

## MONOFILAMENT POLYPROPYLENE TAPES FOR TREATMENT OF STRESS INCONTINENCE - ARE THEY ALL ALIKE? A PROSPECTIVE STUDY COMPARING OUTCOMES AND FRICTION FORCES BETWEEN 2 VERSIONS OF THE SAME TAPE, A BASIC AND A LIGHTWEIGHT TAPE

### Abstract Title

#### MONOFILAMENT POLYPROPYLENE TAPES FOR TREATMENT OF STRESS INCONTINENCE - ARE THEY ALL ALIKE?

A prospective study comparing outcomes and friction forces between 2 versions of the same tape, a basic and a lightweight tape.

### Hypothesis/aims of study

There are various brands of monofilament polypropylene tapes for treatment of stress incontinence (SUI). Each system uses a unique formulation of the tape, and there is no evidence to support one in favor of another. Density and composition of the mesh are important factors concerning healing and complications; extend of chronic inflammation is related to the amount of foreign material left in the body. Differences in mechanical properties have been examined in the laboratory, but the impact on the body is almost unknown. Furthermore, the impact of mechanical and physical properties of the tape on friction force in the early, vulnerable phase of healing has not been studied in humans. The ideas for the present study turned up from the clinical observation that the friction force of the lightweight tape was lower than the basic tape, and from informal looks at outcomes data that predict lower cure rate in women operated with the lightweight tape.

The aim of the present study was to compare outcome and fixation force of 2 versions of a monofilament polypropylene tape with different mechanical properties and densities, a basic Intramesh® LIFT tape (LIFT) and a lightweight Intramesh® SOFT LIFT tape (SOFT).

### Study design, materials and methods

In a one-center prospective observational study, a total of 326 women with urodynamic SUI were enrolled consecutively; all had anterior vaginal wall prolapse < stage 2 (POPQ). All women underwent as the sole procedure a retropubic tension-free mid-urethral tape operation (TVT) under local anesthesia and received prophylactic cefuroxim under surgery. Postmenopausal women were treated with local estrogen. The TVT tape was available in two versions: the density of the LIFT tape was 100g/m<sup>2</sup> and the SOFT tape was 60g/m<sup>2</sup>. Another important difference was the physical configuration: the LIFT tape has very rough edges and the SOFT tape is smooth with non-aggressive edges. Besides, the latter displays a reduced elasticity. One hundred and sixty women got a LIFT tape and 166 a SOFT tape; IUGA-ICS Joint Terminology 2009 is used.

Patient characteristics were equal in the groups, age 58 (25-91), BMI 28 (19-51), Parity 2.3 (0-6), previous incontinence surgery 5% and mixed UI 36%. To evaluate outcomes at 3 and 12 month's follow-up both objective and subjective criteria were considered: objective cure was defined as a negative cough stress test as well as a negative short-term pad test (pad weight gain <1 g). Subjective cure was defined as a reduction in incontinence episodes >90%. Subjective improvement was defined as a reduction in incontinence episodes ≥75% and the patient was satisfied. Both provocative stress tests were performed at standard bladder volume of 300 ml saline.

A model for measurement of friction forces were set up: The tapes were drawn through a filet of pork (diameter 10 cm) with the velocity of 2.4 mm/sec and the force was given in gram. The LIFT was pulled 70 times and the SOFT 64 times.

Bivariate analyses were carried out using Mann-Whitney test (non-paired) and Wilcoxon Signed ranks test (paired). Probability values less than 0.05 were considered statistically significant. Odds ratio (OR) and its 95% confidence interval (CI) was calculated. Power calculation is presented along with data in Results.

### Results

At 12 months follow-up the LIFT tape had a significantly higher objective cure rate than the SOFT tape, 95% vs. 82% (OR 4.52, 95% CI 1.55-13.16), statistical power 81%; also the subjective cure rate was higher in the LIFT group, 81% vs. 69% (OR 1.97, 95% CI 1.02-3.78) (Table 1). Concerning the SOFT tape, the inferior cure rates at 3 months follow-up were especially pronounced in women older than 70 years of age compared to younger ones, obj. cure 66% vs. 92% (p<0.001) and subj. cure 43% vs. 76% (p<0.001), statistical power 87%. BMI had no impact on cure rates. No healing defects or vaginal erosions were observed.

There was a considerable change in voiding function after surgery in terms of free maximum flow rate (Q<sub>max</sub>) and postvoid residual (PVR). The reduction in Q<sub>max</sub> was significantly higher in the LIFT group compared to the SOFT group, 46% (from 28 to 15 ml/s) vs. 36% (from 30 to 19 ml/s) (p<0.001). The increase in PVR was equal in the groups, from 10 ml to 41 ml in LIFT vs. 8 to 29 ml in SOFT group (p>0.05).

The mean pullout force of the LIFT tape was significantly higher than the smooth SOFT tape, 963g (range 650-1800g) vs. 750g (range 400-1500g) (p<0.001). Elasticity of the SOFT tape is significantly lower than the LIFT tape (Fig 1).

### Interpretation of results

The hypothesis, that cure rate and friction force of 2 versions of the same monofilament polypropylene tape were significantly different, was confirmed in this study. In the group treated with the smooth SOFT tape the objective cure rate was significantly lower and so was the subjective cure - especially pronounced for women older than 70 years of age. BMI had no impact on cure rates. The mean pull-out force of the smooth SOFT tape was significantly lower than the rough LIFT tape. Furthermore, the confirmation of the hypothesis was reinforced by the greater fall in free max flow in the group with the LIFT tape. A plausible explanation for these results is the insufficient fixation force of the smooth SOFT tape in the very early phase of the healing process, where the only present force is the friction. The fact that the elasticity of the SOFT tape is significantly reduced

compared to the LIFT tape may also play a role. The theory, that the SOFT tape cannot hold its position during the first days of healing, may also explain the less obstructive effect of the SOFT tape. The lacking impact of BMI on cure rate is hard to explain, but it is well known from previous studies that the cure rates for obese patients is equal to normal weights.

### Conclusions

The cure rate and friction force of the newer smooth version of a monofilament polypropylene tape, the SOFT tape, are significantly lower than the results of the basic LIFT tape.

Apparently equal monofilament polypropylene tapes are not exchangeable and consequently we must remind the importance of proper evaluation of new tapes introduced for the treatment of stress incontinence.

Table 1 Objective and subjective cure rates in the LIFT group compared with the SOFT group at 12 months follow-up

	Objective cure	Subjective cure
LIFT tape	95% (100/105)	81% (90/111)
SOFT tape	82% (62/76)	69% (61/89)
OR (95% CI)	4.52 (1.55-13.16)	1.97 (1.02-10.12)

OR is Odds Ratio. 95%CI is 95% Confidence interval

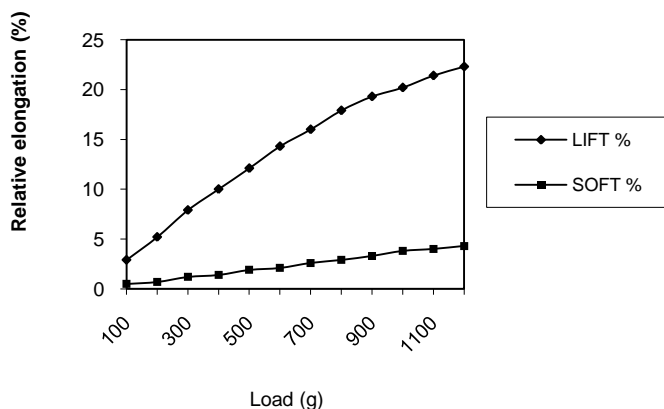


Fig 1 Load and relative elongation curve of the Intramesh® LIFT 1 x42 cm, and Intramesh® SOFT tape 1 x 42 cm.

<b>Specify source of funding or grant</b>	Tapes used for the pull-out force study were donated by Cousin Biotech
<b>Is this a clinical trial?</b>	No
<b>What were the subjects in the study?</b>	HUMAN
<b>Was this study approved by an ethics committee?</b>	No
<b>This study did not require ethics committee approval because</b>	It is an observational database study
<b>Was the Declaration of Helsinki followed?</b>	Yes
<b>Was informed consent obtained from the patients?</b>	Yes