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

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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.

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Complications cited in this summary are specific to this study.

The following adverse events have been reported due to suburethral sling placement, any of which may be ongoing, but are not limited to: As with all implants, local irritation at the wound site and/or a foreign body response may occur, Foreign body reaction may be acute or chronic, Pain (pelvic, vaginal, groin/thigh, suprapubic, dyspareunia) (acute or chronic), Dyspareunia, Tissue responses to the mesh implant could include: erosion into organs (urethra, bladder or other surrounding tissues); exposure/extrusion into the vagina, Mesh contact with urine via erosion/exposure/extrusion may result in stone formation, scarring/scar contracture, Necrosis, fistula formation (acute or chronic), inflammation (acute or chronic), Mesh contracture, Tissue contracture, Vaginal shortening or stenosis that may result in dyspareunia and/or sexual dysfunction, Pain with intercourse that may not resolve, Exposed mesh may cause pain or discomfort to the patient's partner during intercourse, Sexual dysfunction, including the inability to have intercourse. Like all foreign bodies, the mesh may potentiate an existing infection. Allergic reaction has been reported. Known risks of surgical procedures for the treatment of incontinence include: pain, ongoing pain (pelvic, vaginal, groin/thigh, suprapubic, dyspareunia), Severe, chronic pain, Apareunia, Leg weakness, Infection, De novo detrusor instability, Complete failure of the procedure/failure to resolve a patient's stress urinary incontinence, Voiding dysfunction (incontinence, temporary or permanent lower urinary tract obstruction, difficulty urinating, pain with urination, overactive bladder, and retention), Bruising, bleeding (vaginal, hematoma formation), Abscess, Vaginal discharge, Dehiscence of vaginal incision, Edema and erythema at the wound site, Perforation or laceration of vessels, nerves, bladder, urethra or bowel may occur during placement. The following additional adverse events have been reported for the Solyx SIS System: Dysuria, Hematuria. The occurrence of these events may require surgical intervention and possible removal of the entire mesh. In some instances, these events may persist as a permanent condition after surgical intervention or other treatment. Removal of mesh or correction of mesh-related complications may involve multiple surgeries. Complete removal of mesh may not be possible and additional surgeries may not always fully correct the complications.

Caution: Federal (US) law restricts this device to sale by or on the order of a physician trained in use of surgical mesh for repair of stress urinary incontinence. Refer to package insert provided with this product for complete Indications for Use, Contraindications, Warnings, Precautions, Adverse Events, and Instructions prior to using these products.

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