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Study Title: COMPARISON OF TWO SINGLE INCISION SLINGS ON THE VAGINA IN AN OVINE MODEL

Authors: Katherine K. Shapiro, MD, Katrina M. Knight, PhD, Rui Liang, MD, Justin Cook, BS, Gabrielle E. King, BS, Steven D. Abramowitch, PhD, Pamela A. Moalli, MD, PhD

Background

Stress Urinary Incontinence carries a significant healthcare burden for women worldwide. Single incision slings are minimally invasive mesh devices designed to treat stress urinary incontinence. For prolapse repair, meshes with higher porosity and lower structural stiffness have been associated with improved outcomes.

Objective

We compared the higher stiffness, lower porosity Altis sling (SIS-B; Coloplast, Humlebaek, Denmark) to the lower stiffness, higher porosity Solyx sling (SIS-A; Boston Scientific, Marlborough, MA) in an ovine model. We hypothesized that SIS-B would have a negative impact on the host response.

Study Design

13 SIS-A (Solyx) and 11 SIS-B (Altis) were implanted sub-urethrally into sheep according to the manufacturer's instructions on minimal tension. The mesh-urethral-vaginal complex and adjacent ungrafted vagina (no mesh control) were harvested en bloc at 3 months. Masson's trichrome and picrosirius staining of 6mm thin sections was performed to measure inter-fiber distance and tissue integration. Smooth muscle contractility to a 120mM KCl stimulus was performed in an organ bath to measure myofiber driven contractions. Standard biochemical assays were used to quantify glycosamingoglycan, total collagen and elastin content, and collagen subtypes. Bending stiffness was performed in response to a uniaxial force to define susceptibility to folding/buckling. Statistical analysis was performed using Mann-Whitney, Gabriels' pairwise post-hoc, Wilcoxon matched pairs and Chi-Square tests.

Results

Animals had similar age (3-5 years), parity (multiparous) and weight (45-72 kg). Trichrome cross sections showed that the SIS-B (Altis) buckled in a "C" or "S" shape in most samples (8/11), while buckling following SIS-A (Solyx) implantation was observed in only a single sample (1/13, P = 0.004). Tissue integration, as measured by the presence of collagen or smooth muscle between mesh fibers on Trichrome 4x imaging, was increased in SIS-A implanted samples as compared to SIS-B (P < 0.05). Total collagen content decreased significantly with both products when compared to ungrafted vagina consistent with stress shielding. There was no difference in the two groups with regards to glycosaminoglycan or elastin content. SIS-B mesh tissue complex demonstrated significantly higher amounts of both collagen I and III than SIS-A implanted tissue and ungrafted control. Smooth muscle contractility in response to 120mM potassium chloride was decreased following implantation of both slings compared to Sham (P = 0.011, P < 0.01), with no difference between mesh types (P = 0.099). Bending stiffness in SIS-B was over 4 times lower than SIS-A indicating an increased propensity to buckle (0.0186 vs 0.0883).

Conclusions

The structurally stiffer SIS-B (Altis) had decreased tissue integration and increased propensity to buckle after implantation. Increased collagen I and III following implantation of this device suggests that these changes may be associated with a fibrotic response. In contrast, SIS-A (Solyx) largely maintained a flat configuration and had improved tissue integration. The deformation of SIS-B is not an intended effect and is likely caused by its lower bending stiffness. Both meshes induced a decrease in collagen content and smooth muscle contractility similar to previous findings for prolapse meshes and consistent with stress shielding. The long-term impact of buckling warrants further investigation.

Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752
www.bostonscientific.com

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