SATURDAY, MAY 19, 2018
SESSION 10: BASIC/TRANSLATIONAL SCIENECE

127

A New Hernia Mesh Precisely Engineered to Prevent Hernia Recurrence

Mohamed M. Ibrahim, MD, Richard R. Glisson, BS, Jason L. Green, BS, Ken Gall, PhD, Howard Levinson, MD

Duke University Medical Center, Durham, NC, USA

PURPOSE: Approximately 405,000 ventral hernia repairs are performed annually in the US and the recurrence rate is approximately 20% as a result of failure at the suture, mesh, tissue anchor interface. To overcome this failure mode, we invented a knitted polypropylene hernia mesh with suture-like integrated mesh extensions that are 15X the surface area of #0 suture and anchor the mesh akin to suture. Physicomechanical benchtop and sterility testing was completed to FDA standards and the test mesh was implanted in swine to determine anchoring strength compared to a control reference mesh.

METHODS: The polypropylene T-line mesh was fabricated with extensions .5-1cm wide, 50cm long, and spaced 2cm apart. Mesh thickness was 0.5mm, average pore size 2.8mm and density was 90g/m2. Tongue tear resistance, ball burst, suture retention, tensile strength-strain, and extension tensile strength testing were performed (n=10 per each test) and compared to a control reference polypropylene mesh. Meshes were sterilized by ethylene oxide, gas, and gamma sterilization (n=10 per each mesh) and physicomechanical testing performed post sterilization. The test mesh and predicate mesh were implanted in a swine ventral hernia model (n=4) and harvested 1 day post-operatively for mechanical testing to model mesh/suture/tissue failure in the peri-operative period when most meshes are thought to be at greatest risk of failure.

RESULTS: In vitro mechanical performance demonstrated that the T-line mesh outperformed the control predicate mesh in all tested parameters. Mechanical analysis of swine specimens demonstrated the mean peak load to failure for T-line mesh was 134.5 N (SD +/- 54.5 N), compared to 49.0 N for the control reference mesh (SD +/- 13.4 N). The T-line mesh failure always occurred by the extensions tearing through tissue. The control mesh failed 60% of the time by one suture tearing through tissue and the second suture tearing through mesh, and the remaining 40% of failures was from both sutures tearing through mesh. The T-line mesh significantly outperformed control mesh and averaged 275% stronger on peak load performance.

CONCLUSION: The T-line mesh is a polypropylene, macroporous, heavyweight mesh that meets all FDA standards and outperforms a control predicate mesh in all mechanical performance tests. The T-line mesh can be sterilized by ethylene oxide, gas, or gamma sterilization without undue effects. The T-line mesh is 275% stronger than a control reference mesh in the immediate post-operative period when anchor strength is needed most. Future efforts are directed towards manufacturing the T-line mesh mesh with needles swaged onto the extensions, determining packaging conformations, and completing systemic and local tissue toxicity testing per FDA standards for 510(k) clearance. The T-line mesh has the potential to dramatically reduce hernia occurrence and recurrence.

M.M. Ibrahim: None. **R.R. Glisson:** None. **J.L. Green:** None. **K. Gall:** None. **H. Levinson:** None.

128

Poly-caprolactone Nanofiber Nerve Wrap Improves Nerve Regeneration and Rodent Functional Outcomes after Delayed Nerve Repair

Joseph Lopez, MD MBA, Kevin Xin, BS, Amy Quan, MD MPH, Kimberly Xinan, BS, Angelo A. Leto, MD, Joshua Budihardjo, BS, Zuhaib Ibrahim, MD, Hai-Quan Mao, MD, WP A. Lee, MD, Gerald Brandacher, MD

Johns Hopkins Hospital, Baltimore, MD, USA

PURPOSE: Proper nerve repair plays a critical role in facilitating a neuron's ability to regenerate an axon after nerve injury. Unfortunately, nerve repairs can be compromised by scar proliferation and inter-fascicular connective tissue formation. These factors can have a deleterious impact on patient recovery. As a result, there has been a long-standing clinical interest in developing neuroprotective agents that can reduce the scar burden and improve peripheral nerve regeneration after nerve transection. The purpose of this study was to assess the efficacy of biodegradable, electrospun poly-caprolactone (PCL) nanofiber nerve conduits in improving nerve regeneration. We hypothesized that PCL