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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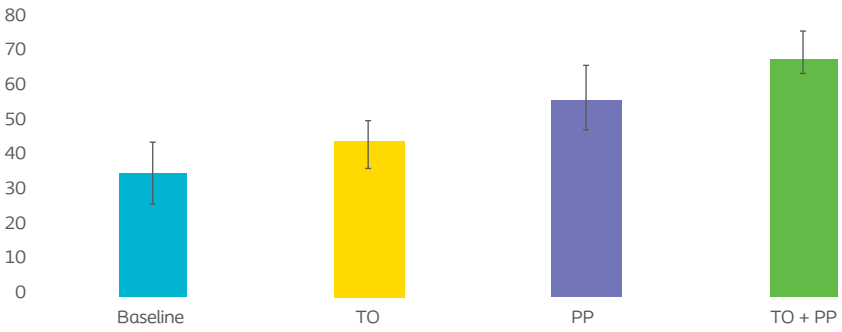
ABSTRACT

Introduction: 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 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.

RLPP Measurements
(cm of water)



Results: Mean patient age was 70 years. Mean baseline retrograde leak point pressure was 33.4 6 8.8 cm water. After transobturator tensioning, mean retro-grade leak point pressure increased to 43.3 6 6.8 cm water. After prepubic tensioning mean retrograde leak point pressure was 55.8 6 8.7, and final retro-grade leak point pressure after transobturator and prepubic fixation increased to 68.8 6 6.0 cm water. Each mean retrograde leak point pressure value was significantly higher than the preceding value.

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Conclusion: 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.

KEY TAKEAWAYS

- Tensioning the prepubic arms (PP) of the Virtue 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.

VIRTUE® MALE SLING SYSTEM

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

Contraindications:
It is the responsibility of the surgeon to advise the prospective patients or their representatives, prior to surgery, of the contraindications associated with the use of this product. This product is contraindicated for patients with urinary tract infections or urinary tract obstruction; blood coagulation disorders or prescribed anticoagulation therapy; obstructive uropathy; or, are under the age of 18.

Warnings and Precautions:
It is the responsibility of the surgeon to advise the prospective patients or their representatives, prior to surgery, of the possible warnings associated with the use of this product.

Potential Complications:

As with all foreign bodies, the Virtue sling system is likely to exacerbate any existing infection. Transitory local irritation at the wound site and a foreign body response may occur. The resulting response could lead to wound dehiscence, extrusion, erosion, inflammation or fistula formation.

The following complications are known to occur with synthetic slings:
• urethral erosion
• infection
• bladder, urethra, vessel and nerve perforation

Known risks of incontinence surgical procedures include extrusion, erosion, infection, sling migration, pain, transient or permanent retention, bladder outlet obstruction, and, continued stress urinary incontinence and persistent or new overactive bladder symptoms.

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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