

Editorial comment to: Inoue H, Nakamura R, Sekiguchi Y, et al. Tissue Fixation System ligament repair cures major pelvic organ prolapse in ageing women with minimal complications – a 10-year Japanese experience in 960 women. *Cent European J Urol.* 2021; 74: 552-562.

Pelvic ligament repair with slings – a foundation stone for solution of the ageing crisis in female pelvic urology

Peter Emanuel Petros

School of Mechanical and Mathematical Engineering, University of Western Australia, Perth, Australia

Article history

Submitted: Nov. 4, 2021

Accepted: Nov. 6, 2021

Published online: Nov. 18, 2021

Citation: Petros PE. Pelvic ligament repair with slings – a foundation stone for solution of the ageing crisis in female pelvic urology. *Cent European J Urol.* 2021; 74: 563-565.

Key Words: ageing crisis <> prolapse <> Tissue Fixation System <> mesh bans <> ligament repair

Scientific medicine began with Hippocrates some 2400 years. Empirical observations of causation and treatments were tested until one or two of the most effective treatments emerged to become mainstream. Stress incontinence treatment evolved to pelvic floor operations by Marshall Marchetti, then Burch and most recently, the midurethral sling, all reasonably effective, but each with its own special problems. For prolapse and symptoms, there has been little progression for the past 100 years. Native tissue excision of anterior or posterior vaginal bulges repaired cystocele and rectocele, while some type of attachment of vagina to the sacrum or uterosacral ligaments (USL) repaired uterine prolapse. Because of high failure rates from such 'native tissue' operations, mesh sheets were introduced to block descent of the prolapse. However, dismal results from both mesh and native tissue in the Prospect Trial [1], banning of mesh sheets for prolapse by the Food and Drug Administration (FDA) [2] and all mesh surgery in the UK including those for stress urinary incontinence (SUI) [3], have left few options for ageing women beyond sacrocolpopexy, which in any case, is only effective for uterine prolapse and does not consistently cure pelvic symptoms. Causation of bladder/bowel/chronic pelvic pain dysfunctions even today is considered unknown

by learned bodies and other than SUI, no cure is considered possible [4]. This situation is, in every respect, a crisis, especially for older women.

With its rapidly ageing population, Japan is at the forefront of this crisis [5] with pelvic floor dysfunctions increasing in parallel with ageing, resulting in poor quality of life and escalating community and government health costs.

The publication by Inoue et al. [5] lays a strong foundation stone for a solution to this ageing crisis in female pelvic urology.

The sling methodology they used is very different from mesh sheets. Slings, based on the Integral Theory System [6], apply a completely different approach to prolapse and pelvic symptom dysfunctions. Whereas mesh sheets work by blocking descent of the organs, slings work by repairing the suspensory structures, the ligaments which support the organs in the manner of a suspension bridge [6]. Tapes are applied in the exact position of the damaged ligaments and irritate the tissues to produce a wound reaction which in 10 days converts to collagen to create collagenous neoligaments [6]. The Inoue data emphasizes the critical differences between slings and mesh sheet implants. Mesh sheet implantation caused sufficiently severe complications for questions to be raised

by the FDA in 2011, leading to their eventual banning. The device manufacturers did not understand that placing a large mesh behind the anterior vaginal wall would fibrose and limit the forward and backward movements by the pelvic muscles, (Figure 1). Such reflex movements are essential for proper functioning of the bladder, continence, evacuation and control of urge [6]. Nor did they understand that as the scar tissue created by the mesh contracts on its way to becoming collagen 1, any nerves caught in the scar can be compressed to create pain. Tape slings as used by Inoue et al. are applied laterally and so do not interfere with the backward/forward movements of the vagina. Furthermore, their contact with the vagina is very limited to a 7 mm wide strip. Long-term postoperative pain was virtually absent in the 960 women included in the study. Minor vaginal erosions occurred in 2.5% of women and these were trimmed as an outpatient procedure with no further problems.

An important breakthrough in regards to ageing and pathogenesis was the discovery by Shkarupa et al. [7], that cardinal/uterosacral (ICL/USL) ligament repair could give high cure rates for uterine/apical prolapse and overactive bladder (OAB: urge, frequency, nocturia) at 18 months 'but only in premenopausal women'. The results for post-menopausal women were catastrophically low. Shkarupa et al. attributed this to collagen breakdown from ligaments after menopause. They recommended slings for post-menopausal women.

The recent paper by Inoue et al. in the Central European Journal of Urology (CEJU) [5] has completed the circle, by describing how to treat prolapse and pelvic symptoms surgically in older post-menopausal women. They presented impressive 10-year data, implanting a total of 3100 Tissue Fixation System (TFS) minislings to repair damaged pelvic ligaments causing major prolapse (3rd and 4th degree) and pelvic symptom dysfunctions in 70-year-old Japanese women. The surgery was minimally invasive and performed as an outpatient procedure. High cure rates were achieved for prolapse and symptoms. In one cohort from this group, 5-year data showed minimal yearly fall in anatomical and cure of OAB, chronic pain and bowel symptoms.

The reports of high cure rates by Inoue et al. have been validated by others, for prolapse, OAB, nocturia, faecal incontinence [8] chronic pelvic pain [9, 10] underactive bladder and Fowler's syndrome [11, 12]. The accumulated data puts to rest comments by opinion leading articles in learned journals [4], that pathogenesis of OAB and other symptoms such as chronic pelvic pain, urinary retention is unknown and such symptoms are not curable.

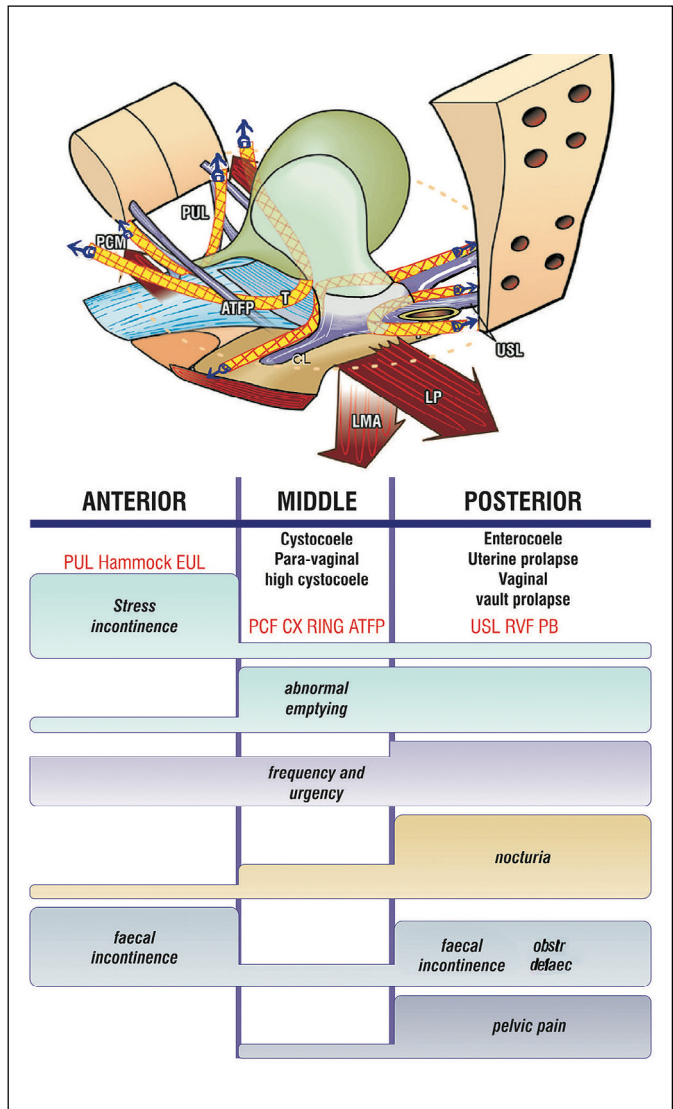


Figure 1. Diagnostic algorithm which summarizes the Integral Theory System for diagnosis and ligament repair [6].

Upper figure

Polypropylene tapes 'T' used to reinforce the main suspensory structures – pubourethral ligament (PUL), uterosacral ligament (USL) and arcus tendineus fascia pelvis (ATFP), cardinal ligament (CL), and perineal body (PB). The tapes create new collagen to restore the 3 reflex muscle forces *m. pubococcygeus* (PCM), levator plate (LP), conjoint longitudinal muscle of the anus (LMA) which contract against the ligaments to close the urethra (continence), evacuate the bladder or stretch the vagina in opposite directions to support the bladder base stretch receptors to prevent urgency.

Lower figure

The Pictorial Diagnostic Algorithm summarizes the relationships between structural damage (prolapse) in the three zones and function (symptoms). The size of the bar gives an approximate indication of the prevalence (probability) of the symptom. Laxities (red lettering) which can be repaired: pubourethral ligament (PUL); external urethral ligament (EUL).

CEJU has shown commendable insight publishing such well-validated discoveries for ‘incurable’ bladder/bowel/pain symptoms [4] and is undoubtedly now the leading journal in this field. Though sophisticated devices such as TFS are not readily available, other options exist at least for premenopausal women: cardinal/uterosacral ligament plications are simple to perform and cost-effective [7]. For post-menopausal women, the artisan tape method by Pinango et al., [13] is similarly easy to perform and also cost-effective. For day-night enuresis in children, squatting-based pelvic floor exercises achieved an 86% cure at 4 months [14]. CEJU’s in-

sightful policy to publish well-validated science free of politics is an encouraging signal to all innovators in the field of urology. Hopefully such publications will be the catalyst for all surgeons, physicians and physical therapists of the pelvic floor to build on such works to improve the quality of life of older (and younger!) women.

CONFLICTS OF INTEREST

The authors declare no conflicts of interest.

Corresponding author

Peter Petros
pp@kvinno.com

References

1. Glazener CM, Breeman S, Elders A, et al. Mesh, graft, or standard repair for women having primary transvaginal anterior or posterior compartment prolapse surgery: two parallel-group, multicentre, randomised, controlled trials (PROSPECT). *Lancet*. 2017; 389 :381-392.
2. U.S. Food & Drug. FDA news release. 9 FDA takes action to protect women’s health, orders manufacturers of surgical mesh intended for transvaginal repair of pelvic organ prolapse to stop selling all devices. April 16, 2019 .
3. Baroness Cumberlidge Press conference speech, 8th July 2020. The Medicines and Medical Devices Safety Review – UK.
4. Koelbl H, Igawa TY, Salvatore S, et al. Pathophysiology of urinary incontinence, faecal incontinence and pelvic organ prolapse. In: Abrams P, Cardozo L, Khoury S, Wein A, eds. *Fifth International Consultation on Incontinence*. Bristol, UK: International Consultation on Urological Diseases; 2013. pp. 261-360.
5. Inoue H, Nakamura R, Sekiguchi Y, et al. Tissue Fixation System ligament repair cures major pelvic organ prolapse in ageing women with minimal complications – a 10-year Japanese experience in 960 women. *Cent European J Urol*. 2021; 74: 552-562.
6. Petros P. The Integral System. *Cent European J Urol*. 2011; 64: 110-119.
7. Shkarupa D, Zaytseva A, Kubin N, Kovalev G, Shapovalova E. Native tissue repair of cardinal/uterosacral ligaments cures overactive bladder and prolapse, but only in pre-menopausal women. Shkarupa D, Zaytseva A, Kubin N, Kovalev G, Shapovalova E. Native tissue repair of cardinal/uterosacral ligaments cures overactive bladder and prolapse, but only in pre-menopausal women. *Cent European J Urol*. 2021; 74: 372-378.
8. Liedl B, Inoue H, Sekiguchi Y, et al. Is overactive bladder in the female surgically curable by ligament repair? *Cent European J Urol*. 2017; 70: 53-59.
9. Petros P, Abendstein B. Pathways to causation and surgical cure of chronic pelvic pain of unknown origin, bladder and bowel dysfunction- an anatomical analysis. *Cent European J Urol*. 2018; 71: 448-452.
10. Enache T, Bratila E, Abendstein B. Chronic pelvic pain of unknown origin may be caused by loose uterosacral ligaments failing to support pelvic nerve plexuses - a critical review. *Cent European J Urol*. 2020; 73: 506-513
11. Petros PE, Abendstein B, Swash M. Retention of urine in women is alleviated by uterosacral ligament repair: implications for Fowler’s syndrome. *Cent European J Urol*. 2018; 4: 436-443.
12. Petros P, Goeschen K, Inoue H. Underactive bladder may be caused by uterosacral ligament laxity- a critical review of two paradigms. *Cent European J Urol*. 2018; 71: 444-447.
13. Piñango-Luna S, Level-Córdova L, Petros PE, Yassouridis A. A low cost artisan tension-free tape technique cures pelvic organ prolapse and stress urinary incontinence - proof of concept. *Cent European J Urol*. 2020; 73: 490-497.
14. Garcia-Fernandez A, Petros PE. A four month squatting-based pelvic exercise regime cures day/night enuresis and bowel dysfunction in children aged 7-11 years. *Cent European J Urol*. 2020; 73: 307-314. ■