

INITIAL OUTCOMES OF A STABILIZED ADJUSTABLE MINISLING FOR FEMALE URINARY STRESS INCONTINENCE

Hypothesis / aims of study

To assess the short-term efficacy of the stabilized and adjustable minisling, Minitape (Mpathy Medical Inc) in a group of women with urodynamically proven stress incontinence (USI)

Study design, materials and methods

Retrospective cohort series

2 private surgical centers (urogynecology, urology), with single-physician care.

76 consecutive women who underwent the Minitape procedure for USI

of whom 9 had mixed incontinence and 22 had intrinsic sphincter deficiency (ISD). One had previously undergone incontinence surgery. 62 underwent simultaneous concomitant pelvic surgery.

8 had Minitape placed retropubically and 68 by the subfascial or transobturator route.

Minitape is an 8cm mesh tape constructed of ultralightweight polypropylene mesh with a non-extensible closed knit construction and 100 micron interstitial pores.

Results

Patients were assessed at a mean of 21 weeks postoperatively.

74 of 76 (97%) patients were dry and therefore symptomatically cured. One more became dry after postoperative adjustment.

There were no major tape-related complications. One bladder perforation occurred with a retropubic needle passage.

An MRSA urinary infection occurred in a woman taking steroids for Addison's Disease.

Interpretation of results

Evidence of high effectiveness of unstabilized minislings is lacking. It is suggested that this class of device fails early because of unpredictable anchor traction in poor or indeterminate soft tissue.

This series of stabilized minislings, albeit early, demonstrates high cure rates and the possibility of early postoperative sling adjustment to add a further increment of clinical effectiveness.

Concluding message

In a heterogeneous group of women with USI and a high proportion of ISD, Minitape shows a high early efficacy with a low complication profile. Postoperative tape adjustment is feasible.

These results suggest benchmark effectiveness, associated with full length slings. This is achieved by short-term stabilization of the sling anchors.

Longer term follow-up and controlled trials are planned to further assess Minitape and to determine whether postoperative adjustment can give sustained superior results.

<i>Specify source of funding or grant</i>	Drs Alinsod and Safir are both consultants to Mpathy Medical Inc.
<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>	It is a postoperative data collection from procedures performed with an approved device that required no specific intervention nor additional patient burden.
<i>Was the Declaration of Helsinki followed?</i>	Yes
<i>Was informed consent obtained from the patients?</i>	Yes