Hydrogel Barrier - An Alternative to PTFE in Preventing Adhesion Formation during Anterior Spine Surgery in a Sheep Lumbar Fusion Model

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**Objective:** Despite serious vascular complications that may arise, the anterior approach to the vertebral spinal column is often preferred when treating a variety of degenerative, dysmorphic or neoplastic conditions of the spine. In these procedures, access to the anterior lumbar spine is obtained using a trans or retroperitoneal exposure that requires mobilization of the aorta, vena cava and iliac vessels. Vascular complications as high as 5-10\% have been reported. Revision spine surgery from the anterior approach is even more difficult due to extensive scare formation that prevents mobilization of the great vessels required to reach the affected levels of the spine. PTFE based adhesions barriers (Preclude\textsuperscript{®}) have been used to prevent scarring of the great vessels during anterior spine surgery. In this study, a hydrogel cloth material EnGuard™ is evaluated as a potentially more effective barrier to prevent scar formation following anterior spine surgery.

**Methods:** A trans-retroperitoneal approach was made to expose the lumbar levels of the sheep spine. Interbody fusion at L2/L3 and L4/L5 levels of sheep (n=3) was performed using commercially available PEEK spacers (Synthes). At alternating levels within the same sheep, the fusion site was covered with Preclude\textsuperscript{®} (Gore, Phoenix, AZ) or EnGuard™ (Replication Medical, Inc., Cranbury, NJ) barrier materials. The sheep were humanely euthanized at 7 and 30 days. A force gage was used to measure the amount of force required to release the barrier sheets from the fusion site. Histology was performed to evaluate tissue response to the barrier materials.

**Results:** The EnGuard™ exhibited significantly less tissue attachment force than the Preclude\textsuperscript{®}. The implant served as a physical barrier between tissue, preventing tissues from adhering to one another with no obvious degradation of the implants over the course of this study. 30 day implant pullout force of Preclude\textsuperscript{®} was over four times greater than EnGuard™ (significant at p< 0.05).

A thin, but organized layer of cells was seen adjacent to the implant at three weeks and did not appear to change over time. Tissue between bone and the implant surfaces and muscles and the implant surface shows a thin layer of fibrous tissue adjacent to the hydrogel without penetration of cells into the hydrogel layer. Surrounding the hydrogel, a normal tissue response with minimal signs of inflammation was observed.

**Conclusion:** In this study, hydrogel sheet is an effective barrier to tissue ingrowth. The visible plane of dissection coupled with the presence of a thin layer of fibrous tissue suggest that it may be an effective barrier material for use in anterior spine surgery.
[Implant Pullout Force]

[EnGuard Histology]