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VIRTUE® QUADRATIC MALE SLING: AN INNOVATIVE TREATMENT FOR POST-PROSTATECTOMY INCONTINENCE

Hypothesis / aims of study

Objective methods of assessing stress urinary incontinence (SUI) are essential for proper evaluation of post-prostatectomy incontinence (PPI) and measuring therapy response. When given a choice regarding surgical treatment of PPI, most patients choose sling surgery, in avoidance of receiving a mechanical device.[1] While symptom score and pad weight may be the most useful methods to evaluate pre-operative versus post-operative SUI status, neither can be used for intra-operative guidance regarding proper sling tensioning. The Virtue Male Sling is an innovative, minimally invasive 4 arm mesh sling comprised of 2 transobturator (TO) arms and two prepubic (PP) arms. The surgical advantages to this sling include: 1) VENTRAL urethral elevation and DISTAL urethral compression; 2) the procedure is completed with one, universal passer; and 3) the passer is designed to efficiently and safely facilitate graft placement via an inside-out TO approach. Sling resistance to leakage was measured via retrograde leak point pressure (RLPP) during the key intra-operative fixation steps. This video shows the evolved surgical procedure, and an Alexis® wound retractor was used, which provides novel exposure. The Alexis is a cylindrical wound retractor, which has two beneficial properties: 1) it may decrease the incidence of skin infections; and 2) the entire case can be completed with the retractor in place to ensure excellent exposure.

Study design, materials and methods

As part of the evaluation of a new surgical technique for treating PPI, men who elected Virtue male sling surgery were evaluated with RLPP prior to surgery, and at critical stages of sling fixation during surgery. RLPP was measured via perfusion sphincterometry. With a 12F foley catheter in the penile urethra, and the balloon inflated with 1 cc water, a 1-liter saline bag was connected to the catheter via cystoscopy tubing. The RLPP was recorded in centimeters water as the height of the fluid column from top of the water level of the bag to just above the symphysis. RLPP was measured: 1) at baseline (sling arms are passed, but not tensioned); 2) after the TO arms were tensioned; 3) after the PP arms were tensioned (assistant pulling PP arms); and 4) after PP arms were secured in final position. Tensioning and fixation were performed as follows: for the TO arms, re-enter the perineal incision in the subcutaneous space with a tonsil clamp and tunnel to the ipsilateral arm exit site incision. Grasp the TO arm with the tonsil clamp and pull back through the new subcutaneous plane to the perineal incision. Repeat on contralateral side. Trim the mesh within the perineal incision. The PP arms are fixated to the surface of the pubic rami bilaterally with a figure eight 0 prolene suture, as the arms are tensioned at minimum 60cm water.

Results

Each RLPP measurement is significantly higher than the preceding value.

Interpretation of results

The Virtue quadratic sling provides elongated distal urethral compression using a straightforward prepubic (PP) approach, and ventral elevation of the bulbous urethra using a transobturator (TO) approach.

Concluding message

Virtue provides a long segment of urethral coaptation while avoiding the risks associated with bone screws and retropubic needle passage. The Alexis wound retractor provides better exposure throughout the complete procedure, and may also reduce wound site infections. Fixation of both the TO and PP components as an evolved surgical modification provides quadratic fixation contributing to increased urethral resistance, as measured by intra-operative RLPP.

References

1. Kumar, A., Litt, E. R., Ballert, K. N. et al.: Artificial urinary sphincter versus male sling for post-prostatectomy incontinence--what do patients choose? J Urol, 181: 1231, 2009

Specify source of funding or grant	**No funding**
Is this a clinical trial?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**No**
This study did not require ethics committee approval because	**It is a review of a surgical procedure with a 510K cleared product.**
Was the Declaration of Helsinki followed?	**No**
This study did not follow the Declaration of Helsinki in the sense that	**This was not a clinical study.**
Was informed consent obtained from the patients?	**Yes**