

VERITAS® COLLAGEN MATRIX FOR USE AS A UROLOGICAL SLING: RESULTS FROM A PROSPECTIVE STUDY AT THREE U.S. SITES**Hypothesis / aims of study**

Sub-urethral sling procedures are currently recognized as the treatment of choice for the correction of stress urinary incontinence (SUI) with or without intrinsic sphincter deficiency (ISD), but the ideal material has yet to be determined. Although synthetic materials and the TVT procedure presently dominate the field, many physicians continue to prefer slings made of biologic materials including autografts, allografts (cadaveric dermis) and xenografts (bovine and porcine materials) [1]. The Veritas Collagen Matrix (VCM), a non-crosslinked, propylene oxide-treated, acellular material composed of bovine pericardium, was evaluated to determine its safety and efficacy as a urological sling. We present 12-month follow-up data on the VCM sling from a prospective, non-randomized investigation at three U.S. sites.

Study design, materials and methods

This study was conducted with approval by the institutional review boards of the three study centers. From June 2001 to November 2002, 45 women underwent implantation of the VCM sling; 43 of whom are evaluated. Only patients with 12-month follow-up are included in the analysis (n=35). A preoperative evaluation consisted of a complete history and physical exam, SUI symptom assessment, Stamey continence status grading, provocative pad testing, 3-day voiding diaries and urodynamic evaluation (CMG). A VCM sling (sizes ranged from 2x3 cm to 2x8 cm) was implanted in each patient. Postoperatively, patients were evaluated at 1 week, 6 weeks, 3 months, 6 months and one year where changes in physical examination, symptom assessment, vital signs, continence grade and voiding diaries were evaluated and pad tests were performed. The safety of the VCM implant was assessed by tracking adverse events intraoperatively and postoperatively in all patients.

Results

Of the 35 patients, 5 (14%) underwent only the sling procedure, 30 (86%) underwent concomitant procedures including anterior colporrhaphy (cystocele repair), posterior colporrhaphy (rectocele repair), enterocele repair, and hysterectomy. Patients had a mean age of 46.8 years (range 34-75) and a mean BMI of 28.2 (range 19-35), with an average of 7.2 years (range 0.5-25) of prior SUI complaints and an average of 3.5 (± 2.2) SUI episodes per day. At 12-month follow-up, 29 patients (83%) were dry or improved according the continence grading scale, 3 (8.5%) reported substantial improvement and 3 (8.5%) remained the same. There were also significant reductions in the numbers of patients experiencing frequency, timing, urge, and nocturia symptoms. In 31 patients, average self-reported stress events over a 3-day period decreased from 6.26 (± 4.89) pre-procedure to 0.74 (± 2.18) at 12 months. There were no material-related adverse events such as graft infections, extrusions or rejections.

Interpretation of results

The dry/improved rate at 12-month follow-up was 83% according to the Stamey continence status grading scale, with 91% of women reporting substantial improvement. These rates fall within the range of published success rates of 65-98% for sub-urethral sling procedures [2]. The success rates of this study are partially shaped by a high attrition rate, the inclusion of patient perspectives in measuring outcomes, and the inability of the Stamey grading scale to accurately reflect clinical improvement. Analysis of reductions in symptoms, precipitants causing stress events, numbers of self-reported events, and urine lost during provocative pad testing further demonstrate the efficacy of the VCM sling. The safety of the VCM sling is demonstrated by the absence of patient adverse events, including graft infections, extrusions and rejections.

Concluding message

Our findings demonstrate that the Veritas Collagen Matrix sling is safe and efficacious in the treatment of stress urinary incontinence, with 91% of women experiencing resolution or substantial relief of stress symptoms.

References

1. Pelvic floor dysfunction management practice patterns: a survey of members of the International Urogynecological Association. *Int Urogynecol J Pelvic Floor Dysfunct*, 13: 319, 2002.
2. M. Pudo vaginal and sub urethral slings: review. *J Gynecol Obstet Biol Reprod (Paris)*. 2002 Apr; 31(2 Pt 1): 131-43.

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