

# TFS (Tissue Fixation System) minisling reinforcement of uterosacral ligaments cures nocturia, urgency, frequency, even with minimal prolapse. A 6 months review

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**Abstract:** *Background:* Nocturia is said to have no known cause or treatment. The aim of the study is to help 12 patients with severe nocturia, urgency and frequency given no other hope of cure by minimally invasive surgical reinforcement of damaged uterosacral ligaments. *Exclusion criteria:* patients with other pelvic symptoms such as stress incontinence. *Materials and methods:* Twelve patients with frequency, urgency, nocturia of serious entity, with POP-Q stage 1, without prior hysterectomy or stress urinary incontinence, were selected for the study. Median age was 63.2 years (37-81), BMI 27.8 (19-44), parity 2.1. Posterior TFS minisling operation with transvaginal access was performed to reinforce the uterosacral ligaments. *Results:* Mean operating time was 15', with no intra/perioperative complications, and mean hospitalization time 2 days. Review at 3 and 6 months with the ICIQ-N QoL questionnaire showed average score reductions from 7.8 to 2.7 for frequency and 7.2 to 1.9 for nocturia. The score for the OAB questionnaire reduced from 17.6 to 9.8. The cure-rate of symptoms was 62.5% for frequency, 75% for nocturia, and 66.7% for urgency, with no age-related differences. *Conclusions:* The use of the TFS has allowed us to verify, albeit on short follow-up, that this minimally invasive procedure can also be applied solely towards the resolution and/or improvement of symptoms which limit the QoL in patients with severe symptoms of nocturia, frequency and urgency without major POP. It is therefore applicable to elderly patients, even with tissues of poor quality.

**Key words:** Nocturia; Urgency; Frequency; TFS; Posterior Sling; Integral Theory.

## INTRODUCTION

In a recent review,<sup>1</sup> Van Kerrebroek et al stated that "Unlike other LUTS (lower urinary tract symptoms), nocturia has a specific and detrimental effect on the sleep period, and when  $\geq 2$  voids per night are experienced, it is associated with various sequelae including reduced QoL and productivity, and increased morbidity and perhaps mortality. Many sources suggest that nocturia is associated with chronic medical illness, but little evidence demonstrates that successful treatment of these conditions results in normalization of nocturia. It is likely that more than one contributory factor is responsible for nocturia, and management ought to better reflect this multifactorial pathophysiology. Indeed, traditional perspectives assuming nocturia to be part of the OAB or BPE symptom complex may have helped to propagate the misconception that therapy for these conditions is sufficient to improve nocturia. In reality, improvements in nocturia with anticholinergics, alpha blockers and/or 5 alpha reductase inhibitors have been consistently disappointing. Antidiuretic therapy may represent a more tailored approach to management for many nocturia patients, given the high rates of nocturnal polyuria reported. Combination therapy may be required. Further high quality research on pathophysiology, management and patient-reported outcomes with treatment is needed to augment existing limited data." The authors discuss the relationship between diabetes insipidus and nocturia, its treatment with Desmopressin, but warn of the failure, indeed, hazard of such treatment in other cases of nocturia. Another perspective is provided by the Integral Theory,<sup>2</sup> that nocturia is part of the "posterior fornix syndrome",<sup>2</sup> a grouping of symptoms deriving from the posterior zone of the vagina (figure 1). The Integral Theory which has an integrated and dynamic anatomic approach to pelvic floor dysfunction, is based on the principle that the organs are suspended by bands, maintained in suspension by ligaments connected and straightened muscle forces acting in turn in the opposite direction to the ligaments, determining the form and resistance (analogy of suspension bridge). A deficiency of ligaments and bands undermines the pelvic floor structural integrity by altering the balance of muscular tensions. The Visual

Diagnostic Algorithm, (figure 1), represents the clinical expression of the Integral Theory. It visually depicts the correlation between symptoms and connective tissue damage (bands/ligaments). The algorithm identifies ligament damage in 3 different anatomical areas. Therefore, the importance of an accurate diagnosis, to locate the damaged structure, is the prerequisite for the choice of the surgical site-specific options for ligament repair offered by the TFS (Tissue Fixation System) tape, on the basis of the principle that the "restoration of shape (structure) leads to the restoration of function".<sup>3</sup> According to the theory, structural deficit of ligaments of the rear zone (uterosacral ligaments 'USL') allows excessive descent of the bladder base during filling, providing an early stimulus on the bladder base stretch receptors. At night, in the supine position, the uterosacral ligaments become an important support system for the filling bladder, (figure 2). The afferent impulses travel to the pontine centre of urination, to activate the micturition reflex (voiding reflex), eluding the cortical inhibitory closure mechanism "C", (figure 2).<sup>3</sup> The patient experiences this as symptoms of urgency, frequency, nocturia ("posterior fornix syndrome"). The TFS minisling (Tissue Fixation System), through 2 small polypropylene anchors and the attached tape, when inserted into the uterosacral ligaments<sup>4</sup> and then tensioned, uniquely restores the position and tension of the uterosacral ligaments, allowing the pelvic muscles to now effectively tension the vaginal membrane during the day (urgency, frequency control) and at night (nocturia control). The polypropylene tape reinforces the linear strength with the deposition of collagen, "neoligament formation".<sup>5</sup>

**Background to the study.** A tertiary referral urogynecological clinic in Rome. Only patients with severe symptoms of nocturia, urgency and frequency, who had only minimal prolapse, who had failed conventional drug therapy, and who had been advised that they had no hope of cure with existing conventional therapy, were selected for the study. On the basis of results from a previous study which reported high cure rates for nocturia, frequency and urgency,<sup>4</sup> and that the proposed intervention (TFS posterior sling)

was a minimal operation with few reported complications, it was recommended to patients that they had a reasonable hope for longer term cure with this procedure, with minimal if any sequelae if it failed.

**Inclusion criteria.** Patients with severely affected quality of life due to their symptoms of nocturia, urgency and frequency, who had only minimal prolapse.

**Exclusion criteria.** Patients with other pelvic symptoms such as stress incontinence, fecal incontinence.

**Aim of the study.** The primary goal of our preliminary study, was to help those patients with severely affected quality of life due to their symptoms of nocturia, urgency and frequency, patients who were given no other hope of cure. A secondary aim was to challenge the Integral Theory's prediction that nocturia was mainly a result of damaged uterosacral ligaments.

Written informed consent was obtained from all the study participants. No Ethics Committee approval was required for the studies as the TFS had already been approved by the Hospital Board as a standard surgical procedure. The principles outlined in the Declaration of Helsinki were followed.

**MATERIALS AND METHODS**

Between January 2009 and June 2010, we selected 12 patients from our Urogynecological Clinic who after full urogynecological work-up, complained of at least 2 of the triad of symptoms frequency, urgency, nocturia said to originate from the posterior vaginal fornix<sup>4</sup> of serious entity, with POP-Q staging 1 (Aa-2, Ba-2, C-6, Ap-2, Bp-2) and in the total absence of stress urinary incontinence (subjective/objective/urodynamic). Median age was 63.2 years (37-81), BMI 27.8 (19-44), parity 2.1.<sup>1-4</sup> None of the 12 patients had been subjected to hysterectomy. According to the Visual

ANTERIOR ZONE	MIDDLE ZONE	POSTERIOR ZONE
URETHROCELE PUL	CYSTOCELE central lateral high	
	PCF CL/CX ring	USL RVF PB
	Svuotamento anomalo	(emptying)
	Frequenza e urgenza minzionale	frequency urge incontinence
		nocturia
fecal incontinence		fecal incontinence
		pelvic pain

Figure 1. – Visual diagnostic algorithm. Symptoms are related to ligamentous laxity in 3 zones of the vagina. The areas in yellow denote the basis for diagnosing that the origin of the frequency, urgency and nocturia symptoms addressed in this study was from damaged uterosacral ligaments. The red letters below the prolapses denote the ligaments which can be repaired by the TFS: PUL, pubourethral ligament; PCF, pubocervical fascia; CL/CX ring, the cardinal ligament/cervical ring complex; ATFP, Arcus Tendineus Fascia Pelvis; USL, uterosacral ligament; RVF, rectovaginal fascia; PB, perineal body. Adapted from Pelviperineology<sup>6</sup> by permission.

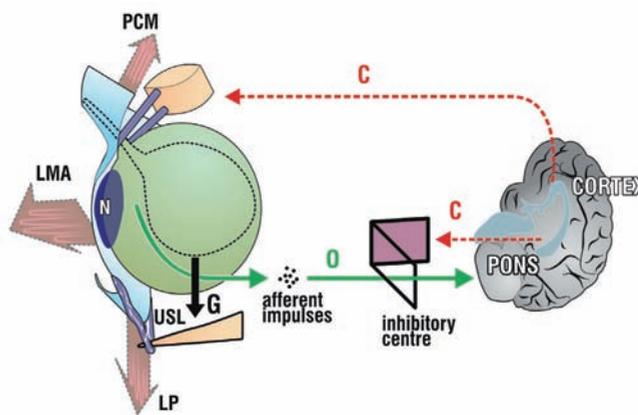


Figure 2. – Mechanical origin of nocturia- patient asleep. Pelvic muscles (arrows) are relaxed. As the bladder fills, it is distended downwards by gravity G. If the uterosacral ligaments (USL) are weak it continues to descend until the stretch receptors 'N' are stimulated, activating the micturition reflex once the closure reflex 'C' has been overcome. Printed by permission.<sup>3</sup>

Diagnostic Algorithm, clinical symptoms reported (frequency, urgency, and nocturia) were related to structural damage of the connective tissue of the rear area.<sup>6</sup> According to the psychometric validated questionnaire ICIQ-N QoL,<sup>7</sup> the average score was 7.8 for frequency and for nocturia 7.2. This was severely impairing the quality of life; the questionnaire OAB score average for urgency was s.f.=17.6. On full urodynamic examination, 9 of the 12 patients had hyperactivity of the detrusor with reduced compliance and CVF < 280 ml. Of 12 patients symptoms frequency was present in 8, nocturia in all, and urgency in 9.

The patients have undergone intravenous antibiotic prophylaxis with ceftazidime + metronidazole, and the procedure was performed under spinal anesthesia.

Posterior TFS minisling operation with transvaginal access was performed.<sup>8</sup> A transverse incision 2,5 cm. long was made in the apex 2 cm. from the cervix, to facilitate the identification of 2 uterosacral ligaments with Allis forceps. The apex was stretched towards the introitus to stretch the uterosacral ligaments, and one finger was placed in the rectum to identify them. A tunnel approximately 4 cm long was now made with fine scissors angled 30° to the vertical through the ligaments. The TFS surgical applicator was placed into the channel angled 30° to the vertical, and pushed so as to penetrate the ligament approximately 2 cm distal to its insertion into the sacrum. This protocol avoids the ureter which is supero-medial, and the rectum also. Pressing the applicator button releases the 1st anchor which is then checked for grip by pulling it gently. The procedure is repeated on the contralateral side, and holding the applicator firmly, grip of the 2nd anchor is also tested, exercising traction on the tape. Redundant tape is then cut, and the fascia overlying the tape is approximated with a No1 Vicryl suture. The tape is lightweight, and is specially knitted from polypropylene monofilament fibrils. It is macro-porous and non-stretch, and it forms an artificial neoligament.

**RESULTS**

The average operating time was 15'. There were no intra/perioperative complications, no ureteric/rectal perforations, no abscesses/haematomas, and no postoperative buttocks pain. The mean hospitalization time was 2 days. Review at 3 and 6 months with the ICIQ-N QoL question-

naire showed an average score = 2.7 for patients treated for frequency and 1.9 for those treated for nocturia. The score of the OAB questionnaire was 9.8. The cure-rate of the symptoms was 62.5% for frequency, 75% for nocturia, and 66.7% for urgency. The results of the questionnaires did not reveal any age-related differences.

## DISCUSSION

In a previous study on TFS surgical reinforcement of the uterosacral ligaments,<sup>4</sup> 28 of the 67 patients who had only minimal prolapse reported high rates of cure with major pelvic symptoms such as urgency, frequency, nocturia, abnormal emptying, pelvic pain and fecal incontinence.

Other investigators have confirmed that all these symptoms can be cured/improved by a posterior sling.<sup>9-13</sup> However, the wide diversity of such symptoms stated to be cured/improved, made it difficult for our team to challenge the full array of "posterior zone" symptoms, fig1, in the tightly controlled way which science demands. The prediction that nocturia, urge incontinence and frequency were ultimately said to be different clinical expressions of a normal but prematurely activated micturition reflex,<sup>14,15</sup> gave us the opportunity for a simple tightly controlled clinical trial, that if we could repair the uterosacral ligaments, we could repair the function, and its clinical manifestations (nocturia, urge incontinence and frequency) in this severely affected group of patients. The emergence of the Tissue Fixation System (TFS) gave us the correct surgical (and ethical) tools to attempt both goals. The TFS is a very minimal technique with very few reported short or long-term complications. It directly reinforces specific ligaments, in this study, the uterosacral ligaments, and it tensions the lax vaginal membrane, a critical part of the stated pathogenesis.<sup>2-4</sup> Questions remain about the longer term prospects for cure. Shull et al.<sup>16</sup> observed in 1992 that herniations, usually in other parts of the vagina, occur in up to 38% of patients following vaginal surgery. Therefore we could predict that some patients may present with recurrence of urgency in the future, as urgency may be caused by any zone in the vagina, for example, a subsequent cystocele. The longer term results for nocturia may possibly be more encouraging. At least for apical/uterine prolapse surgery using the TFS posterior sling, the results reported are 86% cure at 3 years.<sup>8</sup> The perspective from our clinic is that subsequent symptoms or prolapse are bound to occur in some, perhaps many patients, given the deterioration of collagen/elastin with age,<sup>3</sup> but they can be potentially addressed using the same TFS method for connective tissue repair, albeit applied in another part of the vagina.

## CONCLUSION

The use of the TFS minisling in the treatment of nocturia, frequency and urgency as part of the posterior fornix syndrome symptoms has allowed us to verify, albeit on an initial causal basis, and short follow-up, that the severity of symptoms is not related to the magnitude of prolapse, and that this minimally invasive procedure can also be applied solely towards the resolution and/or improvement of symptoms which limit the QoL, in patients without major POP. It is therefore applicable to elderly patients, even with tissues of poor quality. It is our hope that this study will be a catalyst for not only further studies on urgency and nocturia in females, but also to test other predictions of the theory, such as pelvic pain, abnormal emptying, and idiopathic fecal incontinence, all major causes of debility in the aged.

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