Clinical Article Summary

Virtue Male Sling for Post-Prostatectomy Stress Incontinence: A Prospective Evaluation and Mid-Term Outcomes

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Abstract

Objective: To evaluate the efficacy and safety of the Virtue® male sling (Coloplast, Humlebaek, Denmark) in a cohort of patients affected by post-prostatectomy stress urinary incontinence (SUI).

Methods: All 29 consecutive patients treated with a Virtue male sling at our Institution between July 2012 and October 2013 were included in the present prospective, non-randomized study. Patients were evaluated preoperatively and at 1, 3, 6, 12, 24 and 36 months after surgery using a 24-h pad weight test, the International Consultation on Incontinence short-form questionnaire (ICIQ-SF), Urinary Symptom Profile (USP) questionnaire, a bladder diary, uroflowmetry and the Patient Global Impression of Improvement (PGI-I) and Patient Global Impression of Severity questionnaires.

Results: The mean patient age was 65.5 years. A total of 72.4% of patients had preoperative mild incontinence (1-2 pads/day), while nine patients used 3-5 pads/day. There were a total of 17 complications, which occurred in 29 patients (58.6%); all were Clavien-Dindo grade I. At 12-month follow-up patients showed a significant improvement in 24-h pad test (128.6 vs 2.5 g), number of pads per day (2 vs 0), ICIQ-SF score (14.3 vs 0.9) and USP score for SUI (4 vs 0), and outcomes remained stable at 36 months. At last follow-up, the median score on the PGI-I questionnaire was 1 (very much better).

Conclusion: The Virtue male sling is an effective treatment option for low to moderate post-prostatectomy incontinence.

Figure 1: Mean 24-h pad weight over the 12 months of follow-up

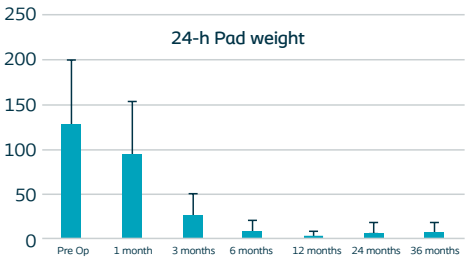


Figure 2: Mean number of pads/day over the 12 months of follow-up

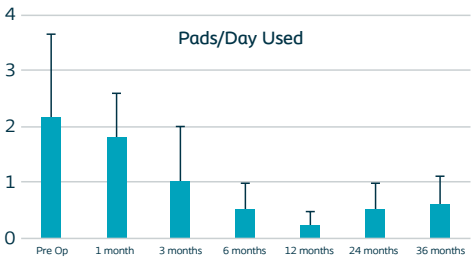
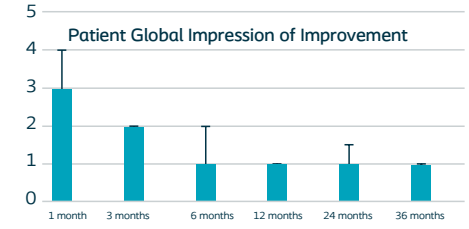


Figure 3: Results of Patient's Global Impression of Improvement questionnaire over the 12 months of follow-up



At a mean (range) follow-up of 14.5 (12-22) months, the patients had considerable improvements in 24-h pad weight, numbers of pads/day, PG-I scores (Figures 1-3)

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Coloplast Key Takeaways

- 82.7% of patients in this study used 0 pads/day at 12 months post-operation with the Virtue® sling.
- At the 3-year follow-up, patient pad use was a maximum of 1 pad/day.
- 86.2% of patients reported their condition as very much better (PGI-I score 1) up to 3 years following their Virtue sling placement.
- The Virtue male sling has a reconstructive rather than merely obstructive role by providing bidirectional compression and elevation of the bulbous urethra.
- The goal of the Virtue suburethral sling is to restore position and function of the pelvic floor through outflow obstruction and urethra repositioning.
- In this study, all complications were grade I on the Clavien-Dindo scale supporting Virtue as a safe treatment for patients suffering from mild and moderate 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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Coloplast Corp. Minneapolis, MN 55411 / Interventional Urology Surgical Support 1-800-258-3476

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