Clinical Article Summary

A New Quadratic Sling for Male Stress Incontinence: Retrograde Leak Point Pressure as a Measure of Urethral Resistance

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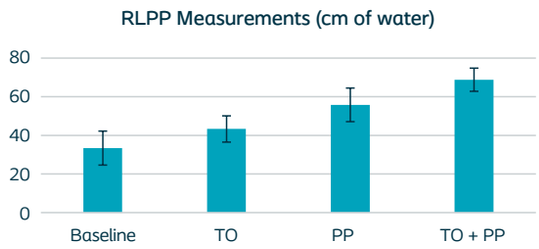
Abstract

Purpose: Objective methods are essential for evaluating post-prostatectomy incontinence. While symptom score and pad weight may be the most useful methods to evaluate preoperative vs postoperative continence, neither is useful for guiding intraoperative sling tension. The Virtue quadratic sling (Coloplast, Humlebaek, Denmark) is a new device for treating post-prostatectomy incontinence that combines a transobturator and prepubic surgical approach. We examined urethral resistance by measuring retrograde leak point pressure during key portions of the surgery.

Materials and Methods: A total of 22 consecutive men who elected to undergo Virtue sling surgery were evaluated with retrograde leak point pressure before and during the surgery. Retrograde leak point pressure was measured via perfusion sphincterometry at baseline, after transobturator tensioning, after prepubic tensioning, and after transobturator and prepubic arms were secured in place.

Results: Mean patient age was 70 years. Mean baseline retrograde leak point pressure was 33.4 ± 8.8 cm water. After transobturator tensioning (TO), mean retrograde leak point pressure increased to 43.3 ± 6.8 cm water. After prepubic tensioning (PP) mean retrograde leak point pressure was 55.8 ± 8.7, and final retrograde leak point pressure after transobturator and prepubic fixation (TO + PP) increased to 68.8 ± 6.0 cm water. Each mean retrograde leak point pressure value was significantly higher than the preceding value.

Conclusions: The Virtue sling provides ventral urethral elevation using a transobturator approach, and a long segment of urethral compression against the genitourinary diaphragm via a straightforward prepubic technique without the risks of bone screws or retropubic needle passage. Transobturator and prepubic components of the quadratic fixation contributed to increasing urethral resistance as measured by intraoperative retrograde leak point pressure. This quadratic technique has a potentially greater ability to provide urethral compression than does a purely perineal or transobturator sling.



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Coloplast Key Takeaways

- Tensioning the prepubic arms (PP) of the Virtue® Male Sling creates urethral compression which causes greater resistance than tensioning the transobturator arms (TO) which creates urethral relocation.
- Combining both the TO and PP approach by the tensioning and fixation of the arms in a quadratic sling creates greater urethral resistance than the independent actions of either mechanism.
- The Virtue Male Sling provides both the benefits of elevation and compression for the treatment of stress urinary incontinence.

Virtue® Male Sling System
Brief Statement

Indications
The Virtue Male Sling System is an implantable, suburethral support sling indicated for the treatment of male stress urinary incontinence (SUI).

Contraindications
The Virtue Male Sling is contraindicated in patients with one or more of the following conditions: Documented hypersensitivity or allergic reaction to polypropylene. Active infection, including untreated urinary tract and/or infection in the operative field. Patients with untreated or serious blood coagulation disorders. Patients with obstructive uropathy. Patients under the age of 18.

Warnings and Precautions
It is the responsibility of the physician to advise prospective patients prior to surgery, of the warnings associated with the use of this product and the associated surgical risks. The Virtue Male Sling should only be implanted by physicians experienced in the surgical procedures and techniques involving placement of stress urinary incontinence slings.

A thorough assessment of each patient should be conducted, based on current medical practice guidelines, to determine the suitability of a sling procedure. Patients should be counseled that the Virtue Male Sling is permanent.

It is recommended that sling candidates are evaluated for overactive bladder syndrome and post-void residual. Residual sphincteric function should be considered prior to sling surgery.

It is recommended that sling candidates are evaluated for the presence of bladder neck contracture or urethral strictures prior to sling surgery.

The patient should be counseled to consider conservative incontinence treatments as well as other treatments.

Sling associated complications may result in one or more revision surgeries which may lead to partial or complete removal of the sling. Complete removal of the sling may not always be possible, and removal may not fully correct these complications. De novo complications may occur.

The additional risks versus benefits of Virtue Male Sling should be considered in patients with one or more of the following conditions: Auto-immune disease, Coagulation disorder, Connective tissue disease, Debilitated or immunocompromised state, Diabetes, Pelvic radiation therapy, Physical characteristics (e.g., body mass index), Renal insufficiency, Smoking related underlying conditions.

Potential Complications
Adverse events are known to occur with sling procedures and implants. Adverse events following sling implantation may be immediate or delayed, localized or systemic, de novo or worsening, acute or chronic, transient or permanent.

Adverse events may include but are not limited to: Allergic reaction, hypersensitivity, Autoinflammatory / autoimmunity syndrome, Bladder storage symptoms (e.g., increased daytime frequency, urgency, nocturia, overactive bladder, urinary incontinence), Bleeding/ hemorrhage or hematoma, Delayed/ impaired/abnormal wound healing, Exposure, extrusion or erosion of sling into other structures or organs, Fistula formation, Foreign body granuloma/scar tissue formation, Genital paresthesia, Infection, Inflammation/irritation, Male dyspareunia, Necrosis, Neuromuscular disorder, Palpable mesh, Pain, Perforation or injury to adjacent muscles, nerves, vessels, structures, or organs (e.g., bone, bladder, urethra, ureters, bowel), Seroma, Sexual dysfunction, Sling migration, Urinary tract infection, Urinary tract obstruction, Voiding symptoms (e.g., dysuria, urinary retention, incomplete emptying, bladder outlet obstruction, straining, position-dependent voiding, slow stream).

The information provided is not comprehensive with regard to product risks. For a comprehensive listing of indications, contraindications, warnings, precautions, and adverse events refer to the product's Instructions for Use. Alternatively, you may contact a Coloplast representative at 1-800-258-3476 and/or visit the company website at www.coloplast.com.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

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