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A RETROSPECTIVE REVIEW OF SURGICAL MORBIDITY AND LONG-TERM PATIENT SATISFACTION WITH TWO SUB-URETHRAL SLINGS FOR STRESS URINARY INCONTINENCE: TVT-O VERSUS CONTASURE NEEDLELESS. (SINGLE INCISION TOT).

Objective:

The purpose of this study was to retrospectively review and compare two different surgical techniques for female stress incontinence, and the levels of patient satisfaction associated with each: TVT-O (Gynecare) versus Contasure Needleless (Neomedic Inc.). Our objective was to determine whether or not the Needleless procedure was equal in long-term efficacy to the TVT-O.

Background:

There are numerous sub-urethral slings available today, and several randomized prospective studies have documented the efficacy of one or another of these slings to other slings which have been available for a longer period of time. What is lacking are the long-term data verifying the success of these slings in the context of patient satisfaction, morbidity and recovery.

Material and Methods:

From June 2006 to January 2009, 154 women were treated for pelvic floor disease (Genuine Stress urinary incontinence [SUI], with or without associated prolapse). Of the 154 women, 76 were treated with the TVT-O, and 78 were treated with the Contasure Needleless.

We evaluated the age, weight, ethnicity and the presence or absence of a concomitant procedure. A symptom questionnaire, physical examination and urodynamic studies were performed pre-operatively on all patients. Objective outcomes were assessed by clinical examination and with a urodynamic evaluation six months postoperatively. Annual physical examinations were performed thereafter.

Subjective outcomes were assessed by interviewing the patients, as well as having each patient fill out questionnaires at three, twelve and 24 months postoperatively. Patients were asked to categorize their postoperative pain and urinary symptoms, as well as categorizing their level of satisfaction with the surgery by selecting one of three grades: highly satisfied, satisfied, or unsatisfied. Success was demonstrated by the patients being either satisfied or highly satisfied 24 months post-operatively.

All procedures were performed by the same surgeon in the same hospital. Patients with ISD or recurrent SUI (previous failed incontinence procedure) were excluded.

Patient demographics are illustrated in Table1:

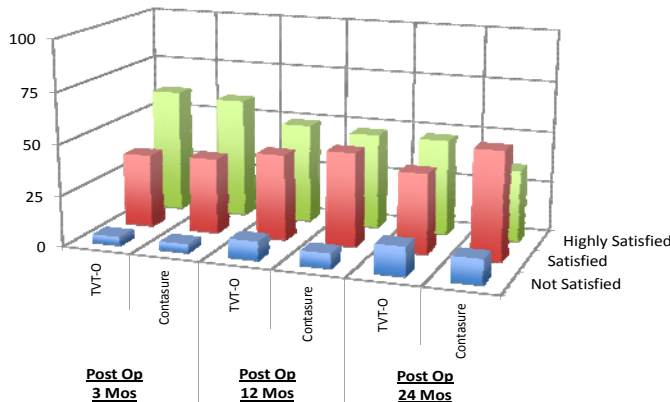
Demographics

	TVT-O	CONTASURE	p Value
Age (mean)	52.4	54.7	0.96
Weight (mean)	174.8	167.9	0.21
Race			0.39
Caucasian	69 (91%)	75 (96%)	
African Am	4 (5%)	2 (3%)	
Other	3 (4%)	1 (1%)	
Concomitant Procedure			0.41
Yes	38 (50%)	32 (43%)	
No	38 (50%)	42 (57%)	

Results:

The results are illustrated in Tables 2 and 3. 70 of the patients had additional surgery at the time of sling placement for one or more of the following: Cystocele, Rectocele, apical detachment or uterine prolapse. There were no significant differences between the two groups in regard to additional procedures. There were no major intra-operative or post-operative complications. There was a statistically significant difference in the post-operative pain experienced by the patients, with the Needleless sling being significantly less painful than the TVT-O (p=0.03). The follow up time was 24 months. The success rate was: TVT-O (84%); Contasure Needleless (87.5%).

Patient Reported Satisfaction



Surgical Outcomes

	TVT-O	CONTASURE	p Value
Complications			0.89
None	72 (95%)	74 (96%)	
Bleeding	1 (1%)	1 (1%)	
Retention	3 (4%)	2 (3%)	
Surgical Pain			0.03
None	32 (42%)	53 (68%)	
Minimal	19 (25%)	11 (14%)	
Moderate	4 (5%)	3 (4%)	
Severe	5 (7%)	3 (4%)	

Conclusion:

The present data suggest that the TVT-O and Needleless sling have the same surgical outcomes, and overall patient satisfaction is acceptable for both groups. As with all slings, patient satisfaction (success) seems to very gradually decrease over time, however, satisfaction with the Needleless sling is consistent with all of the long term data we have for other slings with those data available. The surgical pain scale shows a significantly lower incidence of pain with the Needleless group, so patient morbidity and recovery are favorably affected. We believe that our data show the Needleless sling is at least equal to the long term clinical efficacy of the TVT-O. Given the significant decrease in patient morbidity, along with the cost savings compared with other slings, the Contasure Needleless sling remains an excellent first line choice for the treatment of Genuine Stress Urinary Incontinence.