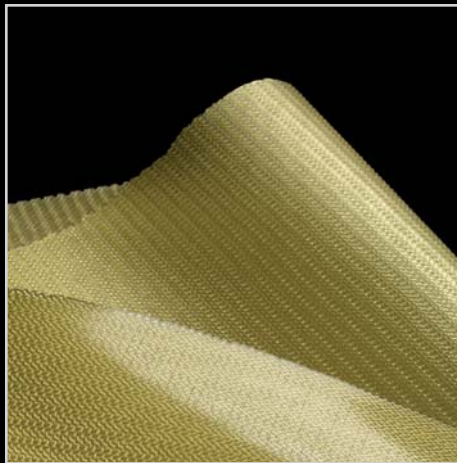


## **TECHNICAL DATA REPORT**

**C-QUR™ Mesh Comparison to Other Commercially Available Coated, Composite and PTFE Film Products in an In-vitro Biofilm Model Using Human Staphylococcus Aureus and Epidermis Sourced From An Abdominal Wound Infection**

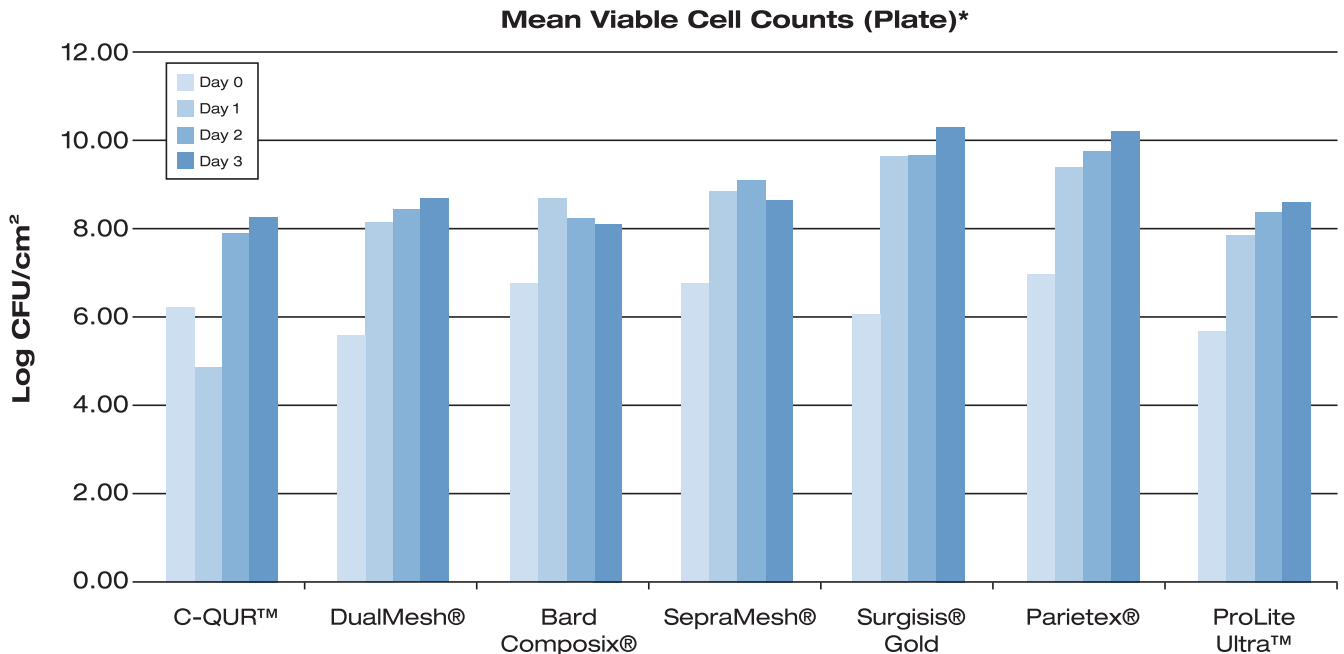


# C-QUR™ Mesh Comparison to Other Commercially Available Coated, Composite and PTFE Film Products in an In-vitro Biofilm Model Using Human Staphylococcus Aureus and Epidermis Sourced From An Abdominal Wound Infection

## Introduction

Although a relatively rare occurrence, mesh infection is a serious complication requiring removal of a prosthetic mesh device if the infection cannot be cleared by antibiotics or other treatments or intervention. Questions that often arise about the use of a mesh device include the propensity of a prosthetic mesh to become infected and how a pros-

thetic mesh device will behave in the presence of infection. To answer these questions for C-QUR™ Coated Mesh, Atrium took multiple steps in evaluating the product and its behavior regarding infection. These steps, outlined below, include in vitro testing using clinical strains isolated from a wound infection, an extensive literature review on fatty acids and their behavior in the presence of infection, and a full gross and histological analysis



**Figure 1**

of a human C-QUR Coated Mesh explant from a patient that developed an infection on an adjacent prosthetic mesh device.

## **In-vitro Testing**

C-QUR™ Coated Mesh was tested in an in-vitro model of biofilm formation using clinical bacterial isolates from chronic wounds. The testing was conducted according to a method published by William Costerton Ph.D., a world leader in biofilm research.<sup>1</sup>

The testing model system was adapted from the colony biofilm model. For the purposes of this testing, the surgical mesh was placed on a low-nutrient agar. Agar is a medium used to grow cells in culture. The use of a low nutrient agar prevented excessive biofilm accumulation and helped address the question of whether the fatty acid coating on C-QUR™ Coated Mesh promotes or prevents bacterial growth. C-QUR™ Coated Mesh was compared in this model to bare polypropylene mesh and to competitor meshes used in visceral hernia repair, such as DualMesh®, Composix® EX, SepraMesh®, Surgisis® Gold, and Parietex®.

The test bacteria used in this study were a mixed culture of clinical isolates of *Staphylococcus aureus* and *Staphylococcus epidermidis* sourced from an abdominal wound infection, pathogens frequently isolated from surgical site infections. The sterile mesh samples were inoculated in a known concentration of bacteria ( $10^7$  CFU/ml) and evaluated for the presence of bacteria via measurement of cell counts and microscopy over a 3 day period. Figure 1 shows the results of the plate count assay for each product tested at each timepoint.

There was no statistical difference in biofilm formation between C-QUR™ Coated Mesh, DualMesh, Composix, SepraMesh and ProLite Ultra products. Parietex and Surgisis Gold exhibited statistically significant greater biofilm formation than all the other products tested.

The results of the microscopic analysis agreed with the plate count results, with meshes showing high biofilm populations (Parietex and Surgisis Gold) in the plate count analysis also showing large accumulations of biofilm by direct microscopic observation.

## **Clinical Experience**

Finally, clinical experience with C-QUR™ Coated Mesh in the presence of infection was obtained in a case where C-QUR™ Coated Mesh was explanted after approximately 90 days due to an infection of a competitor mesh product adjacent to the C-QUR™ Coated Mesh. During removal of the C-QUR™ Coated Mesh, it was noted that the mesh was well incorporated on the abdominal wall side of the implant, while exhibiting minimal attachment on the visceral surface. No signs of infection were noted on the C-QUR™ Coated Mesh, despite being located next to a competitor product that was infected. A sample of the C-QUR™ Coated Mesh was submitted for full histopathological evaluation.

The histopathology findings showed a complete capsule of fibrous tissue formed around the implant. The mesh was completely incorporated into the underlying muscular layer. On the surface exposed to the peritoneal cavity, a smooth continuous cellular surface was observed with few adherent red cells and no apparent inflammatory response. The capsule formed between the peritoneal space and the coating consisted of cells with phenotypes characteristic of fibroblasts.

Additional analysis was conducted using various stains for further evaluation. Evaluation of sections stained with trichrome revealed extensive evidence of new collagen synthesis and deposition in the tissue that formed in association with the C-QUR™ Coated Mesh.

*continued* ►



Sections stained with antibodies against human von Willebrand factor, a marker of human endothelium, showed the presence of newly formed vascular endothelium in the explanted tissue.

In summary, despite being located adjacent to an infected prosthetic mesh, 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.

### **Literature Review**

An extensive literature review was conducted on fatty acids and their performance in an infected environment. The C-QUR™ Coated Mesh coating is a mixture of randomly cross-linked and non-cross-linked fatty acids, glycerides, and fatty alcohols. There have been no reports in the literature suggesting that any of the components or by-products of the C-QUR™ Coated Mesh coating will perform in an adverse manner in an infected environment. On the contrary, several reports in the literature suggest that many of the components of the C-QUR™ Coated Mesh coating may, in fact, demonstrate antimicrobial properties.<sup>2,3,4</sup> The susceptibility of bacteria and viruses to the antimicrobial properties of fatty acids is dependent on many things, including the strain of bacteria, the structure of the virus, and the concentration and type of fatty acids present. Two of the most prevalent fatty acids in the C-QUR™ Coated Mesh coating, C14 and C16, have been shown in many references to be inhibitory to *Candida*, *S. aureus*, and *S. epidermidis*, three organisms of concern in mesh implant infections.

### **Conclusion**

Mesh infection is a serious complication that will often require the removal of the prosthetic device if the infection cannot be cleared by

traditional methods. Through extensive research and testing, Atrium Medical Corporation has shown that C-QUR™ Coated Mesh will not perpetuate an infection. Literature suggests that fatty acid components present in the C-QUR™ Coated Mesh coating may have an antimicrobial effect. In-vitro testing confirmed that the fatty acid coating on C-QUR™ Coated Mesh will not accentuate biofilm formation and showed that C-QUR™ Coated Mesh behaved similarly to many other commercial mesh products in terms of biofilm formation, and showed significantly less biofilm formation than two products tested (Parietex® and Surgisis® Gold). Finally, clinical experience in one case demonstrated that despite being located adjacent to an infected prosthetic mesh, the C-QUR™ Coated Mesh did not become infected and was well healed with minimal attachment on the visceral surface, as confirmed through histopathological evaluation.

\*Data on file at Atrium Medical Corporation.

1. Cook, G., J.W. Costerton, and R.O. Darouiche, "Direct Confocal Microscopy Studies of the Bacterial Colonization in vitro of a Silver-coated Heart Valve Sewing Cuff," *International Journal of Antimicrobial Agents*, 13:169-173 (2000) Abstract 00-043.
2. C. Nieman, "Influence of Trace Amounts of Fatty Acids on the Growth of Microorganisms." *Bacteriol. Rev.* 1954, 18: pgs 147-163.
3. J.J. Kabara et al., "Fatty Acids and Derivatives as Antimicrobial Agents." *Antimicrobial Agents and Chemotherapy*, 1972, 2(1): pgs 23-28.
4. H. Thormar, "Inactivation of Enveloped Viruses and Killing of Cells by Fatty Acids and Monoglycerides." *Antimicrobial Agents and Chemotherapy*, 1987, 31(1): pgs 27-31.

## TECHNICAL DATA REPORT No. 12



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MESH PRODUCTS

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