Effect of a Fatty Acid Based Coated Mesh Material on Visceral Adhesion Formation and Tenacity

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Introduction: Polypropylene meshes have been widely used since the 1960's to perform "tension-free" hernia repair, and are the most commonly used due to handling characteristics and relatively low cost. With newer laparoscopic repair, the mesh is implanted intraperitoneally and is exposed directly to the viscera. Polypropylene mesh materials are known to promote rapid ingrowth which is a desired trait of the mesh, as it ensures the mesh will stay attached over time and adequately repair the defect. However, this rapid penetration of fibrous tissue may cause undesired adhesion formation to occur to the implant if the polypropylene is exposed to the visceral cavity. Particularly, concern exists regarding the development of adhesions between bowel and mesh. What is desired is tissue attachment on the abdominal wall surface of the implant, and the avoidance of tissue attachment on the visceral side of the device.

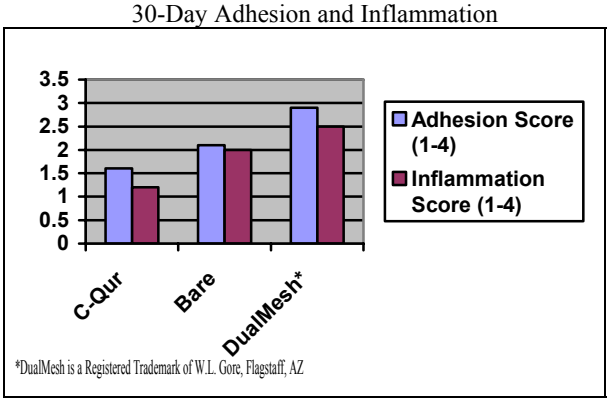
Several products for hernia and soft tissue repair have been commercialized to minimize visceral tissue attachment to the mesh device. Opinion differs as to the effectiveness of these devices in terms of minimizing tissue attachment or reducing the tenacity of adhesions. Also, physician preference is often dictated by the handling and fixation characteristics of the material, as well as its ability to be implanted by laparoscopic procedures.

Materials and Methods: Atrium Medical Corporation has developed an alternative mesh for intraperitoneal soft tissue repair. C-Qur™ Coated Mesh consists of a lightweight polypropylene mesh material coated with a bioabsorbable omega-3 fatty acid cross-linked gel. The coating completely covers the polypropylene monofilaments and creates a smooth film surface on one side of the mesh, providing a tissue separating layer between the polypropylene mesh and visceral cavity. The cross-linked fatty acid gel coating undergoes hydrolysis in vivo, and is converted into naturally occurring fatty acids, fatty alcohols, and gycerides. These smaller components are readily absorbed by local tissue, and are consumed by normal lipid metabolism. The bioabsorption of the coating material leaves lightweight polypropylene mesh behind as a permanent repair for the defect.

C-Qur™ Coated Mesh has been evaluated in several preclinical animal models prior to clinical use, including two rat full muscle wall defect repair models. In both models, visceral tissue attachment and histopathology were assessed.

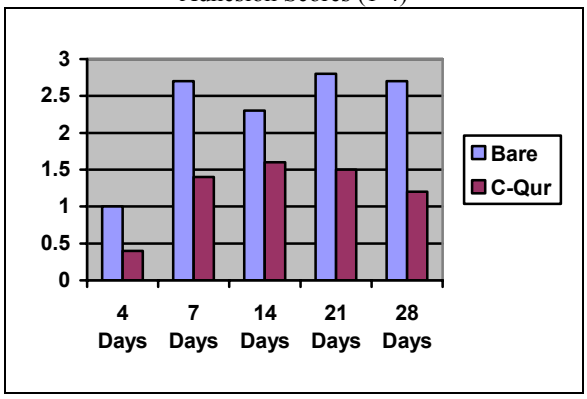
Results and Discussion: The first preclinical evaluation was conducted in a well established 30-day rat full thickness abdominal wall defect model. Upon gross examination at explant, Atrium's C-Qur™ Coated Mesh product demonstrated similar or less tissue attachment with lower tenacity than the currently marketed devices. Results of the histological evaluation demonstrated a lower inflammatory and foreign body response with this material than with the other tested materials. The scores are summarized in Figure 1.

Figure 1
30-Day Adhesion and Inflammation



The second model was a similar rat full muscle wall defect model in which C-Qur™ Coated Mesh was compared to uncoated polypropylene at various timepoints. Figure 2 summarizes the adhesion scores at the various timepoints studied, indicating less adhesion formation and tenacity at each timepoint with the C-Qur™ Coated Mesh.

Figure 2
Adhesion Scores (1-4)



Conclusions: A lightweight polypropylene mesh coated with a fatty acid based cross-linked gel was successful at minimizing visceral adhesion formation and tenacity, as well as minimizing the inflammatory response, in two rat models. Clinical evaluation is ongoing.