Presentation Title: RETROSPECTIVE REVIEW OF EARLY EXPERIENCE USING THE BOSTON SCIENTIFIC SOLYX™ SINGLE-INCISION SLING SYSTEM TO TREAT STRESS URINARY INCONTINENCE IN WOMEN – INTRAOPERATIVE EXPERIENCE.

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Objective

The Solyx Single-Incision Sling System was developed to be easier and safer to use than retropubic and obturator slings. It was the objective of this study to retrospectively assess the short-term safety and efficacy of the Solyx Single-Incision Sling System.

Introduction

There are 3 main types of slings with differing anchoring points:

- **Retropubic**: rectus fascia / rectus muscle
- **Obturator**: obturator internus, obturator membrane, obturator externus
- **Single incision**: obturator internus muscle

The main reasons to use single incision slings includes the potential for:

- Less morbidity
- More simplistic procedures
- Less post-operative pain due to reduced tissue trauma

**Anchorage points**

Single incision → obturator internus muscle

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[Image of the Solyx Single-Incision Sling System with labels for delivery device, needle tip, midline marker, deployment mechanism, handle, mesh assembly, mesh carrier, and polypropylene mesh.]
Methods

Chart reviews of 63 subjects implanted with the Solyx™ Sling were completed at 3 sites. Study participants included female subjects with stress urinary incontinence (SUI). All procedures were performed at local medical centers, with chart review occurring by clinic staff at each site respectively. Procedural data for all subjects were identified. All of the patients had urethral hypermobility with a Q-tip test of greater than 30 degrees. The patients thus far have been followed up for 5-8 months with a mean of 6.5 months. All subjects received the Solyx Single-Incision Sling System, a minimally invasive single-incision sling, with mesh placed under the urethra and anchored in the obturator internus muscles. The polypropylene mesh was placed with a single delivery device through a 1.5 cm vaginal incision at the mid-urethra. Subjects included in this data collection had a mean age of 51 years (range 30 – 87). The dominant type of incontinence within the study patients was SUI, which was found in all subjects, while 18 (29%) of the subjects also had a component of urge incontinence. 37/63 (59%) of study patients had concomitant procedures. Patients evaluated post-operatively with a cough test and a subjective evaluation.

<table>
<thead>
<tr>
<th>Chart review from 3 sites, all had clinical SUI (All had q-tip &gt;30° and positive cough stress test)</th>
<th>n = 63</th>
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<tbody>
<tr>
<td>Mean age</td>
<td>51 (30 – 87)</td>
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<tr>
<td>Presented with Urge Incontinence</td>
<td>29% (18/63)</td>
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<tr>
<td>Concomitant Repair</td>
<td>59% (37/63)</td>
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<td>Mean follow-up (5 – 8 months)</td>
<td>6.5 months</td>
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Results

Objective Cough Stress Test & Subjective cure rate at follow-up 95%

- 1:1 correlation of subjective and objective patients
- 2 reports of transient retention which resolved
- No serious adverse events including:
  - No bladder, bowel, vessel or nerve perforations
  - No erosions or extrusions
  - No pain was reported that was attributed to the implant

Conclusions

Chart reviews indicated that the Solyx Single-Incision Sling System reduces risks and is an efficacious and less-invasive option for patients requiring SUI surgery.

Patients remarkably did not report any significant pain related to the sling procedure.