

TREATMENT OF STRESS INCONTINENCE IN THE MALE WITH THE VIRTUE VENTRAL URETHRAL ELEVATION SLING SYSTEM -- INITIAL CADAVERIC STUDY

Hypothesis / aims of study

Bone anchored perineal slings for the treatment of stress urinary incontinence following prostate cancer surgery have become popular, based on intermediate term safety and efficacy studies. In addition, a trans-obturator sling has recently gained popularity, despite a general lack of published safety and efficacy data. The mechanism of action of the former appears to be urethral compression due to forces applied perpendicular to the sling. The latter appears to cause proximal relocation of the bulbous urethra, affecting closure of the urethral lumen with realization of limited force perpendicular to the sling. We describe a pilot cadaveric study of the Virtue™ Ventral Urethral Elevation Sling System – which combines the two concepts of ventral compression and proximal urethral relocation. Prior to human use of this novel sling, we aim to obtain urodynamic proof of concept.

Study design, materials and methods

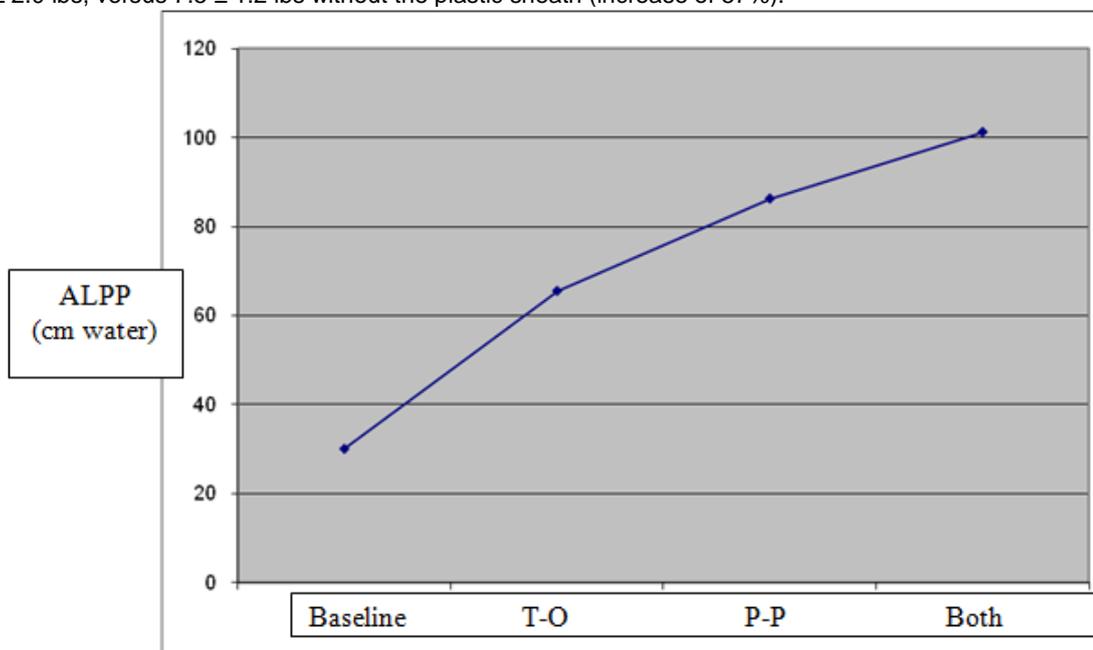
The Coloplast Virtue™ Ventral Urethral Elevation Sling System is a permanent, synthetic suburethral sling composed of knitted, monofilament polypropylene. The sling measures 5.5cm x 7 cm, with 1.5 cm x 25 cm superior extensions and 1.5 cm x 22.5 cm inferior extensions. Through a 5-cm perineal incision, the bulbous urethra and the descending pubic rami were exposed bilaterally leaving the bulbospongiosus muscle intact. The bulbous urethra was detached from the central tendon to the perineal body, to allow ventral urethral elevation by the transobturator component of the sling. The inferior extensions were passed via an inside-out transobturator (T-O) approach using a hooked needle passer. The superior extensions are passed using a pre-pubic approach (P-P), with the same passer.

In 4 male cadavers, abdominal leak point pressure (ALPP) was measured via 7 French transurethral urodynamic catheter at baseline, and after transperineal placement of the Virtue™ sling Measurements with tensioning of only the T-O extensions, only the P-P extensions, and with tensioning of both components were recorded. Additionally, the pull force needed to tension the sling was measured for both the P-P and T-O components,, These measurements were taken with and without the plastic sheath covering the sling extensions. Values are presented as mean ± standard error.

Results

Sling placement took less than 20 minutes in each specimen. Baseline ALPP averaged 30 ± 17 cm water. Tightening only of the T-O extensions mediated an increase in ALPP to 66 ± 49 cm water. Tightening only of the P-P extensions mediated an increase in ALPP to 86 ± 48 cm water. Tightening of both components increased the ALPP to a mean of 101 ± 39 cm water.

Tensioning of the P-P component required an average pull force of 3.1 ± 1.5 lbs with the protective plastic sheath, and required an average pull force of 4.8 ± 1.6 lbs without the sheath (increase of 54%). T-O tensioning required a pull strength of 4.8 ± 2.0 lbs, versus 7.5 ± 1.2 lbs without the plastic sheath (increase of 57%).



T-O = transobturator sling tensioning only

P-P = prepubic sling tensioning only

Both = T-O and P-P sling tensioning

Interpretation of results

Each of the two main sling components mediated an increase in urethral resistance as measure by ALPP. The increase in ALPP was approximately additive, increasing by 36 cm water (120%) with T-O tensioning, and increasing by 56 cm water (187%) with P-P tensioning. Tightening of both components simultaneously resulted in an increase in ALPP of 71 cm water (237%) compared to baseline. Combining both the T-O and P-P tensioning in 1 device appears to increase the urodynamic improvement greater than either component alone.

Unlike the outside in T-O male sling, the inside-out passage of the T-O component makes urethral injury highly unlikely. Moreover, an inside-out pass allows precise placement of the sling at the level of the bulbous urethra, as the sling passage is begun just lateral to the urethra under direct vision. The pre-pubic passage should eliminate the risk of bladder injury, which can occur with retropubic needle passage.

The plastic protective sheath allows sling positioning with approximately half the tension compared to a bare sling. However, the sling remained adjustable (tightening and loosening) even with the sheath removed.

Concluding message

The Virtue™ Sling provides urethral compression via a straightforward pre-pubic approach, and ventral elevation of the bulbous urethra using an inside-out T-O approach, avoiding the risks of bone screws and retropubic needle passage. Each component (urethral compression and bulbous urethral elevation) appears to contribute, in approximately additive fashion, to increasing urethral resistance to leakage.

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<i>Is this a clinical trial?</i>	No
<i>What were the subjects in the study?</i>	HUMAN
<i>Was this study approved by an ethics committee?</i>	No
<i>This study did not require ethics committee approval because</i>	Cadaver study only
<i>Was the Declaration of Helsinki followed?</i>	No
<i>This study did not follow the Declaration of Helsinki in the sense that</i>	Cadaveric study only
<i>Was informed consent obtained from the patients?</i>	No