen Matrix, a new remodelable staple line reinforcement derived from bovine pericardium. Peri-Strips Dry with Veritas is designed to provide strength throughout the healing process, particularly in cases in which a permanent buttress is not preferred.

The purpose of this Technical Review is to assess how strength over time is impacted by resorption in three types of reinforcement materials:

- Peri-Strips Dry in a permanent format
- Peri-Strips Dry with Veritas in a remodelable format
- SEAMGUARD® Bioabsorbable in a resorbable format

SEAMGUARD Bioabsorbable is a copolymer of glycolide and trimethylene carbonate manufactured by W.L. Gore & Associates.

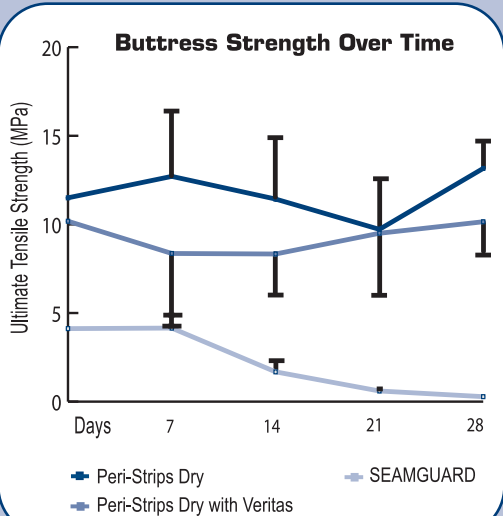


FIGURE 2

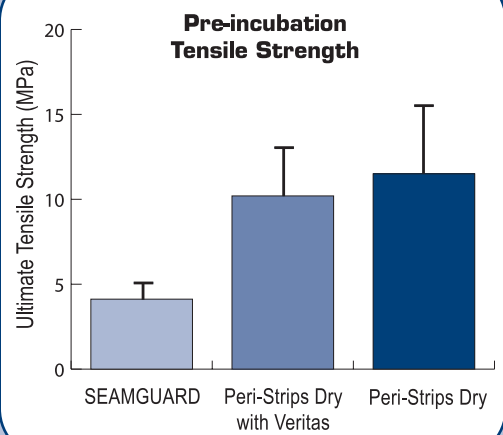


FIGURE 3

To assess resorption rates, a hydrolysis study was performed using methods described by Kangas J, et al.¹ In brief, individual samples of Peri-Strips Dry, Peri-Strips Dry with Veritas 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 TENSILE STRENGTH OVER TIME

As seen in Figures 2 - 3, at time zero (e.g., before incubation in saline) the tensile strength of the three products varies considerably. Peri-Strips Dry was the strongest of the three products at 11.5 ± 3.99 MPa ($n = 12$). Peri-Strips Dry with Veritas was nearly as strong at 10.18 ± 2.77 ($n = 12$), while the SEAMGUARD Bioabsorbable material was 4.12 ± 0.96 MPa ($n = 6$).

Before incubation both Peri-Strips Dry products were 2 - 3 times stronger than the SEAMGUARD Bioabsorbable product; this difference is statistically significant (Peri-Strips Dry = $p < 0.001$; Peri-Strips Dry with Veritas = $p < 0.001$, One Way ANOVA, SigmaStat®). The difference between the pre-incubation strength of Peri-Strips Dry and Peri-Strips Dry with Veritas is not statistically significant ($p = 0.310$, One Way ANOVA, SigmaStat).

Following 7 days in sterile saline at 37°C, all three buttress materials demonstrated no statistically significant change in tensile strength from their pre-incubation tensile strength. Peri-Strips Dry tensile strength was 12.71 ± 3.79 MPa ($p = 0.454$, Student's t-test, SigmaStat); Peri-Strips Dry with Veritas was 8.36 ± 4.27 MPa ($p = 0.229$, Student's t-test, SigmaStat); SEAMGUARD Bioabsorbable was 4.15 ± 0.84 MPa ($p = 0.955$, Student's t-test, SigmaStat).

However, there was a statistically significant decrease in tensile strength of the SEAMGUARD Bioabsorbable material between day 7 and day 14 ($p < 0.001$, One Way ANOVA, SigmaStat®). In fact, at 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 the Peri-Strips Dry products did not significantly decrease over time. In fact, there was no statistically significant decrease in the tensile strength of either Peri-Strips Dry product during the 28-day period (Peri-Strips Dry: $p = 0.101$, One Way ANOVA, SigmaStat; Peri-Strips Dry with Veritas: $p = 0.378$, One Way ANOVA, SigmaStat).

A COMPARISON OF STRENGTH

Both Peri-Strips Dry products started out significantly stronger and remained stronger throughout incubation in saline (Figures 3 - 5). Unlike the SEAMGUARD Bioabsorbable buttress, the Peri-Strips Dry products undergo little or no resorption in saline. As a result, the Peri-Strips Dry products maintain strength while the SEAMGUARD Bioabsorbable material rapidly declines in strength. Of significance is the widening gap between the strength of the Peri-Strips Dry products and the SEAMGUARD Bioabsorbable material that occurs over the duration of 28 days. Prior to incubation both Peri-Strips Dry products were 2 - 3 times as strong as SEAMGUARD Bioabsorbable product (Figure 3). After 28 days, Peri-Strips Dry was 47 times stronger and Peri-Strips Dry with Veritas was 36 times stronger than the SEAMGUARD Bioabsorbable product (Figure 5).

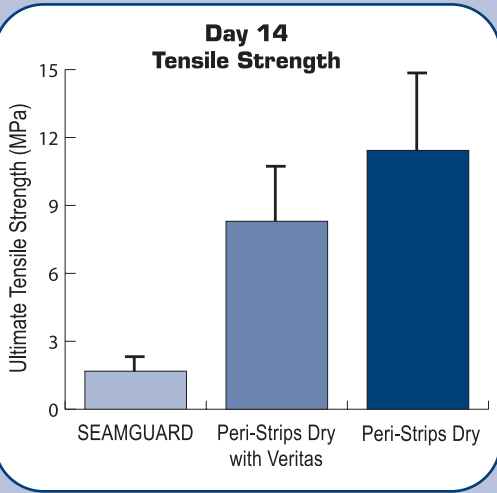


FIGURE 4

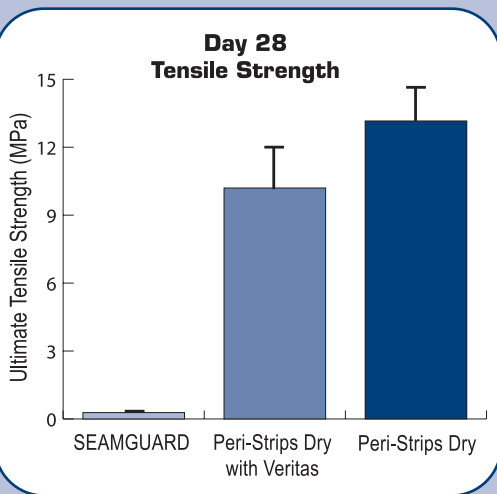


FIGURE 5

TYPES OF BUTTRESSING MATERIALS

Represented in this series are three types of buttressing materials: permanent (Peri-Strips Dry), remodelable (Peri-Strips Dry with Veritas) and resorbable (SEAMGUARD Bioabsorbable). As a permanent product, Peri-Strips Dry is designed to resist degradation *in vitro* and *in vivo*. While both the Peri-Strips Dry with Veritas and the SEAMGUARD Bioabsorbable materials are considered non-permanent, this data suggests that the mechanism by which they resorb is vastly different. The SEAMGUARD product chemically breaks down by hydrolysis at a predetermined rate. On the other hand, Peri-Strips Dry with Veritas is designed to remodel, a biological process in which a combination of bioresorption and biosynthesis occur during the course of normal wound healing.

Thus, as a remodelable product, the strength of Peri-Strips Dry with Veritas is designed to be dependent on not only bioresorption, but also biosynthesis. As a result, its strength remains unchanged when evaluating the effect of chemical hydrolysis. Ultimately, it is the rate of bioresorption combined with the rate of biosynthesis that will determine strength *in vivo* of the Peri-Strips Dry with Veritas product.

SUMMARY

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 alone, Peri-Strips Dry products are the clear choice for staple line buttressing. Before incubation, Peri-Strips Dry products provide superior tensile strength when compared to the SEAMGUARD Bioabsorbable buttress. The effectiveness of Peri-Strips Dry products in controlling leaks and bleeding has also been documented in published clinical papers.²⁻⁴

Moreover, because the staple line remains at risk for leakage during the critical post-operative period,⁵ the ideal buttress is one that retains sufficient strength throughout the healing process. 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.⁶

The rapid hydrolytic degradation of the SEAMGUARD Bioabsorbable material could raise concerns about long-term staple line integrity. As a permanent product Peri-Strips Dry is designed to resist degradation *in vitro* and *in vivo* and, consequently, it maintains strength throughout the healing process. Peri-Strips Dry with Veritas, as a remodelable product, does not demonstrate significant loss of tensile strength as a result of the hydrolytic resorption process but provides staple line strength as a result of biosynthesis in conjunction with bioresorption.

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