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Update of the Integral Theory and System for Management of Pelvic Floor Dysfunction in Females

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Abstract

Context: The 1990 integral theory (IT) stated that urinary stress and urge symptoms mainly arise (for different reasons) from lax suspensory ligaments, a consequence of altered collagen/elastin. The first surgical application of IT was repair of the pubourethral ligament (PUL), now known as tension-free vaginal tape repair. **Objective:** To update the 1990 IT to the present day (2016).

Evidence acquisition: Published data in peer-reviewed journals concerning IT evolution were evaluated.

Evidence synthesis: In its present form (2016), IT states that pelvic organ prolapse and symptoms of chronic pelvic pain and bladder and bowel dysfunction are mainly caused by laxity in five main suspensory ligaments. The IT explains cure for bladder and bowel dysfunction via the dual function of the ligaments: organ suspension and insertion points for three oppositely acting muscle forces. Lax insertion points weaken muscle forces so they cannot adequately close the urethral or anal tubes (incontinence) or evacuate them (constipation, bladder emptying), or tension the bladder and rectum sufficiently to prevent inappropriate activation of the micturition and defecation reflexes by peripheral stretch receptors (urge incontinence, tenesmus). Up to 80% cure/improvements for the above conditions have been achieved by repair of one or more damaged ligaments via precisely positioned tissue fixation system tapes: "Repair the structure (ligaments) and you will restore the function". Exactly the same operations are performed for patients with major symptoms and minimal prolapse and major prolapse with no symptoms.

Conclusions: This method can reduce costs, improve quality of life for older women, and potentially reduce admissions to nursing homes.

Patient summary: This paper introduces a new way of thinking. Many bladder and bowel symptoms not considered curable via existing methods may be caused by

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loose pelvic ligaments, and thus are potentially curable by reinforcing the ligaments. These symptoms include an inability to hold on to the bladder (urge incontinence), going frequently to pass urine during the day (frequency), getting up at night to pass urine (nocturia), involuntary soiling from the bowel, and chronic pelvic pain. These symptoms are major indications for nursing home admission. In this paper we give examples of cure of these conditions in a group of 70-yr-old Japanese women whose ligaments were strengthened using a tissue fixation system (TFS) in a very minimal way. The TFS involves insertion of a thin (7 mm wide) tape through the ligaments that support the uterus. The tape creates new collagen to strengthen damaged ligaments. The new ligaments act as efficient anchoring points for muscles that open and close the urethra and anus, so these can now function more efficiently. A minimum cure rate of 72% was achieved for all the above symptoms. The method is different from large mesh insertions. Only a thin tape is used to repair damaged ligaments. This method can reduce costs, improve quality of life for older women, and potentially reduce admissions to nursing homes.

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1. Background

The integral theory (IT) of female urinary incontinence [1] is a universal theory of pelvic organ function and dysfunction. It is a different way of thinking, consistent with Thomas Kuhn's description of a theory as "A fundamental change in the basic concepts and experimental practices of a scientific discipline" [2]. In its present form (2016), the IT states

Pelvic organ prolapse, chronic pelvic pain, and bladder and bowel dysfunction are mainly caused by lax suspensory ligaments as a result of altered collagen/elastin.

Repair the structure (ligaments) and you will restore the function.

The IT explains cure of bladder and bowel dysfunction via the dual function of the ligaments: organ suspension and insertion points for three oppositely acting muscle forces. Lax insertion points weaken muscle forces so they cannot close the urethral or anal tubes adequately (incontinence), evacuate them (constipation, bladder emptying), or tension the bladder and rectum sufficiently to prevent inappropriate activation of the micturition and defecation reflexes by peripheral stretch receptors (urge incontinence, tenesmus).

The IT predicts that all these conditions are potentially curable by repair of one or more damaged ligaments. The update has two streams, the IT and surgical practice of the IT, the IT system (ITS). Both are related. Both are critically examined in this update in relation to existing concepts and practice.

2. Methodology

We applied Karl Popper's deductive criteria [3] to the "old" paradigm (existing practices as recommended by learned societies) and the "new" ITS paradigm.

The "old" paradigm is essentially what has been defined, recommended, and practiced by learned societies, in particular the International Continence Society (ICS) [4]. According to this paradigm, bowel, bladder, and pain symptoms are major problems in up to 30% of women. The causation is essentially unknown [5–7]. Other than urinary stress incontinence (USI), such symptoms are not considered surgically curable and are major reasons for patient disability, costs to the community, and admission to nursing homes. Treatment of these conditions is fragmented, reductionist, and discipline-based (Fig. 1), employing muscular rehabilitation, targeting nerve structures and receptors (eg, electrotherapy, drugs, botox, sacral nerve stimulation) and, in extreme cases, surgical interventions such as cystoplasty, graciloplasty, and artificial sphincter insertion.

The "new" paradigm, the IT, began as an Endeavour to create a new operation for repair of USI. On the basis of experimental work in canines, a new surgical principle was established, involving the creation of an artificial neoligament [8,9] via implantation of a tape in the position of the pubourethral ligament (PUL). This principle was applied using a prototype PUL sling [10] for repair of USI and is now known as the midurethral sling or tension-free vaginal tape (TVT), and has become the standard operation to cure USI. Anomalies in the experimental data led to conceptualization of the IT. The core discovery was three oppositely acting directional forces that act against the anterior (pubourethral) and posterior (cardinal/uterosacral) ligaments (Fig. 2):

- To open and close the urethral tube;
- To prevent the stretch receptors activating the micturition reflex to cause urge incontinence and nocturia; and
- To create a "zone of critical elasticity" in the bladder neck area of the vagina that allows separate action of these oppositely acting vector forces.

As originally published in 1990, the IT was a new holistic way of thinking about the pelvic floor in which the ultimate

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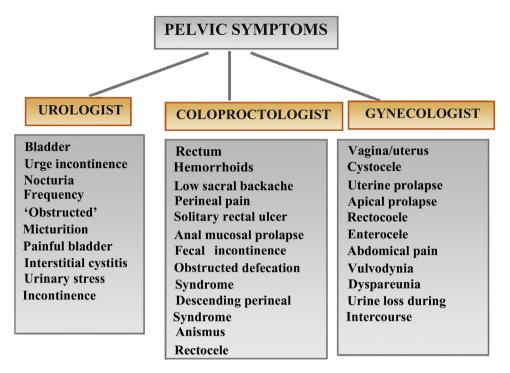


Fig. 1 – Existing treatment for pelvic floor dysfunctions is discipline-based, with widely varying treatments for each condition within each discipline and even for each symptom.

cause was ligament laxity [11]. In the years from 1990 to 2016, the IT has expanded in step with surgery to become the ITS (Fig. 3). The findings for cure/improvements for nocturia, chronic pelvic pain (CPP), abnormal bladder emptying, fecal incontinence, and obstructive defecation via posterior sling surgery [12–18] created an IT obligation [3] to deductively explain how all these conditions could be caused by lax suspensory ligaments. Further requirements for the IT to explain came with the development of the

tissue fixation system (TFS). The TFS was able, for the first time, to repair other ligaments: arcus tendineus fascia pelvis (ATFP), cardinal ligaments, and the deep transversus perinei [19–28]. This expanded the range of conditions that could be cured to include descending perineal syndrome, obstructed defecation, perineocele, central and lateral cystoceles, and divergent urinary stream caused by pubococcygeus muscle dislocation [29]. The mechanisms for all these conditions are explained later in the paper.

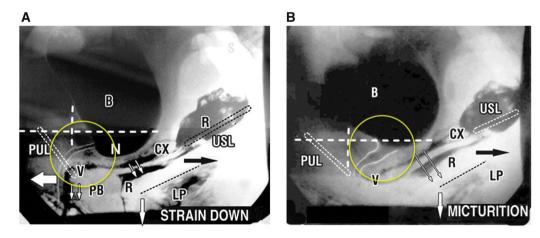


Fig. 2 – Sitting sagittal X-ray view with radiopaque dye in the bladder(B), vagina (V), rectum (R), and levator plate (LP). (A) Urethral closure. Three opposing directional forces (arrows) stretch the vagina in opposite directions around competent pubourethral ligament (PUL) to close the distal and proximal urethra and to support bladder base stretch receptors (N). Note the action of the backward/downward vector forces (arrows) against the uterosacral ligament (USL). The yellow circle represents the zone of critical elasticity (ZCE) in the bladder neck area of the vagina. This allows the separate action of the opposite muscle vectors (arrows). If ZCE (yellow circle) is scarred or extended by previous Burch surgery, the posterior vectors overcome the forward vector, so the bladder opens exactly as occurs during micturition. (B) Micturition. The forward vector relaxes. This allows the backward/downward vector forces (arrows) to contract against a competent USL to open out the posterior urethral wall, expanding the outlet tube, exponentially decreasing the resistance to emptying of the bladder.

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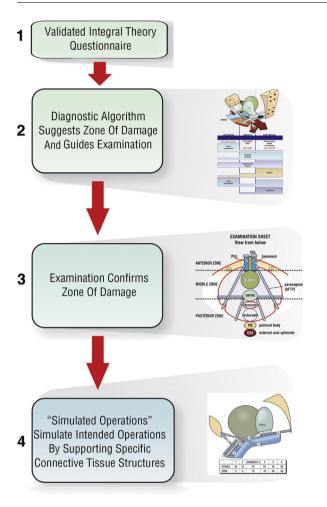


Fig. 3 – The Integral Theory diagnostic system uses symptoms to locate damaged ligaments. (1) Symptoms from the questionnaire are applied to (2) the diagnostic algorithm. (3) Specific anatomic criteria allow accurate diagnosis of ligament damage. The impact of ligament damage on function is tested using simulated operations, mechanically supporting the ligament and observing its effect on urge stress incontinence, urge, pelvic pain, and, with an overnight tampon, nocturia.

3. The ITS: a ligament-based system of surgery

In 1992, the original midurethral sling methodology was applied to the uterosacral ligaments for repair of apical prolapse, literally a reverse TVT. By 1993, the IT had evolved into the ITS, a holistic method for repair of the female pelvic floor, comprising a ligament-based diagnostic system [30], a questionnaire [31], a pictorial algorithm [30], a structured ligament examination system, and outpatient "simulated operations" supporting damaged ligaments per vaginam to reverse symptom changes such as USI, urinary urge, pelvic pain, and (with an overnight apical tampon), nocturia. From these evolved objective interventional urodynamics and ultrasound, in which pressure or anatomical changes are observed while specific ligaments are supported [32,33]. A new minimalist surgical methodology evolved with the aim of built-in safety and minimal postoperative pain and urinary retention. The key element in reducing the surgery to a minimum was application of the artificial neoligament surgical principle [8,9]. The same operations are applied for patients with major organ prolapse and for patients with major symptoms with minimal prolapse: "Repair the structure (ligaments) and you will restore the function".

4. Discussion and critical analysis

4.1. Anatomical repair

4.1.1. Analysis of existing surgical practice for pelvic floor repair Hysterectomy is almost general practice for third- or fourthdegree uterine prolapse, as is excision of the vagina for cystocele and rectocele. Hysterectomy is a major operation with associated morbidity and even mortality. It is generally assumed that the cause of cystocele and rectocele is a structural weakness in the central part of the vaginal wall, so this is excised, or mesh sheets are inserted behind the vagina. By removing a portion of the elastin and collagen, excision of the vagina can only diminish its strength and elasticity. Mesh and scar tissue cause fibrosis. Scar tissue and fibrosis arising from mesh can only inhibit the critical elasticity required to allow separate movements of the directional muscle forces that open and close the urethra and anal tubes and stretch the vagina to support the stretch receptors at the bladder base (Fig. 2). The end point of fibrosis in the zone of critical elasticity (Fig. 2) is the condition known as tethered vaginal syndrome [34], in which the patient loses massive amounts of urine on getting out of bed in the morning, or is even wet continuously. The smooth muscle components of the vagina and ligaments are innervated by visceral nerves and act in concert via neurological feedback mechanisms. Any excessively tensioned mesh can stretch the nerves and cause severe pelvic pain.

Laparoscopic sacrocolpopexy is a major operation. It generally requires hysterectomy and a 5-cm-wide strip of mesh, which erodes in 2% of cases and can result in intestinal obstruction in cases in which the tissue reaction is intense. If its attachment to the sacral promontory is overtight, it may inhibit the downward vectors (Fig. 2) and lead to evacuation difficulties.

4.1.2. Analysis of the ITS for pelvic floor surgery

A major conceptual difference exists between the ITS for surgery and standard practice. From an anatomical perspective, the ITS is a ligament-based system of surgery. It views the uterus as the keystone of an arch for apical support and an essential anchoring point for the major suspensory ligaments. Therefore, it must be conserved where possible. The ITS views the ligaments as the principal support for the organs (estimated breaking strain ~300 mg/ mm²) [35], with the vagina providing a supplementary elastic supporting system (estimated breaking strain \sim 60 mg/mm²) [35]. A good analogy is a domestic ceiling. The ligaments are the joists. The vagina is the plaster board, albeit an elastic one. The elastic component of the vaginal wall (collagen III and elastin) allows it to stretch during intercourse, but it also transmits muscle forces to support the bladder base anteriorly, close the urethra distally, and support the anterior rectal wall posteriorly. Because a far

smaller volume of mesh is inserted, the erosion rates for tapes and incidence rates for pain are lower than for mesh sheets, and are similar to those for TVT surgery.

4.2. Key methodology of the ITS

The ITS emphasizes minimal dissection of tissues, uterine and vaginal conservation, and reinforcement of damaged ligaments with tapes to create artificial neoligaments.

The same operations are applied for patients with major organ prolapse and for patients with major symptoms with minimal prolapse. Guided by the diagnostic system (Figs. 3 and 4), there are five main ligaments that can be repaired (Fig. 5 and Supplementary videos):

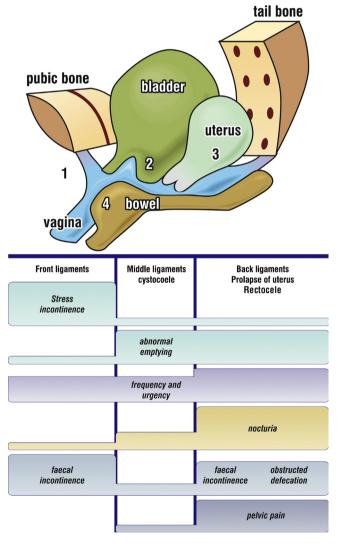


Fig. 4 – Simplified pictorial diagnostic algorithm relating structural damage (prolapse) to symptoms: 1, stress incontinence; 2, cystocele; 3, uterine prolapse; 4, rectocele. The size of the bar gives an approximate indication of the prevalence (probability) of the symptom. Ligaments that can be repaired are: pubourethral ligament (PUL); CX ring/cardinal ligament (CL); arcus tendineus fascia pelvis (ATFP); uterosacral ligament (USL); and perineal body (PB). The main symptom for tethered vagina syndrome is massive urine loss immediately on getting out of bed in the morning. The cause is excessive tightness in the bladder neck area of the vagina. Because pain and urgency have a peripheral neurological origin, even minimal vaginal prolapse may cause major symptoms.

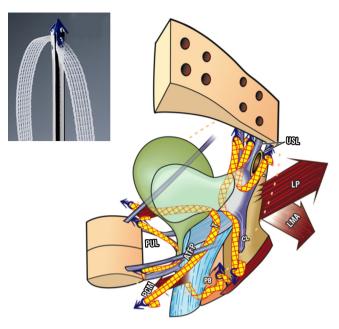


Fig. 5 – Five tissue fixation system (TFS) tapes repair all five ligaments (PUL, ATFP, CL, USL, PB). Three-dimensional standing view. The standing position in particular explains how the TFS USL sling supports the rectum and prevents prolapse downwards of its walls. In addition, it demonstrates the importance of USL support in preventing uterine prolapse and in supporting the sympathetic and parasympathetic ganglions to prevent referred pelvic pain.

- Pubourethral ligament (PUL)
- Arcus tendineus fascia pelvis (ATFP)
- Cardinal ligament (CL)
- Uterosacral ligament (USL)
- Perineal body (PB)

The PUL can be repaired using any midurethral sling. The USL can be repaired with any posterior sling, whether attached to the sacrospinous ligament or reinforcing the USL itself. The PB, ATFP, and CL can only be repaired with a TFS sling.

4.2.1. PUL repair

The neoligament principle was first applied in 1986 at Royal Perth Hospital as a tape at the midurethra to create the midurethral sling operation [8,9] now known as TVT. Later improvements were the transobturator tape (TOT) and the first minisling [19–22]. In a 5-yr randomized controlled trial, Sivaslioglu et al [36] achieved an 89% cure rate for the TFS midurethral sling compared to 78% for the TOT operation.

Cure rates of 90% have been achieved by Sekiguchi et al [37] for patients with intrinsic sphincter defect (ISD) using a TFS tensioned midurethral sling. The authors attribute this to the nonstretch nature of the tape, a precise tensioning mechanism (accurate to 1 mm), and one extra step, repair of the external urethral ligaments and tightening of the suburethral vaginal hammock [37].

The ISD data reported by Sekiguchi et al are in sharp contrast to the poor results reported by Basu et al [38] for non-ISD patients. The explanation is that a non-tensioned

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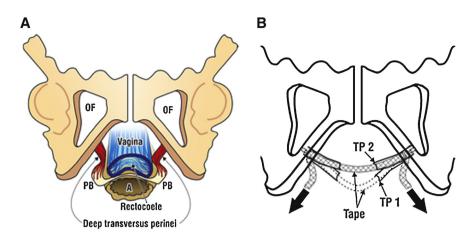


Fig. 6 – (A) Anatomy. Schematic view of the components of a perineal body (PB) in a patient with descending perineal syndrome. The PBs and their attachments to the descending ramus deep transversus perinei have been displaced downwards and laterally. The central part of the PB is stretched and thinned. The rectum (R) everts forward to cause low and mid rectocele. The arrows indicate attachment of the deep transverse perineal (DTP) muscle to the posterior surface of the descending ramus exactly at the junction of the upper 2/3 and lower 1/3. OF = obturator foramen; A = anus. (B) Surgery [21]. Schematic view of repair of prolapsed and laterally separated PBs. The PBs are elevated and approximated via the one-way tensioning action of the tissue fixation system sling. TP1 = prolapsed DTP muscles attached to the posterior surface of the descending ramus of the pubis. TP2 = restored position of the DTP muscle. The tape is inserted through the DTP behind the descending ramus.

minisling is inherently imprecise, requiring insertion and tightening of a loose PUL in one movement.

4.2.2. USL repair for uterine or apical prolapse with infracoccygeal sacropexy

In 1992, the first operation reinforcing USLs to repair uterine prolapse was performed under local anesthesia (infracoccygeal sacropexy). In essence, this was a TVT operation performed in reverse to reinforce the USLs. The tapes were inserted via the perineum, exiting immediately adjacent to the sacrospinous ligament to which they adhered in time. The cure rate for apical prolapse at 4.5 yr was 95% [39]. Goeschen [40] sutured the infracoccygeal sacropexy tape directly to the sacrospinous ligament. He reported an improvement in anatomical cure from 90% at 12 mo to 99%. However, symptom cure remained unaltered: obstructive defecation syndrome, 81%; nocturia, 80%; CPP, 81%; fecal incontinence, 80% [40].

4.2.3. Total ligament repair with TFS [22,24,26]

With the advent of the TFS it became possible for the first time to repair all five ligaments simultaneously in a minimally invasive way (Fig. 5). The first total ligament repairs were performed at Royal Perth Hospital at the end of 2003. Using the diagnostic system (Figs. 3 and 4), tapes were applied as shown in Fig. 5 (Supplementary videos).

Sekiguchi et al [27] reported 12-mo data for total ligament repair for pelvic organ prolapse (POP): 54 patients underwent a total of 162 separate TFS operations, with a 3% erosion rate. Of these, 157 were successful and five failed (4 cystoceles and 1 rectocele). In addition, two patients developed cervical protrusions at the introitus 6 mo after TFS surgery. There was no prolapse of the uterine body; thus, only the elongated cervix was amputated. Fig. 6

Inoue et al [22] performed total TFS ligament repair in 272 patients (989 separate ligament operations; Table 1). They defined surgical failure as any prolapse in any compartment of the patient at or beyond stage 2 according to the ICS POPQ classification. On this basis, the surgical cure rate for POP was 91.2% at 12 mo and 84% at 4 yr.

Including the first cohort, the rate of tape rejection or erosion was 0.4% for ATFP U-slings (1/272), 1.5% for cardinal/cervical ring slings (4/264), 1.6% for posterior slings (USL sling) (4/243), and 2.6% for TFS PB slings in 2012.

4.3. Tethered vagina syndrome and post vesicovaginal fistula incontinence

Incontinence continues in up to 55% of women after successful repair of vesicovaginal fistula. Three oppositely

Table 1 – Data for total ligament repair using the tissue fixation system in 272 patients [22]

Condition	Procedures (n)	Cured (n)	Cure rate observed (%)	Lower 95% CI
Prolapse	279	257	92.10	0.891
Urgency	133	124	93.20	0.879
Nocturia	86	62	72.10	0.597
Daytime frequency	132	120	90.10	0.935
Dragging pain	56	52	92.90	0.862
Fecal incontinence	52	46	88.50	0.798
CI = confidence interval				

CI = confidence interval.

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acting directional vectors close the distal and proximal parts of the urethra (Fig. 2). Adequate elasticity is required in the bladder neck area of the vagina for these two mechanisms to operate independently. Tissue necrosis and consequent scarring in the bladder neck area of the vagina "tether" the stronger posterior vectors to the weaker forward vectors, overcoming them, so that the urethra is opened out instead of being closed. The treatment proposed [41] was to release the vaginal tissue from its scarred attachments to the urethra and pubic bones and apply a skin-on Martius-type graft [34]. This method [41] has cured or improved this condition in more than 40 patients to date (Andrew Browning, personal communication). According to the IT, the graft restores the ability of the two separate closure mechanisms to operate independently of each other and results in continence.

4.4. Application of the ITS to cure symptoms of CPP and bladder and bowel dysfunction

Surgical treatment of overactive bladder (OAB) is the most controversial part of the IT, as it challenges deeply entrenched dogma, in particular the reliance on anticholinergic drug therapy, an industry that is currently worth \$16 billion per annum. According to a recent review [6], "the aetiology of OAB is unclear, but it is usually associated with detrusor overactivity". According to the ICS paradigm, OAB is not surgically curable and is treated mainly with anticholinergics, botox, or neuromodulation. The 1990 IT hypothesized that OAB and DO are different manifestations of a normal but prematurely activated micturition reflex caused by the inability of a lax vagina to support the bladder base stretch receptors. It was urodynamically demonstrated in 1993 that the events occurring in OAB and DO are identical to those occurring during normal micturition: first, a sensation of urgency, then a fall in urethral pressure, a rise in detrusor pressure, and evacuation of urine [42]. Furthermore, it was urodynamically demonstrated that it is possible to suppress the DO trace either by squeezing the pelvic organs upwards or with digital support of the bladder base per vaginam [43]. Using low-compliance urodynamic data and the chaos theory feedback equation

$$X^{\text{NEXT}} = cX(1-X),$$

where c is central inhibition and X is the fraction of possible nerve impulses in the micturition circuit issuing from insufficiently supported stretch receptors, it was possible to explain low-compliance bladder and the sinuous pressure-wave characteristic of DO in terms of the IT as an imbalance in the micturition feedback control system, whereby beyond a steady state, excess afferent impulses X issuing from the stretch receptors destabilize the feedback control system, so it swings between micturition and closure phases. Urodynamically, these swings are recorded as high and low pressures, with the sinuous wave reflecting the time delay in switching from the open phase to the closed phase [43]. Results published

for a 1997 20-mo surgical study involving repair of both PULs and USLs with tapes showed OAB symptom cure for urge incontinence (86%), frequency (85%), and nocturia (80%) [30]. The success was attributed to restoration of the musculoelastic vector forces via ligament repair, which the 1990 IT hypothesized stretched the vagina to support the bladder base stretch receptors, preventing excess afferent impulses from prematurely activating the micturition reflex.

4.4.1. Anorectal applications of the ITS

The ICS and many colorectal societies do not consider nonsphincteric fecal incontinence and obstructive defecation as surgically curable. The ITS considers that these conditions are a result of lax PULs or USLs, and it has been demonstrated that these conditions can be cured or improved by a short-stay operation to repair these ligaments. From the very first midurethral sling operations, patients were reporting cure of their involuntary loss of liquid and occasionally solid feces, and of constipation (obstructive defecation syndrome, ODS) after posterior sling procedures. Studies were performed by several researchers, beginning in 2005, using anal pressure studies, video X-ray myoproctogram studies, magnetic resonance imaging defecation studies, finite element models, and, more recently, interventional manometry in which anal pressure readings were taken before and during PUL, USL, and PB support procedures. It was found that the same three directional forces that control urethral closure and opening also control anorectal opening and closure, albeit slightly differently [44]. Preoperative and postoperative defecating proctograms after a posterior sling procedure confirmed correction of rectal wall intussusception, fecal incontinence, and severe chronic sacral or anal pain [18]. As a consequence of basic anatomical PB studies, a TFS operation was later devised to cure descending perineal syndrome, which is also not considered curable [23].

4.4.2. Chronic pelvic pain

Other than for known anatomical causes such as endometriosis and infection, CPP is not considered curable. CPP is thought to be psychological or caused by hypersensitization of nerves. The ITS considers that the cause of such CPP is firing of nerve plexuses T11-12 and S2-4, which become unsupported when the USLs are lax. The ITS considers the psychological manifestations as secondary to the pain. Following USL repair, cure rates of up to 85% were obtained for low abdominal pain, contact dyspareunia, low sacral backache, and vulvodynia. These sites are innervated by T11–12 and S2–4 nerves. This hypothesis of causation was further advanced by local anesthetic injection into the USLs at their attachment point to the cervix. In patients with vulvodynia, the pain disappeared in 8/10 patients for 20 min on both sides and in 2/10 on one side [45]. Similar results were obtained in three patients with interstitial cystitis via local anesthetic injections into the USL; vaginal, low abdominal, paraurethral, and cervical pain disappeared for 20 min [46].

Sarcomere length (µm)

elongation

E

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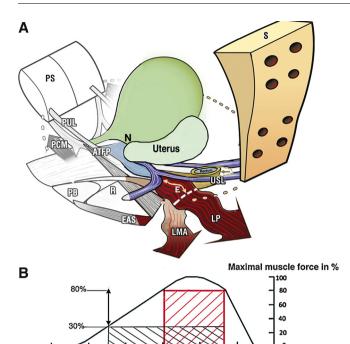


Fig. 7 – (A) Three-dimensional view from above. The uterus has prolapsed to first degree. The USLs have elongated by E, as have the LP and LMA. The rectum also has descended, by virtue of its attachments laterally to the elongated USL. The wavy shape of the LP and LMA indicate diminution of contractile strength. (B) Gordon's law. A striated muscle contracts optimally over a short normal length only (N, red square). Elongation of the muscle results in rapid loss of contractile force (E, black rectangle).

N

weakened

4.5. How can such varied symptoms be cured by ligament reinforcement?

The link between lax ligaments and diminished striated muscle force can be explained as follows. If a ligament is lax, the muscle that contracts against it lengthens (Fig. 7). It also weakens, because an elongated muscle has weaker contractile strength [47].

The muscles can no longer close the urethral and anal outlet tubes (incontinence) evacuate them (ODS, obstructed micturition) or stretch the organs sufficiently to prevent activation of the micturition and defecation reflexes (urge incontinence, tenesmus) or stretch the uterosacral ligaments sufficiently to support the T11–12 and S2–4 nerve plexuses contained therein (chronic pelvic pain).

4.6. Which is the weak link, ligament or muscle?

In a blinded study among 50 patients with USI undergoing a paraurethral midurethral sling procedure with biopsy of the pubococcygeus muscle, 45 had evidence of muscle damage. On the day after surgery, 89% of the patients reported cure

of their USI. It was concluded that ligaments, not muscles, are the most vulnerable structure, at least with regard to USI [48].

5. Conclusions

The IT pathway is consistent with Kuhn's descriptions for new paradigms. IT quickly expanded into an anatomical diagnostic and surgical system and opened up new pathways for fundamental research, all driven by the key elements of the IT: damaged ligaments as the cause, and reinforcement of these ligaments as the cure. The PUL midurethral sling has led to a major scientific direction for USI and is now part of what Kuhn calls "normal science". In this update, we show how consideration of four other ligaments (ATFP, CL, USL, and PB) is similarly evolving into "normal science", albeit more gradually.

Conflicts of interest

The authors have nothing to disclose.

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Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at http://dx.doi.org/10.1016/j.eursup.2017.01.001.

References

- [1] Petros PE, Ulmsten U. An integral theory of female urinary incontinence. Acta Obstet Gynecol Scand 1990;69(Suppl 153):7–31.
- [2] Kuhn T. The structure of scientific revolutions.. , ed. 3. Chicago, IL: University of Chicago Press; 1996.
- [3] Popper KR. Theories, falsifiability, the logic of scientific discovery. London, UK: Unwin, Hyman; 1980: 27–146.
- [4] Bates P, Bradley WE, Glen E, et al. First report on the standardisation of terminology of lower urinary tract function. In: Abrams P, Feneley R, Torrens M, editors. Urodynamics.. Berlin: Springer Verlag; 1983. p. 188–204.
- [5] 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, editors. Fifth International Consultation on Incontinence.. Bristol, UK: International Consultation on Urological Diseases; 2013. p. 261–360.
- [6] Wong J, Tincello DG. Management of the refractory overactive bladder. Obstet Gynaecol 2016;18:173–81.
- [7] Fall M, Baranowski AP, Elneil S, et al. EAU guidelines on chronic pelvic pain. Eur Urol 2010;57:35–48.
- [8] Petros PE, Ulmsten U, Papadimitriou J. The autogenic neoligament procedure: a technique for planned formation of an artificial neoligament. Acta Obstet Gynecol Scand 1990;69(Suppl 153):43–51.
- [9] Petros PE, Ulmsten U. The combined intravaginal sling and tuck operation. An ambulatory procedure for stress and urge incontinence. Acta Obstet Gynecol Scand 1990;69(Suppl 153):53–9.

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- [10] Petros PEP. Creating a gold standard surgical device: scientific discoveries leading to the TVT and beyond. Int Urogynecol J 2015; 26:471–6.
- [11] Petros PE, Ulmsten U. The role of a lax posterior fornix in the causation of stress and urgency symptoms: a preliminary report. Acta Obstet Gynecol Scand 1990;69(Suppl 153):71–3.
- [12] Petros PE. Severe chronic pelvic pain in women may be caused by ligamentous laxity in the posterior fornix of the vagina. Aust N Z J Obstet Gynaecol 1996;36:351–4.
- [13] Petros PE. Surgical cure of faecal incontinence in the female by reconstruction of the anterior ligamentous supports of vagina. In: Proceedings of the 1994 International Continence Meeting, Prague, Czech Republic. Abstract 307.
- [14] Farnsworth BN. Posterior intravaginal slingplasty (infracoccygeal sacropexy) for severe posthysterectomy vaginal vault prolapse, a preliminary report on efficacy and safety. Int Urogynecol J 2002;13: 4–8.
- [15] Goeschen K. Posterior fornix syndrome: comparison of original (2004) and modified (2015) post-PIVS anatomic and symptomatic results—a personal journey. Pelviperineology 2015;34:85–91.
- [16] Abendstein B, Petros PEP, Richardson PA, Goeschen K, Dodero D. The surgical anatomy of rectocele and anterior rectal wall intussusception. Int Urogynecol J 2008;19:513–7.
- [17] Petros PE, Swash M. A musculoelastic theory of anorectal function and dysfunction in the female. J Pelviperineol 2008;27:86–7.
- [18] Abendstein B, Brugger BA, Furtschegger A, Rieger M, Petros PE. Role of the uterosacral ligaments in the causation of rectal intussusception, abnormal bowel emptying, and fecal incontinence—a prospective study. J Pelviperineol 2008;27:118–21.
- [19] Petros PEP, Richardson PA. The midurethral TFS sling—a 'micromethod' for cure of stress incontinence: preliminary report. Aust N Z J Obstet Gynaecol 2005;45:372–5.
- [20] Petros PEP, Richardson PA. The TFS posterior sling for repair of uterine/vault prolapse—a preliminary report. Aust N Z J Obstet Gynaecol 2005;45:376–9.
- [21] Petros PEP, Richardson PA, Goeschen K, Abendstein B. The tissue fixation system (TFS) provides a new structural method for cystocoele repair— a preliminary report. Aust N Z J Obstet Gynaecol 2006;46:474–8.
- [22] Inoue H, Kohata Y, Sekiguchi Y, Kusaka T, Fukuda T, Monnma M. The TFS minisling restores major pelvic organ prolapse and symptoms in aged Japanese women by repairing damaged suspensory ligaments—12-48 month data. Pelviperineology 2015;34:79–83.
- [23] Wagenlehner FM, Del Amo E, Santoro G, Petros P. Perineal body repair in patients with 3rd degree rectocele. A critical analysis of the tissue fixation system. Colorectal Dis 2013;15:e760–5.
- [24] Haverfield M. Tissue fixation system (TFS) neoligament pelvic organ repair procedures—12 and 24 month results. Pelviperineology 2015;34:70–4.
- [25] Abendstein B, Petros PE, Richardson PA. Ligamentous repair using the tissue fixation system confirms a causal link between damaged suspensory ligaments and urinary and fecal incontinence. J Pelviperineol 2008;27:114–7.
- [26] Petros PEP, Inoue H. How I do it? Transvaginal perineal body repair for low rectocoele Tech Coloproctol 2013;17:449–54.
- [27] Sekiguchi Y, Kinjo M, Maeda Y, Kubota Y. Reinforcement of suspensory ligaments under local anesthesia cures pelvic organ prolapse: 12-month results. Int Urogynecol J 2014;25:783–9.
- [28] Petros PEP, Inoue H. Pelvic pain may be caused by laxity in the uterosacral ligaments as part of the "posterior fornix syndrome". Aust N Z J Obstet Gynaecol 2013;53:325-6.

- [29] Scheffler KU, Petros PE, Hakenberg OW. A hypothesis for urinary stream divergence in the female: unilateral dislocation of the pubovisceral muscle. Pelviperineology 2014;33:10–3.
- [30] Petros PE. New ambulatory surgical methods using an anatomical classification of urinary dysfunction improve stress, urge, and abnormal emptying. Int J Urogynecol 1997;8:270–8.
- [31] Wagenlehner FM, Fröhlich O, Bschleipfer T, Weidner W, Perletti G. The integral theory system questionnaire: an anatomically directed questionnaire to determine pelvic floor dysfunctions in women. World J Urol 2014;32:769.
- [32] Petros PE, Von Konsky B. Anchoring the midurethra restores bladder neck anatomy and continence. Lancet 1999;354:997–8.
- [33] Petros PE. Changes in bladder neck geometry and closure pressure following midurethral anchoring suggest a musculo-elastic mechanism activates closure. Neurourol Urodyn 2003;22:191–7.
- [34] Goeschen K, Müller-Funogea A, Petros P. Tethered vagina syndrome: cure of severe involuntary urinary loss by skin graft to the bladder neck area of vagina. Pelviperineology 2010;29:100–2.
- [35] Yamada H. Aging rate for the strength of human organs and tissues. In: Evans FG, editor. Strength of biological materials.. Baltimore, MD: Williams & Wilkins; 1970. p. 272–80.
- [36] Sivaslioglu AA, Unlubilgin E, Aydogmus S, Keskin L, Dolen I. A prospective randomized controlled trial of the transobturator tape and tissue fixation mini-sling in patients with stress urinary incontinence: 5-year results. J Urol 2012;188:194–9.
- [37] Sekiguchi Y, Kinjyo M, Inoue H, et al. Outpatient mid urethral tissue fixation system sling for urodynamic stress urinary incontinence. [Urol 2009;182:2810–3.
- [38] Basu M, Duckett J. A randomised trial of a retropubic tension-free vaginal tape versus a mini-sling for stress incontinence. Br J Obstet Gynaecol 2010;117:730.
- [39] Petros PE. Vault prolapse II: restoration of dynamic vaginal supports by the infracoccygeal sacropexy, an axial day-care vaginal procedure. Int J Urogynecol Pelvic Floor Dysfunct 2001;12: 296–303.
- [40] Goeschen K. Posterior fornix syndrome: comparison of original (2004) and modified (2015) post-PIVS anatomic and symptomatic results—a personal journey. Pelviperineology 2015;34:85–91.
- [41] Petros PEP, Williams G, Browning A. Post vesico-vaginal fistula repair incontinence—a new hypotheses and classification potentially guide prevention and cure. Pelviperineology 2015;34:48–50.
- [42] Petros PE, Ulmsten U. Bladder instability in women: a premature activation of the micturition reflex. Neurourol Urodyn 1993;12: 235–9.
- [43] Petros PE. Detrusor instability and low compliance may represent different levels of disturbance in peripheral feedback control of the micturition reflex. Neurourol Urodyn 1999;18:81–91.
- [44] Petros P, Swash M, Bush M, Fernandez M, Gunnemann A, Zimmer M. Defecation 1—testing a hypothesis for pelvic striated muscle action to open the anorectum. Tech Coloproctol 2012;16:437–43.
- [45] Bornstein J, Zarfati D, Petros PEP. Re: Causation of vulvar vestibulitis. Aust N Z J Obstet Gynaecol 2005;45:538–41.
- [46] Petros PEP. Interstitial cystitis (painful bladder syndrome) may, in some cases, be a referred pain from the uterosacral ligaments. Pelviperineology 2010;29:56–9.
- [47] Gordon AM, Huxley AF, Julian FJ. The variation in isometric tension with sarcomere length in vertebrate muscle fibres. J Physiol 1966;184:170–92.
- [48] Petros PE, Swash M, Kakulas B. Stress urinary incontinence results from muscle weakness and ligamentous laxity in the pelvic floor. J Pelviperineol 2008;27:107–9.