No. 013

C-QUR™ MESH PRODUCTS

TECHNICAL DATA REPORT

C-QUR™ Coated Mesh Human Explant Gross Pathology and Histological Analysis

ATRIUM

Technical Data Report
No. 013

C-QUR™ Coated Mesh Human Explant Gross Pathology and Histological Analysis

In August of 2006 a 4" x 6" piece of C-QUR™ Coated Mesh was implanted in a patient in an open procedure to repair a ventral hernia defect which had occurred from a previous operation involving a composite PTFE implant intraperitoneally. Approximately 3 months following the surgery, it was noted that the wound was not healing properly and that there was an infection present below the surface of the wound. The abdomen was reopened in order to clear the infection 91 days after the initial C-QUR™ Coated Mesh implantation. At this time, the infected area was discovered to be inferior to and not involving the C-QUR™ Coated mesh, but involving the tissue adjacent to the original composite PTFE material and surrounding tissue adjacent to the C-QUR™ Coated Mesh. This composite PTFE material was found to be contracted and exhibit multiple folds, causing the adventitial surface of the implant to be exposed to the viscera. A bowel fistula had developed and had to be resected. The physician made the decision to remove all prosthetic materials including the non-involved C-QUR™ Coated Mesh to allow the infection to clear.

The surgeon dissected the C-QUR™ Coated Mesh from the fascia. The mesh was found to be very well incorporated everywhere except for one small region directly below the original incision. The visceral side of the mesh was covered with neoperitoneum. The onlytissue attachments requiring sharp dissection were located in the area of the C-QUR™ Coated Mesh immediately adjacent to the folded, infected composite PTFE material. Gross examination of the explanted C-QUR™ Coated Mesh showed no signs of infection. Portions of the explanted sample were placed in formalin and sent for full histopathology analysis.

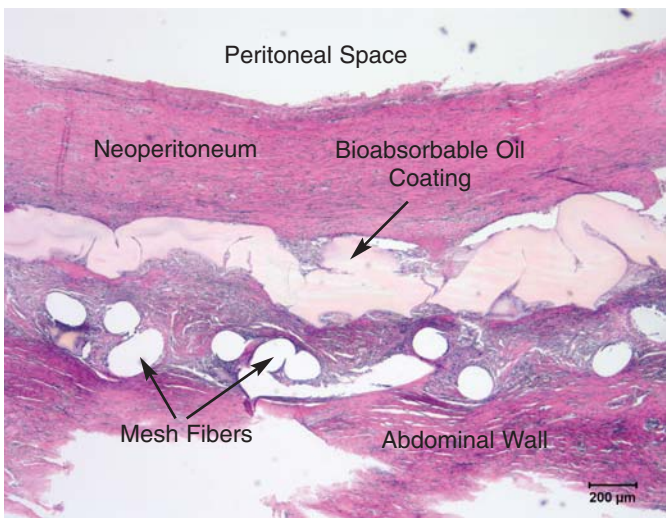

Figure 1

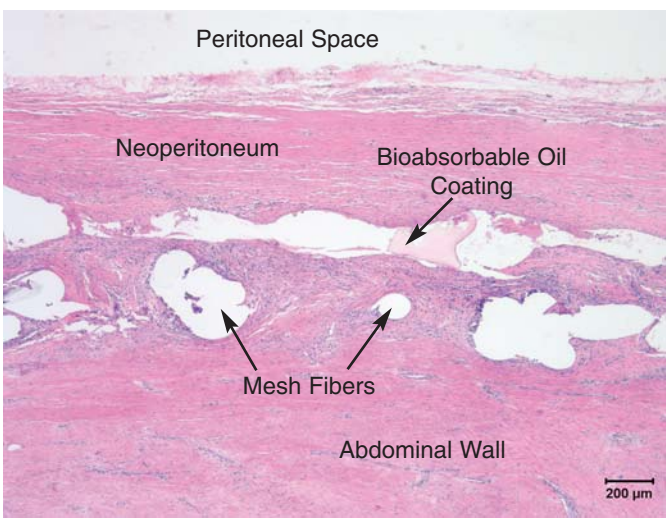

Figure 2

The explanted C-QUR™ Coated Mesh samples were processed and stained with various histochemical agents for pathological evaluation. Standard H&E staining was used for a general histological assessment (4X; Figures 1 & 2). A complete capsule of fibrous tissue formed around the implants. The C-QUR™ Coated Mesh was completely incorporated into the underlying muscular layer. The position of the coating verified that the smooth coated surface was implanted towards the peritoneal cavity space and the fibers toward the abdominal wall. Evidence of neovascularization was seen throughout the formed tissue capsule.

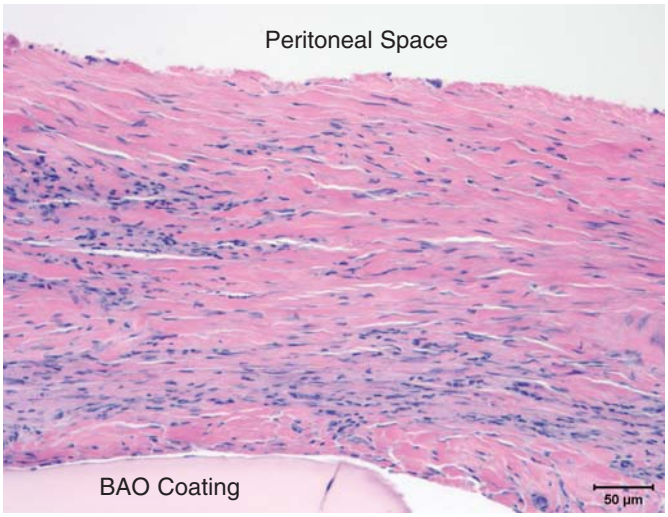

Figure 3

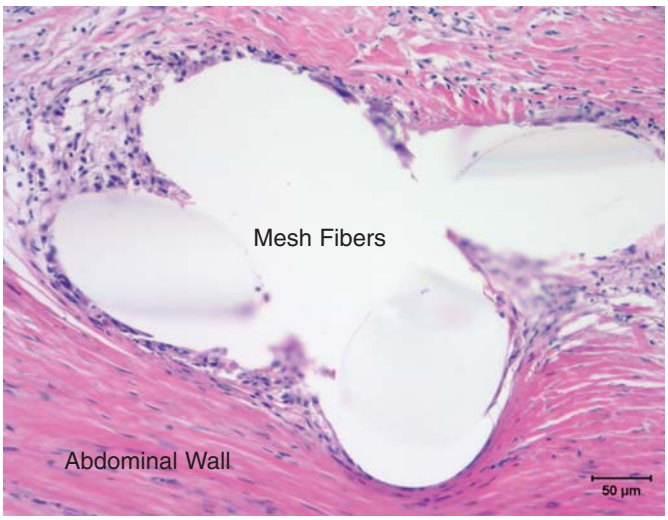

Figure 4

Higher magnification (20X; Figures 3 & 4) revealed a smooth continuous cellular surface on the implant surface associated with the peritoneal cavity, consisting mainly of cells characteristic of fibroblasts (cells that make up connective tissue). Overall there were very few adherent red cells and no apparent inflammatory response. The fibers of the mesh material exhibited complete incorporation with tissue and close association with the muscular layer. Localized areas of inflammation were observed in association with some surfaces of the polypropylene fibers while other fiber surfaces were covered with fibroblasts. There was also evidence of neovascularization of the tissue in association with the fibers.

Additional sections were processed for further evaluation with other stains. Evaluation of sections stained with trichrome (Figures 5a-d) revealed extensive evidence of new collagen synthesis and deposition in the tissue that formed in association with the C-QUR™ Coated Mesh. This collagen deposition (blue stain) was observed in the tissue formed between the mesh and the peritoneal space, within the mesh, and in the new tissue that formed between the mesh and the abdominal muscle.

continued ►

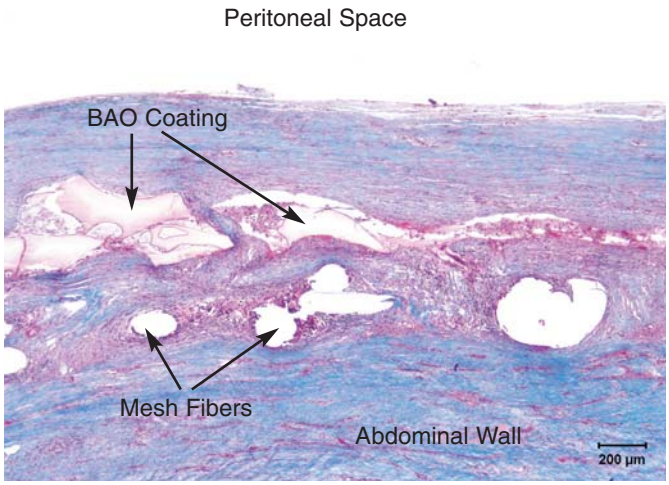

Figure 5a

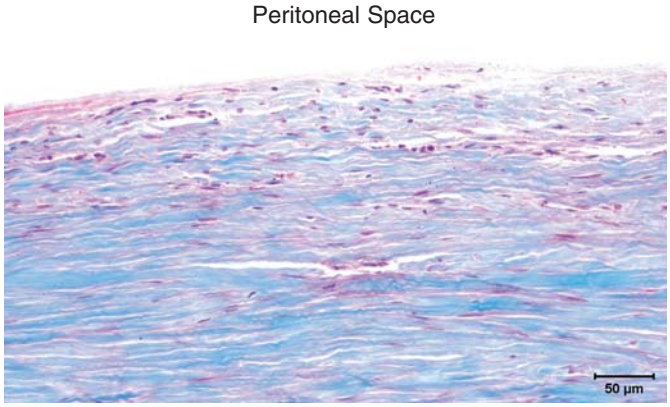

Figure 5b

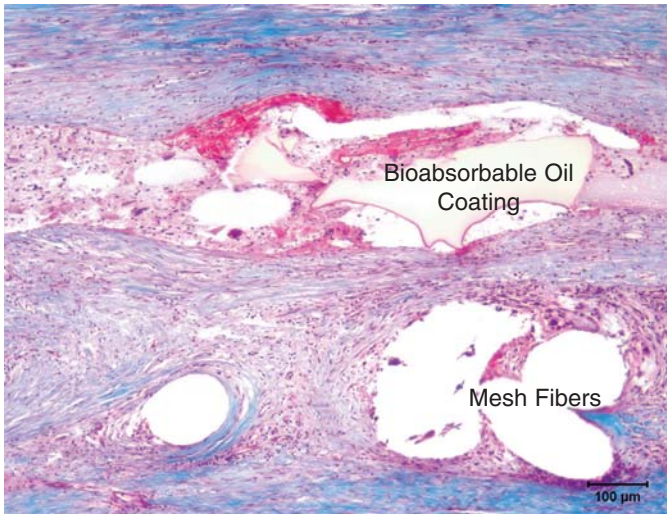

Figure 5c

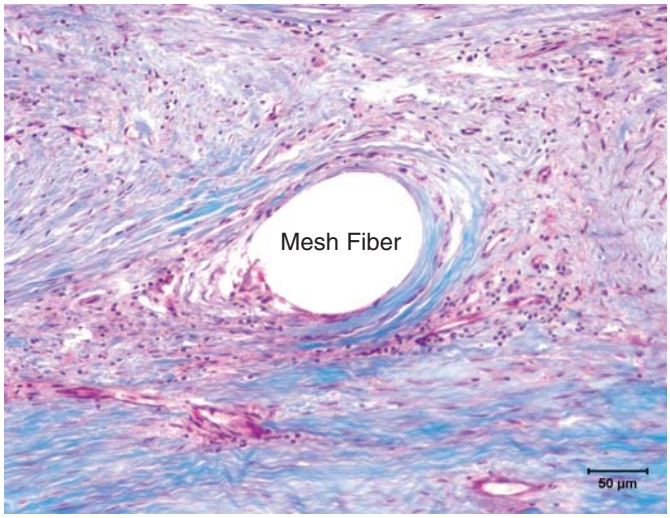

Figure 5d

Sections stained with antibodies against human von Willebrand factor (Figures 6 & 7), a marker of human endothelium, showed the presence of newly formed vascular endothelium in the explanted tissue. This can be seen by the presence of the brown colored sections in the referenced figures.

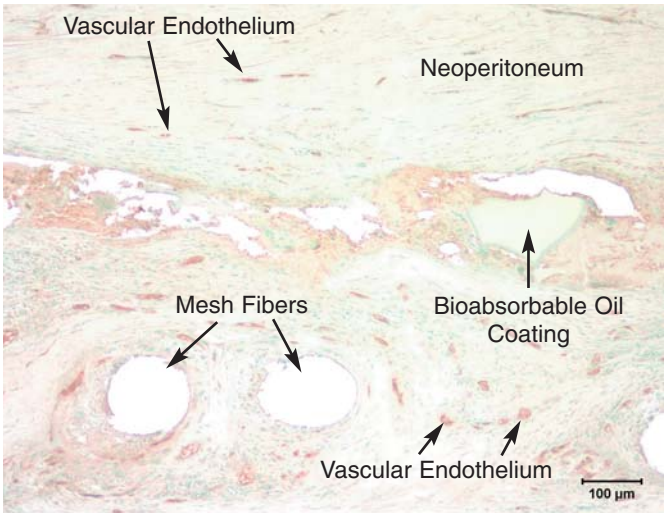

Figure 6

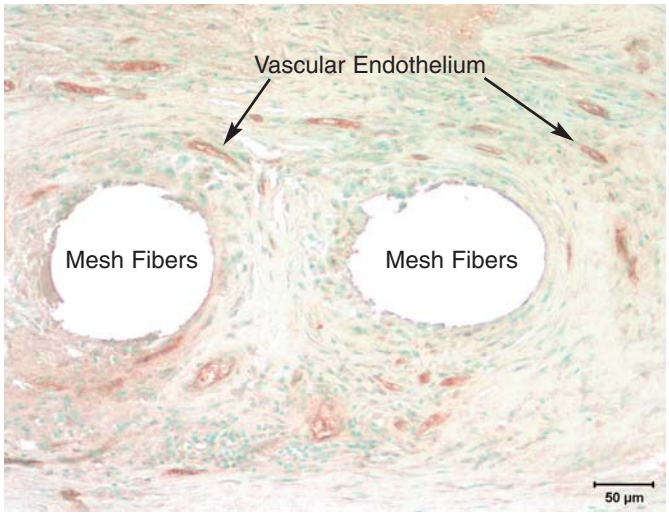

Figure 7

Summary

Gross assessment of the C-QUR™ Coated Mesh explanted after 91 days due to an infection showed minimal attachment formation on the visceral surface and good incorporation into the abdominal wall. No signs of infection were present in the C-QUR™ Coated Mesh despite being located immediately adjacent to a previously implanted infected device.

Histopathology revealed that this explanted C-QUR™ Coated Mesh demonstrated excellent healing and abdominal wall incorporation characteristics. The mesh was completely incorporated with new tissue forming a complete capsule. This new tissue exhibited minimal inflammatory response, was well vascularized, and showed no evidence of infection. New collagen deposition was observed within the mesh as well as within the tissue between the mesh and the visceral space and within the tissue between the mesh and the abdominal muscle.

Data on file at Atrium Medical Corporation.

TECHNICAL DATA REPORT No. 13

C·QUR™
MESH PRODUCTS

ATRIUM MEDICAL CORPORATION
5 Wentworth Drive
Hudson, New Hampshire 03051 U.S.A.
☎ 603-880-1433 603-880-6718

ATRIUM EUROPE B.V.
Rendementsweg 20 B
3641 SL Mijdrecht, The Netherlands
☎ +31-297-230-420 +31-297-282-653

ATRIUM AUSTRALIA-PACIFIC RIM PTY. LTD.
L 1 Bridgepoint , 3 Brady Street
Mosman NSW 2088 Australia
☎ +61-2-9960-0169 +61-2-8969-2735