CLINICAL ARTICLE SUMMARY

VIRTUE MALE SLING OUTCOMES AND APPLICATION TO A CONTEMPORARY NOMOGRAM

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ABSTRACT

Introduction: To report outcomes of our Virtue male sling series and evaluate predictors of surgical success and failure. We also retrofit the Male Stress Incontinence Grading Scale (MSIGS) refined nomogram, including the standing cough test (SCT), to assess its application to our cohort.

Materials and Methods: A retrospective review was completed at a single institution over a 4-year period of all Virtue male slings implanted for stress urinary incontinence (SUI). Patient demographics including pad usage per day (PPD) and MSIGS were obtained on all patients after their bladders were filled cystoscopically. Failure was defined as > 1 PPD and/or conversion to another anti-incontinence procedure. Incidence, management, and outcomes of complications were also evaluated.

Results: 46 men who underwent Virtue male sling at a median follow up of 15.6 months were analyzed with an objective success rate of 78% and a subjective success rate of 85%. Preoperative predictors of surgical success were ability to stop stream on physical exam, lack of total incontinence and no history of posterior urethral stricture. MSIGS alone was not predictive of sling success or failure. Penile numbness occurred in 11% of patients and reoperation with incision of the sutured together transobturator arms improved sensation in all patients.

Conclusion: Virtue male sling has high objective and subjective success rates with a manageable side effect profile. Evidence of residual sphincteric function appears to be more predictive of sling success rather than MSIGS

COLOPLAST KEY TAKEAWAYS

- Incontinence rates at 12 months post radical prostatectomy (RP) can be as high as 31%, yet only 5% of RP patients will elect surgical repair for SUI.
- MSIGS alone was not predictive of sling success or failure (underestimated success for the Virtue® Male Sling)
- While it has been recently shown that patients with higher MSIGS have better outcomes with AUS over sling, this study identified a subset of patients with objectively more severe SUI that still appear to respond well to Virtue.
- Pre-op predictors of success were: 1) Ability to stop stream on physical exam, 2) Lack of total incontinence, and 3) No history of posterior urethral stricture.
- History of radiation is frequently described as being predictive of sling failure, however authors did not find this to be a risk factor in their cohort on univariate analysis.
- Risk factors for surgical failure on univariate analysis included: 1) history of posterior stricture, 2) total incontinence, and 3) inability to stop a stream mid void. Each of these risk factors likely reflects poor sphincteric function.
- At 15.6 months median follow up, Virtue® Male Sling has high objective (78%) and subjective (85%) success rates with a manageable side effect profile.
- The mechanism of the Virtue Male Sling is two-fold including elevation of the urethra, and compression against the pubic bone.
- The larger surface area of the Virtue® Male Sling is unique and allows for revision if a patient does not get to desired continence level.

Virtue® Male Sling System
BRIEF STATEMENT

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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