Clinical Article Summary

The Virtue Sling—A New Quadratic Sling for Postprostatectomy Incontinence—Results of a Multinational Clinical Trial

Craig Comiter, MD,
Eugene Rhee, MD MBA
Le-Mai Tu, MD
Sender Herschorn, MD
Victor Nitti, MD

The study evaluates initial clinical results of a novel fixation mechanism used to prevent early sling loosening. It reports the 1-year results of the fixated quadratic sling and compares it with those of an unfixed device.

Abstract

Purpose: To successfully perform male sling surgery, and the surgery must achieve proximal urethral relocation and/or bulbar urethral compression. The Virtue quadratic sling is a novel device that incorporates both mechanisms of action. We report the 1-year results of the Virtue sling with fixation and compare it with the results of the initial "unfixed" sling trial.

Methods: A prospective trial was performed to assess the efficacy and safety of the Virtue sling. Objective success was predefined as >50% decrease in 24-hour pad weight and subjective success as a score of "much" or "very much" better on the Patient Global Impression of Improvement. Subgroups were analyzed by baseline incontinence: mild (<100 g), moderate (100-400 g), and severe (>400 g). After analysis of the 1-year data, a second clinical trial incorporating a novel "fixation" technique was performed, with similar outcome measures.

Results: In the initial cohort, subjective and objective successes were achieved in 41.9% at 12 months. Median pad weight reduction was 51.1% at 12 months and varied with the degree of baseline leakage. In the fixation cohort, subjective and objective successes were 70.9% and 79.2%, median pad weight reduction was 88.3% at 12 months, and efficacy was similar regardless of baseline incontinence. There were no cases of prolonged retention and no severe adverse events.

Conclusion: The Virtue sling with fixation is a safe and efficacious treatment for postprostatectomy incontinence. Superior 12-month results compared with the unfixed device demonstrate that fixation prevents early sling loosening.

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Coloplast Key Takeaways

- The Virtue® fixation sling is the only male incontinence device that has reported significant improvement in 24-hour pad weight up to 1 year postoperatively.
- The combined mechanisms of compression and proximal urethral relocation increase urethral resistance more than a purely transobturator sling.
- Fixation of the Virtue sling is a crucial step in the surgical technique leading to improved patient outcomes at the 1-year postoperative follow-up mark.
- 80% of mild incontinence patients, 83% of moderate incontinence patients, and 71% of severe incontinence patients realized a 50% or greater reduction in pad weight at 1 year post-operation with quadratic sling fixation in this study.
- With proper fixation of the Virtue male sling, 46% of patients in this study were considered cured at the 1-year postoperative mark.

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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Coloplast Corp. Minneapolis, MN 55411 / Interventional Urology Surgical Support 1-800-258-3476

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