

LONG- TERM EFFICACY OF THE TOPAS™ SYSTEM FOR TREATMENT OF FECAL INCONTINENCE

Hypothesis / aims of study

The TOPAS™ system delivers a minimally invasive, self-fixating polypropylene mesh intended to treat fecal incontinence (FI) in women who have failed conservative therapy. The present study reports the long-term effectiveness and impact on quality of life of the TOPAS™ system for FI in a prospective, multi-center study.

Study design, materials and methods

A total of 152 women were implanted with the TOPAS™ system at 14 centers in the United States. FI was assessed preoperatively and at regular follow-ups with a 14 day bowel diary, Cleveland Clinic Incontinence Scores (CCIS) and Fecal Incontinence Quality of Life (FIQOL), Colorectal-Anal Distress Inventory (CRADI) and the Pelvic Organ Prolapse Incontinence Sexual (PISQ-12) questionnaires. Treatment success was defined as reduction in number of FI episodes of 50% or more compared to baseline. The Wilcoxon signed-rank test was used to compare FI changes.

Results

Mean age at implant was 60 (range, 32-79) years and mean duration of FI was 110 (range, 8-712) months. At a mean follow-up of 2.8 +/- 0.7 years (range, 0.1-4.3 years) 132 (87%) of patients had either 24 or 36 month follow-up data. In these observed cases, 85/132 (64.4%) met treatment success criteria (Figure 1). In a worst case scenario analysis, with missing patients considered treatment failures, 56% of women met the criteria for treatment success. Complete continence was reported in 16% of patients. FI episodes decreased from a baseline median of 18.0 (range 4.0-81.0) to 5.0 (range 0.0-73.0) (p<0.001). Fecal incontinent days on the two week diary decreased from a median of 10.0 (range 3-14) at baseline to 4.0 (range 0-14) (p<0.001). Episodes of FI associated with urgency decreased from a median at baseline of 4.0 (range 0-52) to 0 (range 0.-39) (p<0.001). Mean CCIS decreased 13.9 at baseline to 9.6 (p<0.001) Table 1. FIQOL scores showed significant improvement (p<0.001) in all four domains. Median FIQOL subscale measures at baseline and follow-up were: lifestyle = 2.7 to 3.6, coping = 1.6 to 2.7, depression = 2.3 to 3.4, and embarrassment = 1.7 to 2.7. The mean CRADI scale decreased (indicating improvement in QOL) from a baseline of 54.8 to 34.9. The PISQ-12 questionnaire showed no clinically meaningful change in sexual function from baseline to any time point during the study

Interpretation of results

Objective measures of FI (number of incontinent days, FI episodes associated with urgency) on a fourteen day diary showed statistical improvement. Quality of life measure also showed statistical improvement. The improvement on the Colorectal-Anal Distress Inventory (CRADI) exceeds the Minimal Important Difference (MID) of 5 points with a decrease of 20 points. The MID has not been determined for the other instruments used.

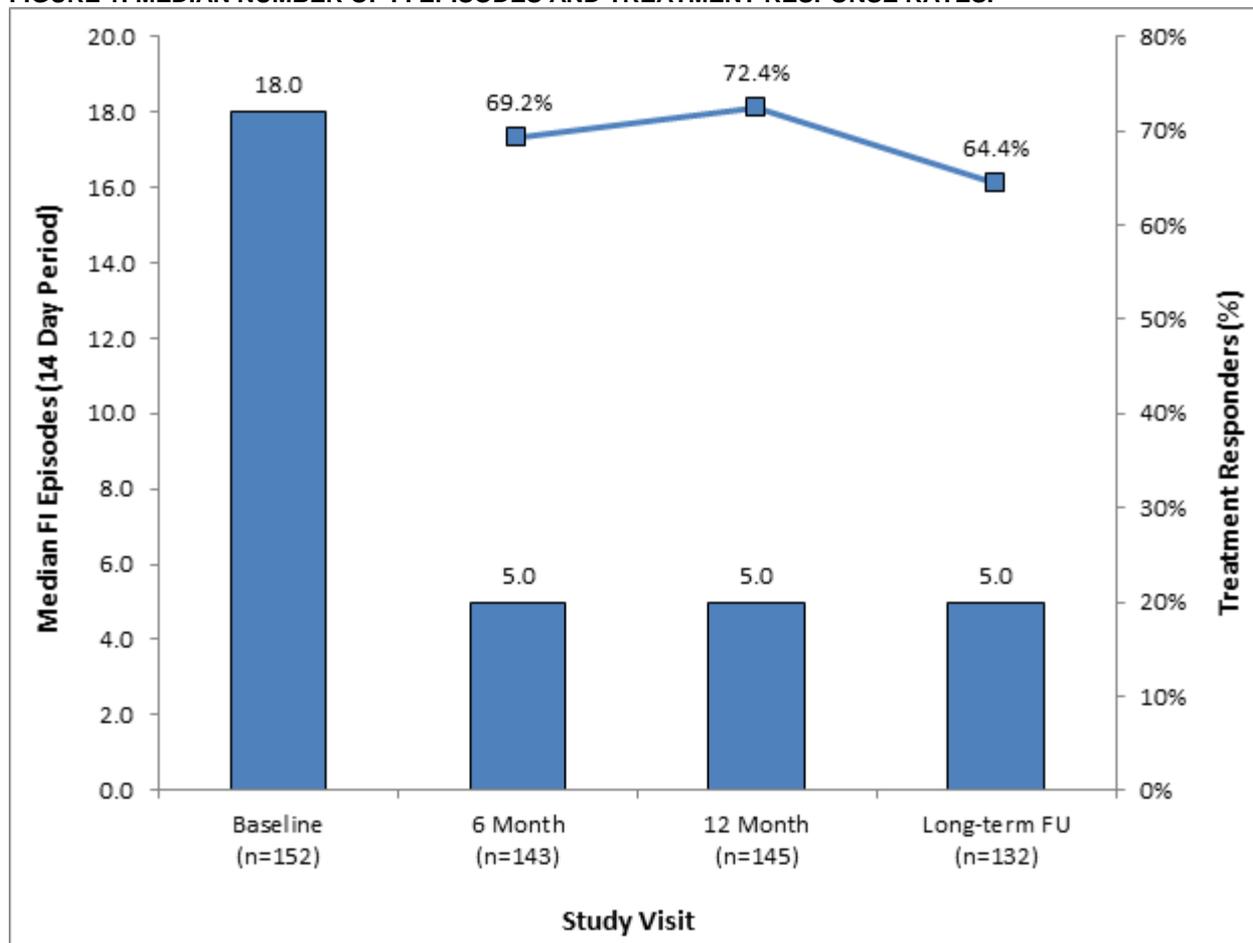
Concluding message

The TOPAS™ system provides significant improvements in FI symptoms, decrease in incontinent days and improved quality of life on multiple instruments. These improvements are sustained through 2.8 years after implant. The TOPAS™ system may therefore be a viable minimally invasive treatment option for FI in women.

TABLE 1: CLEVELAND CLINIC INCONTINENT SCORES SHOW SUSTAINED IMPROVEMENT OVER TIME

Visit	N	Mean ± SD (median, min-max)	Change from Baseline Mean[95% CI]	% Change from Baseline Mean[95% CI]
SCREEN 2	150	13.9 ± 2.7 (14.0, 5.0 - 20.0)		
3 MONTH	146	9.4 ± 4.3 (10.0, 0.0 - 20.0)	-4.4[-5.1,-3.8]	-32.3[-37.1,-27.5]
6 MONTH	145	9.8 ± 4.4 (10.0, 0.0 - 18.0)	-4.1[-4.8,-3.4]	-29.2[-34.1,-24.2]
12 MONTH	145	9.6 ± 4.0 (10.0, 0.0 - 17.0)	-4.2[-4.9,-3.6]	-29.7[-34.5,-25.0]
24 MONTH	128	9.6 ± 4.2 (10.0, 0.0 - 18.0)	-4.1[-4.8,-3.4]	-29.0[-34.1,-23.9]
36 MONTH	72	9.5 ± 4.5 (10.0, 0.0 - 18.0)	-4.6[-5.7,-3.5]	-31.3[-39.2,-23.5]

FIGURE 1: MEDIAN NUMBER OF FI EPISODES AND TREATMENT RESPONSE RATES.



References

1. Jelovsek JE. et al. Minimum Important Differences for Scales Assessing Symptom Severity and Quality of Life in Patients with Fecal Incontinence. FPMRS 2014;1:1-7
2. Markland AD et al. Factors impacting quality of life in women with fecal incontinence. Dis Colon Rectum. 2006;(49):841-851.

Disclosures

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