

Experimental Incisional Hernia Repair with SurgiMend® Collagen Matrix

Short and Long-Term Evaluation

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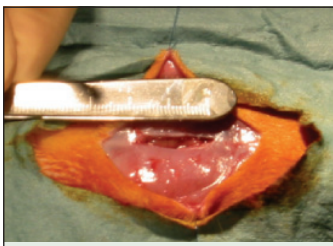
Ventral Hernia Study

Experimental Design & Endpoints

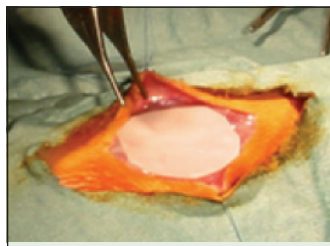
A ventral hernia rat model was used for this study. SurgiMend® was implanted in six male Sprague Dawley rats for each of three timepoints: three weeks (short-term), nine months, and 15 months (long-term). The endpoints for this study included evaluation of surgical adhesions, foreign-body response, new tissue development, and implant remodeling.

Surgical Procedure

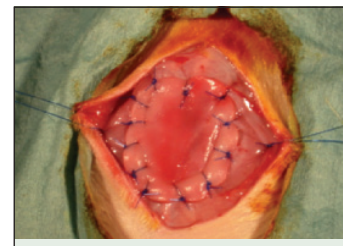
Following anesthesia and surgical preparation, one incision was made through the skin along the ventral midline, and the fascia was separated away to expose the abdominal musculature. A 2.0 cm longitudinal incision was made through the musculature, taking care to avoid puncture of the underlying intestines. Following hydration for approximately one minute in room temperature saline, the implant was cut to size (~ 3 x 4 cm oval) to allow for repair using onlay grafting techniques. The implant was then securely sutured in place to the underlying musculature along its perimeter with non-resorbable interrupted sutures. Finally, the abdominal skin was closed using stainless steel surgical staples.



2.0 cm longitudinal midline incision made in the abdominal wall



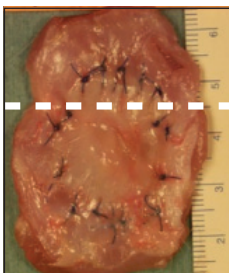
SurgiMend applied as an onlay graft



SurgiMend secured in place using non-resorbable, interrupted sutures

Explantation and Gross Analysis

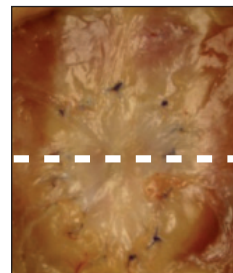
At the designated timepoints, SurgiMend and the surrounding tissues were carefully explanted, noting any significant surgical adhesions or evidence of reherniation. After fixation, the samples were trimmed of extraneous musculature and cut transversely. The cross-sections were examined under low magnification for evidence of encapsulation, adverse reactions, adhesions, and remodeling.



SurgiMend explant at 3 weeks



SurgiMend explant at 9 months



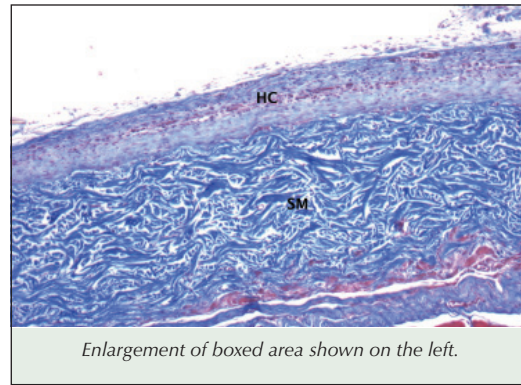
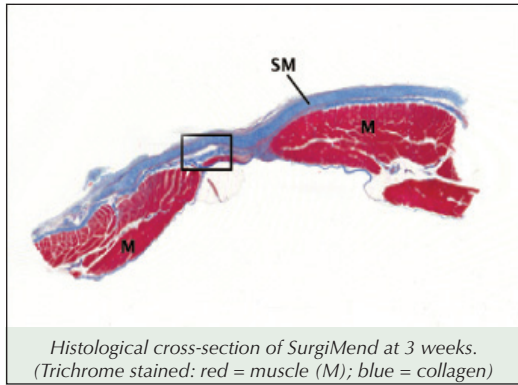
SurgiMend explant at 15 months

No evidence of inflammation or encapsulation was present, and there were no adhesions to the underlying bowel in any animal. The strength of the SurgiMend Collagen Matrix was sufficient to prevent bulging or herniation throughout the remodeling process.

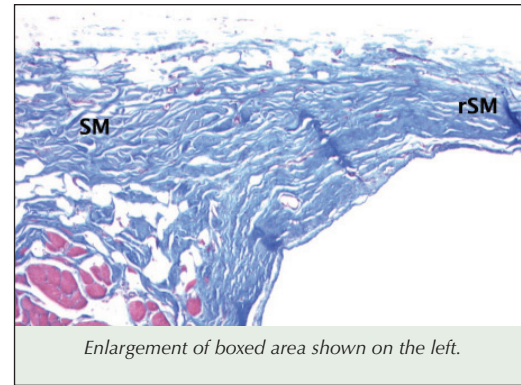
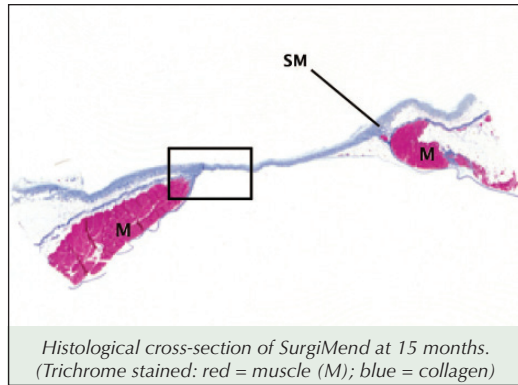
The white dotted lines indicate the orientation in which histological sections were cut (see histology images, next page).

Histopathology

Histopathology was performed on transverse cross-sections using standard techniques. Tissue sections stained with Masson's Trichrome were examined for the presence of inflammatory cells and fibrosis surrounding the SurgiMend as well as evidence of implant remodeling and new tissue development.



There is no significant fibrotic encapsulation of the SurgiMend (SM), nor are there significant numbers of foreign-body giant cells associated with the mesh. The interstices of the porous collagen matrix have been populated by fibroblasts and supporting vasculature. Note the band of new, host collagen (HC) tissue forming on the subcutaneous side of SurgiMend.



The random, woven pattern of collagen fibers, a signature of the SurgiMend Collagen Matrix, is still present in the portion of the mesh overlaying the muscle. However, in the portion of the mesh that spans the incisional defect, SurgiMend has been largely transformed by the populating host cells. SurgiMend has been progressively remodeled (rSM) into a strong, connective tissue consisting of parallel collagen fibers, effectively healing the surgical defect.

Results Summary

There were no incidences of significant inflammatory reaction/foreign-body reaction, surgical adhesions, nor reherniation in any of the 18 animals treated in this study. SurgiMend had been largely remodeled into new host connective tissue by nine months.

Discussion

One of the most notable findings in this study was the lack of a significant inflammatory response to the implanted SurgiMend. There were no adhesions to the underlying bowel, nor was there any significant fibrotic encapsulation of the mesh. These findings demonstrate the biocompatibility of SurgiMend. Close apposition of the graft with the margins of the defect and contact with the healthy tissues surrounding the hernia provides SurgiMend with a source of cells and blood vessels to support the remodeling process. The change in collagen structure of the SurgiMend was apparent both grossly and histologically. At the early timepoint, the product had been populated by cells and was beginning to become vascularized, but still exhibited the random, woven pattern of the collagen fibers typical of dermal tissue. By nine months, the portion of the SurgiMend spanning the incisional defect had been transformed by the host cells populating the mesh. At 15 months, the remodeled collagen fibers were parallel to one another, rather than randomly oriented, providing a strong connective tissue capable of resisting the prevailing circumferential stresses acting on the abdomen. Interestingly, the SurgiMend that extended beyond the suture line, not subject to loading, continued to exhibit the randomly oriented fibers similar to the mesh at three weeks. This finding suggests that remodeling is largely dependent on the function the implanted collagen is to perform. In this case, the collagen fibers responsible for resisting the stresses placed on the abdominal wall were optimized to efficiently oppose the circumferential loading.

An onlay grafting technique was utilized for this study; however, other surgical techniques may be more appropriate depending upon clinical conditions. Please refer to the SurgiMend Instructions for Use for complete indications, instructions, warnings and precautions prior to use of the device.



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