

SURGERY FOR STRESS INCONTINENCE - A NOVEL "NEEDLELESS" SINGLE-INCISION SLING SYSTEM: RESULTS OF 20 PATIENTS

Hypothesis / aims of study

To evaluate the safety and efficacy of a minimally-invasive single incision mid-urethral sling which requires no retro-pubic or groin needle passage for the treatment of female stress urinary incontinence.

Study design, materials and methods

A retrospective evaluation of 20 patients who were treated for stress urinary incontinence (SUI) by placement of the ContaSure™ Needleless Sling System (Neomedic International Spain). Data from this summary includes all subjects who were treated with the Needleless sling from September 2007 until November 2008. All female patients who underwent treatment for stress or mixed urinary incontinence with the Needleless sling with or without concomitant procedures were included in the study. A retrospective chart review was performed and data was collected on the pre-operative evaluation, including history and physical and urodynamic studies.

The sling is made of a 11.4 cm x 1.2 cm, 100% monofilament macroporous AMID I polypropylene with 2.2 cm wide "Pocket Positioning Anchors" on both ends. The pockets allow the device to be introduced with a standard forceps instrument thereby eliminating the need for sharp needle introducers (Fig. 1). The pockets provide firm anchoring in tissue and also facilitate intra-operative repositioning.

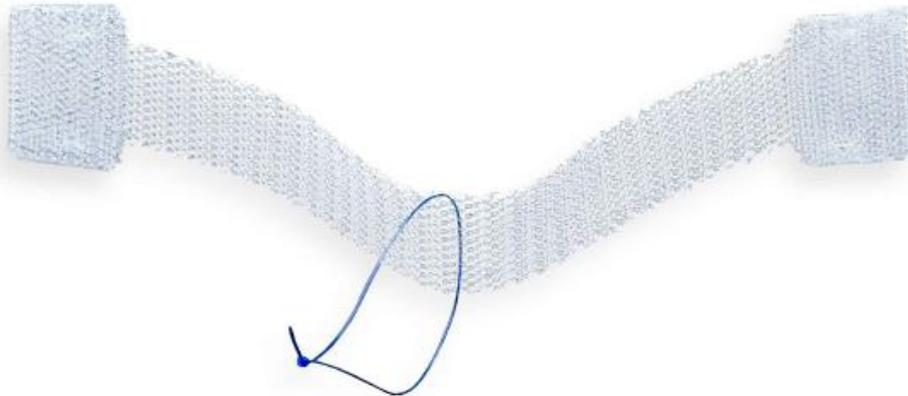


Fig. 1

Patients were placed in the dorsal lithotomy position and general anesthesia was administered. The suburethral tissues were infiltrated with a local anesthetic solution and an approximately 1.5 cm longitudinal suburethral incision was made. The vaginal submucosa was dissected with Metzenbaum scissors to the point that the scissor tips were in contact with the ischiopubic ramus. A pair of surgical forceps (tonsil) was inserted into the pocket of the sling, and the pocket was folded between the jaws of the forceps. The folded pockets were introduced through the dissected spaces directed at approximately 30 degrees from the midline. Once the tip of the sling was in contact with the descending ischiopubic ramus, the forceps were oriented to follow the posterior wall of the ramus and pushed up to the internal obturator muscle. After the forceps penetrated the internal obturator fascia, the tip of the forceps was opened, extending the pocket positioning/anchoring system, and removed. The process was then repeated on the contra-lateral side. The sling was placed flush with the urethra. Intra-operative adjustments of the sling were made by reinserting the forceps into the pockets on either side and advancing the sling further into the muscle. The vaginal mucosa was then closed.

Results

Twenty patients were treated with the Needleless sling. After a mean follow-up of 12 weeks, the patients were directly questioned if they were completely dry, and if not, what percent dry they would use to describe their symptoms. Subjective cure rates were as follows:

- 100% (20/20) of patients were greater than 80% dry
- 85% (17/20) of patients were greater than 90% dry

Subjective failure was defined as patients stating they had no or limited improvement in their incontinence symptoms. The subjective failure rate was zero.

No intra-operative complications were seen. Late complications were limited to one case of vaginal mesh exposure at six weeks post-operatively. This was treated conservatively with topical estrogen and did not require re-operation.

Interpretation of results

These results are consistent with reported success rates of the TOT and TVT type slings (1). The complication rate of 5% (1/20) is also consistent with reported complication rates of the TOT and TVT (1).

Concluding message

The ContaSure™ Needleless sling is a single incision tension-free sling that shows very promising clinical results. The advantage of the Needleless sling as compared with standard slings is the ability to place this sling through a single incision while maintaining comparable success and complication rates. Its potential advantage over other single incision slings is that with the "Pocket Positioning Anchors" the tension can be adjusted intra-operatively as needed, no needle introducers are required to position the sling, and the sling can be placed with any surgical forceps.

References

1. Bezerra CA, Bruschini H. "Suburethral sling operations for urinary incontinence in women." Cochrane Database Syst Rev. 2005;(3):CD001754

<i>Specify source of funding or grant</i>	Partial funding from Neomedic
<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>	No
<i>This study did not require ethics committee approval because</i>	A waiver was granted by Sterling IRB - retrospective study - NONE needed
<i>Was the Declaration of Helsinki followed?</i>	Yes
<i>Was informed consent obtained from the patients?</i>	No