

A RETROSPECTIVE REVIEW OF THE CONTASURE NEEDLELESS SLING SYSTEM

A Retrospective Review of the ContaSure Needleless Sling System

Objective: To determine the 6 week and 3 month subjective cure rates for the single incision ContaSure Needleless Sling.

Methods: A retrospective chart review was performed on all patients who underwent placement of a single incision ContaSure Needleless Sling System for Stress Urinary Incontinence at our institution from August 2008 to March 2010. A total of 69 patients were identified. Eight patients were excluded because they did not demonstrate pre-operative stress urinary incontinence, either by Urodynamic evaluation or by subjective complaint. The eight excluded patients had a sling placed for prophylaxis at the time of their pelvic organ prolapse repair. The remaining 61 patient charts were then reviewed for demographic data, subjective cure rates at six weeks and three months, de-novo urgency, frequency, and nocturia. There were 61 patient charts reviewed for the 6 week post-operative visit. There were 35 patient charts reviewed for the three month visit. Twenty-three patients were lost to follow up. Three patients had not yet reached 3 months post-procedure.

Results:

Table 1: Pre-Operative Data

| Total Patients Included | 61 |
|-------------------------|--------------|
| Age | 51.43 (mean) |
| BMI | 27.5 (mean) |
| Tobacco Use | 9 (14.75%) |
| Frequency | 20 (32.79%) |
| Urgency | 34 (55.74%) |
| Urge Incontinence | 28 (45.90%) |
| Nocturia | 17 (27.87%) |

Table 2: Six Week Post-Operative Data

| Total Patients Included | 61 |
|---------------------------|-------------|
| Subjective Cure | 50 (81.97%) |
| Frequency | 11 (18.03%) |
| De-Novo Frequency | 4 (6.56%) |
| Urgency | 18 (29.51%) |
| De-Novo Urgency | 4 (6.56%) |
| Urge Incontinence | 12 (19.67%) |
| De-Novo Urge Incontinence | 2 (3.28%) |
| Nocturia | 8 (13.11%) |
| De-Novo Nocturia | 0 (0.00%) |
| Mesh Erosion | 1 (1.64%) |

Table 3: Three Month Post-Operative Data

| Total Patients Included | 35 |
|---------------------------|-------------|
| Subjective Cure | 28 (80.00%) |
| Frequency | 6 (17.14%) |
| De-Novo Frequency | 2 (5.71%) |
| Urgency | 10 (28.57%) |
| De-Novo Urgency | 2 (5.71%) |
| Urge Incontinence | 6 (17.14%) |
| De-Novo Urge Incontinence | 1 (2.86%) |
| Nocturia | 7 (20.00%) |
| De-Novo Nocturia | 3 (8.57%) |
| Mesh Erosion | 1 (2.86%) |

Interpretation of Results:

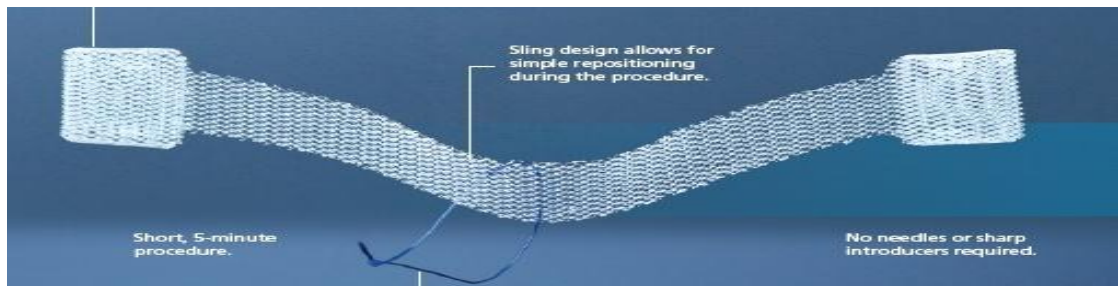
At six weeks post-operatively 81.97% of patients considered themselves cured. There was an 18.03% rate of de-novo urinary frequency. There was a 6.56% rate of de-novo urinary urgency. There was a 3.28% rate of de-novo urinary urge incontinence. There was a 0% rate of de-novo nocturia. There was a 1.64% rate of mesh erosion. The mesh erosion was treated by trimming the exposed mesh in office. The patient has not yet had the 3 month visit.

At 3 months post-operatively 80.00% of patients considered themselves cured. There was a 5.71% rate of de-novo urinary frequency. There was a 5.71% rate of de-novo urinary urgency. There was a 2.86% rate of de-novo urinary urge incontinence. There was an 8.57% rate of de-novo nocturia. There was a 1.64% rate of mesh erosion. The one patient who had a mesh erosion at 3 months, did not have a mesh erosion at 6 weeks. The mesh erosion was treated by trimming the exposed mesh in office.

Concluding Message:

The ContaSure Needleless Sling is a single incision sling made of a 11.4 cm x 1.2 cm monofilament, macroporous, AMID Type I, polypropylene mesh with 2.2 cm wide "Pocket Positioning Anchors" on both ends. The pockets allow the device to be introduced with a standard forceps instrument eliminating the need for sharp needle introducers (fig 1). With six week and 3 month success rates of 81.97% and 80.00% respectively, the ContaSure Needleless Sling is comparable to the success rates of the traditional TOT.

Figure 1



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| <i>Specify source of funding or grant</i> | This is abstract was funded by an unrestricted grant by Neomedic International. |
| <i>Is this a clinical trial?</i> | No |
| <i>What were the subjects in the study?</i> | HUMAN |
| <i>Was this study approved by an ethics committee?</i> | Yes |
| <i>Specify Name of Ethics Committee</i> | Sterling Institutional Review Board |
| <i>Was the Declaration of Helsinki followed?</i> | Yes |
| <i>Was informed consent obtained from the patients?</i> | No |