Review Article | Data-Driven Clinical Practice and Policy Making

Simulated operations (SOs) apply mechanical support to structures to confirm symptom causation

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Abstract: Simulated operations (SOs) are a direct application of the Integral Theory (IT) mantras, "structure and function are related" and "restore the structure and you will improve the function". SOs performed in a clinic setting, are the most effective way possible to test the validity of the IT predictions: stress urinary incontinence (SUI) and urge are mainly caused by laxity in the vagina or its supporting ligaments. The SUI prediction of the IT is validated if a hemostat applied vaginally in the position of the midurethra to mechanically support the pubourethral ligament (PUL) immediately stops urine loss on coughing. The urge and chronic pelvic pain (CPP) predictions of the IT are similarly validated if a patient states her urge and pain symptoms are relieved by insertion of the bottom blade of a bivalve speculum which supports the uterosacral ligaments (USLs). An important use of SOs is to preoperatively assess (by the hemostat test) whether sling surgery for SUI is likely to cure the patient. Similarly, the speculum is very useful for diagnosing whether severe urge or pain symptoms in a woman with minimal prolapse are originating from weak USLs. If digital support of a cystocele relieves urge symptoms, the patient can reasonably be informed that a cystocele repair should improve the urge as well her cystocele prolapse. Used intraoperatively under spinal anesthesia, SOs can determine whether a sling is sufficiently tight to reverse the loose PUL which is causing the SUI. Approximating both cardinal ligaments (CLs) intraoperatively can result in a remarkable disappearance of a transverese defect cystocele; approximating USLs intraoperatively can give an indication of how effective a USL plication would be surgically.

Keywords: Simulated operations (SOs); pubourethral ligaments (PULs); vagina; uterosacral ligaments (USLs); cardinal ligaments (CLs)

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Introduction

Foreword to the 1990 Integral Theory (IT).

"To me, it has always been obvious that, in general, the reason behind female urinary incontinence has to be looked for outside the bladder i.e., in the structures supporting the urethra and bladder neck—specifically ligaments, pelvic floor muscles, and vagina. If symptoms of urinary incontinence arise from a dysfunctional anatomy in the aforementioned structures then function should come with restoration of anatomy."

Axel Ingelman-Sundberg, Karolinska Institutet 1990.

The foreword distils the basis of simulated operations (SOs): urinary control is from outside the bladder, from pelvic muscles contracting against them. If a ligament is weak, say from deficient collagen, the pelvic muscles which contract against them also weaken, so they cannot close the urethra (causing stress incontinence), open it (causing emptying difficulties), or stretch the vagina like a trampoline to prevent premature activation of the micturition reflex (causing urge incontinence) (1).

What are SOs?

SOs mimic a surgical operation. SOs are used to confirm that a particular ligament is causing a particular symptom or prolapse. SOs mechanically support pubourethral and uterosacral ligaments (USLs), the vagina, (for bladder base stretch receptors) while the effect on symptoms [urge, stress urinary incontinence (SUI), pain] is observed. The concept of SOs has expanded to monitoring anatomical changes by ultrasound, and pressure changes on urodynamic graphs. SOs are useful in preoperatively deciding whether to proceed with ligament repair surgery in women who have severe symptoms, but only minimal prolapse. SOs provide the evidence for the IT's statement that ligament laxity is a major cause of lower urinary tract symptoms (LUTSs), prolapse, and chronic pelvic pain (CPP).

The first SO for mechanical control of SUI was performed in 1986 (*Figure 1*) (see Video S1). The 1986 observations provided the insights which led to the midurethral sling; specifically, urine loss on coughing could be controlled by mechanical support of the pubourethral ligaments (PULs) by a hemostat, and, to a lesser extent, plication of the suburethral vaginal "hammock" (demonstrated in Video S1). This observation spawned the hypothesis that loose, collagen deficient PULs may be the cause of SUI (1). The hypothesis was later validated by a series of experiments which led to the IT (1) and the prototype midurethral sling and the tension-free vaginal tape (TVT) operation (1,2). Instead of the hemostat, a tape was used to create new collagen to reinforce PULs (3).

An anatomical rationale for SOs

With reference to *Figure 2A*, the circles 1–4 pictorially represent the structures damaged by the head as it descends down the vaginal birth canal. At each level of the birth canal, the head may damage parts of the vagina itself and the ligaments which suspend the organs, to cause prolapse of the bladder, bowel, and uterus. The same damaged ligaments, contained within the circles 1–4, may cause the symptoms of bladder/bowel and CPP dysfunctions, some of which can be directly tested by SOs. The symptoms caused by the damaged ligaments(circles 1–4) are detailed in the diagnostic algorithm (*Figure 2B*). The numbers and ligaments in each of the four circles 1–4, correlate with the same numbers in the three columns of the diagnostic algorithm (*Figure 2B*).

How SOs test (and demonstrate) the predictions of the IT

"Support the structure and you will improve the function" (IT).

What SOs do is to provide mechanical support so the ligament can do its job. The ligaments damaged at the four levels of the vaginal canal, the PUL, the cardinal ligament (CL), the USL, and the perineal body (PB) (*Figure 2A*),

Highlight box

Key findings

- "Simulated operations" (SOs) mechanically support structures to confirm symptom causation and to help predict symptom outcomes of surgical repair of that structure.

What is known and what is new?

- SOs are not in common use.
- Unilateral support of the pubourethral ligament at midurethra with a hemostat can prevent urine loss on coughing [stress urinary incontinence (SUI)]; uterosacral ligament support in the posterior fornix with a speculum can relieve pain and urge symptoms.

What is the implication and what should change now?

- Disappearance of SUI, urge, and pain by SOs, is direct proof of the Integral Theory's predictions for ligament causation. SOs take a few seconds to perform, provide much information, and should be part of a standard vaginal examination.

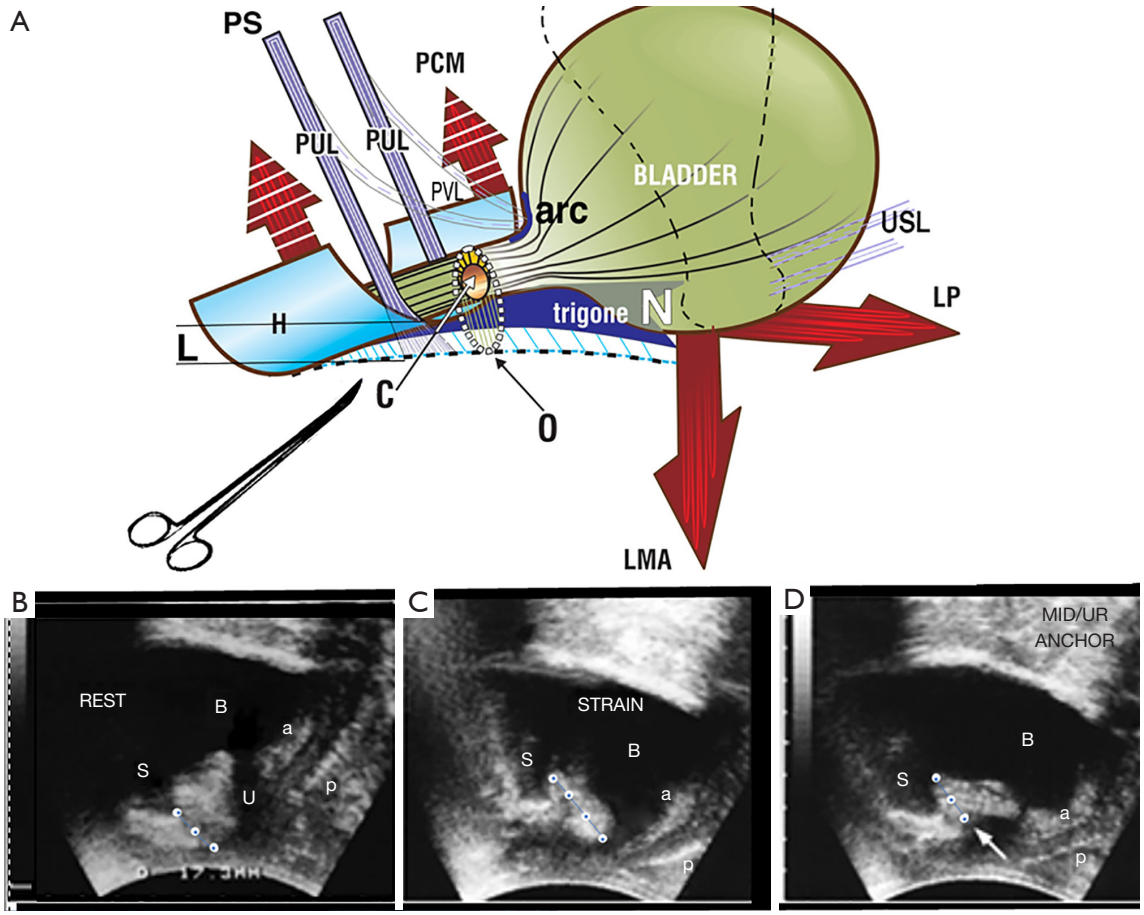

Figure 1 PUL SO restoration of continence by PUL support (Video S1). (A) SUI: if the PUL is weak, it lengthens to "L" on effort and cannot support the urethra; the "PCM" cannot stretch the distal vagina "H" sufficiently to close the distal urethra from behind; the "LP/LMA" forces stretch the upper vagina (broken lines) and trigone backwards to open "H" and the posterior urethral wall, from "C" to "O". The hemostat mimics what a suburethral sling does; it prevents "PUL" extension to "L" and restores urethral closure, as seen in the right ultrasound frame (white arrow). (B-D) Transperineal ultrasound in a patient with SUI. (B) Rest: white circles represent PUL. The organs are in the correct anatomical position. (C) Strain: note elongation of the PUL on straining (four white circles). The funnelling of the bladder neck and expansion of the urethral diameter along the whole urethra exponentially lowers the urethral resistance to urine flow and urine is lost on coughing. (D) Hemostat test: the white arrow represents the hemostat as in Video S1. The hemostat supports a weak PUL, prevents elongation "L", and prevents opening by LP/LMA to cause SUI. Both figures reused from Petros P. The female pelvic floor function, dysfunction and management according to the Integral Theory. 3rd ed. Heidelberg: Springer Berlin; 2010. With permission from Peter Petros; retains ownership of the copyright. PS, pubic symphysis; PCM, pubococcygeus muscle; PUL, pubourethral ligament; PVL, pubovesical ligament; arc, arc of Gilvernet; H, suburethral vaginal hammock; C, closed; O, open; N, urothelial stretch receptors; USL, uterosacral ligament; LP, levator plate; LMA, conjoint longitudinal muscle of the anus; S, symphysis; B, bladder; U, urethra; a, anterior vaginal wall; p, posterior vaginal wall; MID, midurethral anchor; UR, urethra; SO, simulated operation; SUI, stress urinary incontinence.

weaken and stretch when forces are applied to them, from whatever the source, as does the PUL (ultrasound, *Figure 1*). The IT predications that, "Stress, urge and chronic pelvic pain, for different reasons, are mainly caused by laxity in the vagina or its supporting ligaments", can be directly tested during standard vaginal examination by mechanically supporting either the PUL or USL (or both) by a hemostat (as in *Figure 1*) or a speculum (as in *Figure 3*).

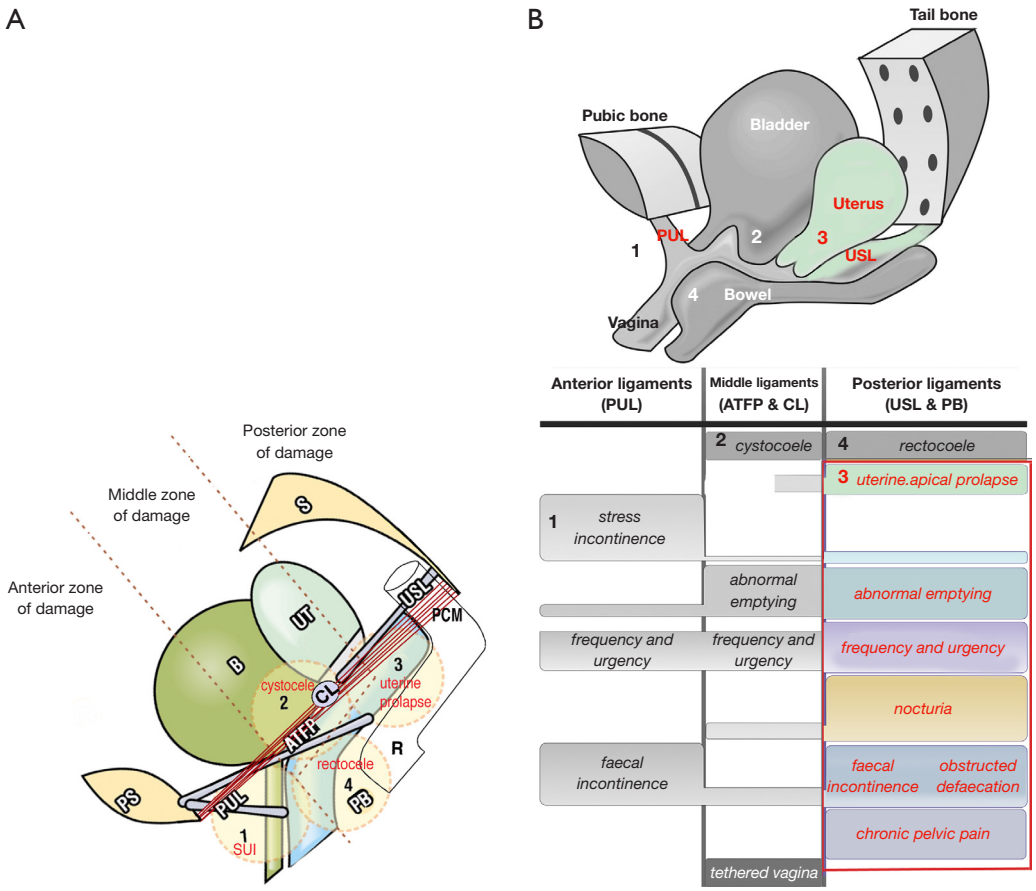

Figure 2 Genesis and application of the diagnostic algorithm. (A) How the descending head causes ligament damage and prolapse. The zones of damage and circle numbers, 1–4 in (A), correlate with the numbers in the three columns in (B). (B) The three columns represent the three anatomical zones of the algorithm. The diagnostic algorithm shows which ligaments may cause which prolapses and which symptoms. The numbers 1–4 correlate with the sites of ligament injury, circles 1–4 in (A). All the symptoms in the rectangle co-occur as part of the Posterior Fornix Syndrome and are potentially curable by USL repair (3). Both figures reused from Petros P. The female pelvic floor function, dysfunction and management according to the Integral Theory. 3rd ed. Heidelberg: Springer Berlin; 2010. With permission from Peter Petros; retains ownership of the copyright. PS, pubic symphysis; PUL, pubourethral ligament; SUI, stress urinary incontinence; B, bladder; UT, uterus; CL, cardinal ligament; ATFP, arcus tendineus fascia pelvis; PB, perineal body; R, rectum; S, sacrum; USL, uterosacral ligament; PCM, pubococcygeus muscle.

The most frequently used SOs

Clinically, the PUL SOs hemostat tests for stress incontinence (*Figure 1*, Video S1), and the USL SOs speculum tests (*Figure 3*), for urge and CPP symptoms, can easily be included in the standard vaginal examination. Other SOs, including intraoperative SOs, will be presented below.

Note: if performed as an outpatient, SO tests must be performed with extreme gentleness, as any excess pressure on the vagina by forceps can cause pain.

SOs which can be performed during clinical examinations

The aim of this work is to present examples of SOs to show that if a particular ligament in the three symptom zones (*Figure 2B*), is mechanically supported, and it relieves the related symptoms (such as urge and pain) in that zone, a cause/effect (damaged ligament/symptom) can be inferred. If surgery is intended, a positive SO indicates a higher probability of cure with surgical repair. Such SOs are standard predictive interventions for surgeons

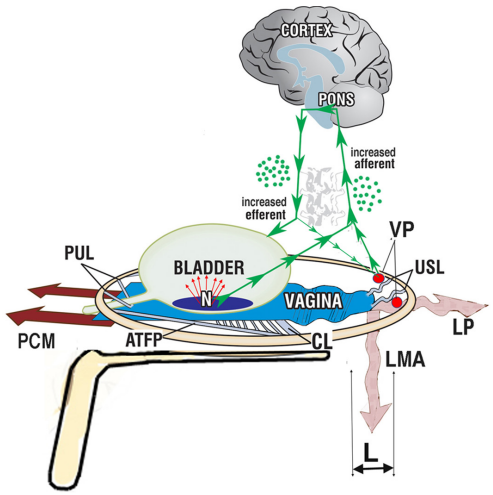

Figure 3 SO speculum test supports USL and stretch receptors to relieve pain and urge. As such, this test is definitive for IC/bladder pain syndrome arising from loose USLs. A gently inserted speculum mechanically supports urothelial stretch receptors "N" and "USLs" which support the pelvic visceral nerve plexuses "VP". Support of "N" prevents "N" firing off afferent nerve impulses which are interpreted as urge. Support of loose USLs "L" prevents the "VP" firing off of "*de novo*" pain impulses. Pain and urge are immediately alleviated in 70–80% of tests. Support of the USL restores LP/LMA contractility enabling it to stretch the vagina backwards. Wavy form of "LP" and "LMA" indicate contractile weakness as a consequence of contracting against loose "USLs". Reused from Petros P. The female pelvic floor function, dysfunction and management according to the Integral Theory. 3rd ed. Heidelberg: Springer Berlin; 2010. With permission from Peter Petros; retains ownership of the copyright. PUL, pubourethral ligament; PCM, pubococcygeus muscle; ATFP, arcus tendineus fascia pelvis; N, urothelial stretch receptors; CL, cardinal ligament; VP, visceral plexus; USL, uterosacral ligament; LP, levator plate; LMA, conjoint longitudinal muscle of the anus; L, laxity in USLs; SO, simulated operation; IC, interstitial cystitis.

who follow the IT Paradigm (ITP) for surgical repair of the symptoms in the three zones of the vagina (4-12) (*Figure 2B*). The SOs which follow will be categorized according to the structural level of damage (yellow circles), numbered 1–4, in *Figure 2A,2B*.

SOs testing PUL for SUI causation

The relationship of loose PULs to stress incontinence is seen in Video S1. The anatomical and ultrasound analogues of the SO are detailed in *Figure 1*; the hemostat (white arrow, right ultrasound frame) prevents the PUL lengthening to "L" and so prevents urine loss on coughing; the anatomy and continence are both restored (13) in a manner similar to that of the curative midurethral sling (2,4).

Proof that a midurethral sling does not work by urethral obstruction

The woman is asked to pass urine while the hemostat test shown by Video S1 is preventing SUI. This is not an easy test, but many women manage to do so. Passing urine with the hemostat *in situ* indicates that the modus operandi of the midurethral sling is not obstructive. Rather it restores anatomy and function, as in the right ultrasound frame (*Figure 1*).

SO testing PUL causation for stress fecal incontinence (FI)

Stress FI is much rarer than SUI. The hemostat test for stress FI on coughing is exactly the same as that for SUI (*Figure 1*) (14).

SO testing for PUL causation of mixed incontinence

The testing for "mixed incontinence" is the same as for "genuine" SUI, except that the patient is asked if urge is also relieved. The PUL anchors the pubococcygeus muscle (PCM) which stretches the vagina forwards to provide 50% of the tensioning force to support the urothelial stretch receptors "N" (*Figure 1*). If the hemostat test (*Figure 1*), reduces both SUI and urge, it can be predicted that both symptoms may be cured or improved by midurethral sling surgery (Video S2). Video S2 indicates lax PUL as cause of an activated micturition reflex, controlled by PUL support.

SO testing USL causation for urge and pain

The speculum test mechanically supports the stretch receptors, "N" and visceral plexuses from below (15) (*Figure 3*). The speculum is estimated to control urge and pain in up to 70–80% of women.

Note: excessive backward pressure by the speculum may stimulate more afferents to worsen the pain and urge symptoms. The pain symptoms originate probably from afferent visceral nerve junctions within the visceral plexus, not from the end organ to which it is attributed, as a "referred" pain.

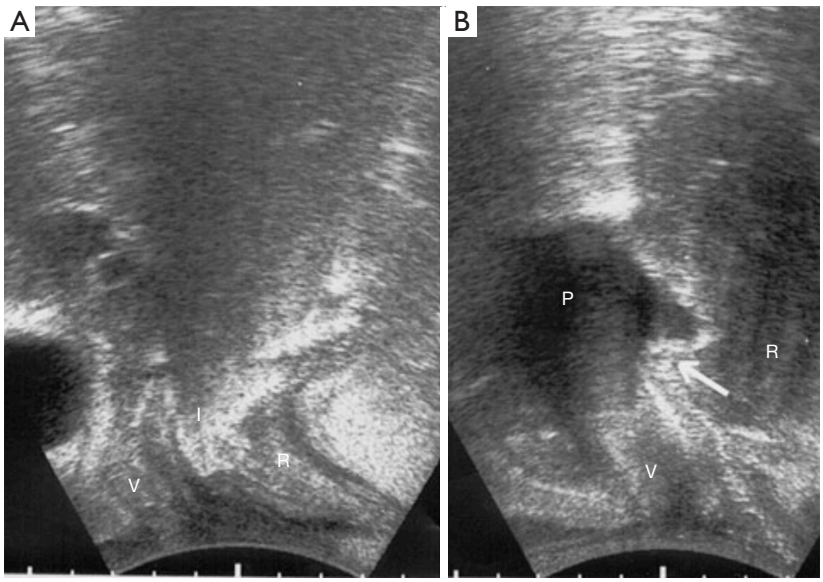

Figure 4 Transperineal ultrasound: (A) at rest, no pessary; (B) patient straining. Pessary "P" in the apical part of the vagina. Note "stretching back" of the intussusception (white arrow). Reused from Petros P. The female pelvic floor function, dysfunction and management according to the Integral Theory. 3rd ed. Heidelberg: Springer Berlin; 2010. With permission from Peter Petros; retains ownership of the copyright. V, vagina; I, intussusception; R, rectum; P, pubic symphysis; USL, uterosacral ligament.

SO local anesthetic (LA) testing for visceral plexus origin of CPP

A definitive test for vulvodynia causation is the Bornstein test: LA injection into the lower part of both USLs reduced vulvodynia pain in ten women who had vulvodynia (16). On testing for vulval hyperesthesia, there was no hyperesthesia in eight women, and in two women, on one side of the vulva only.

The Bornstein test was also applied in women with a validated diagnosis of interstitial cystitis (IC). LA was injected into the lower part of both USLs in three women who had IC and multiple sites of CPP. CPP included vulvodynia, lower abdominal pain, and marked paraurethral tenderness. IC and CPP were relieved for 20 minutes following the LA injection (17).

SO testing loose USL contribution to causation of SUI

In some women, using Allis forceps to approximate USLs can sometimes control SUI on coughing. This is explained by conjoint longitudinal muscle of the anus (LMA) contraction against USL to rotate the bladder base backwards/downwards to close the urethra at the bladder neck (*Figure 1*).

Note: this test must be performed with extreme gentleness, as the excess pressure during grasping of the vagina by forceps can cause pain.

SO testing USL origin of CPP by cervical palpation

Digital pressure on the cervix by cervical palpation in women with CPP usually reproduces the pain in the areas of the pelvis where pain is perceived by the patient (18).

Note: pressing on the cervix in women with CPP can be very painful and the patient must be warned in advance.

SO testing for nocturia with a roll gauze or other tampon

Shkarupa *et al.* inserted a sterile gauze roll tampon for a period from 24 to 36 hours (6). They reported statistically validated reduction in overactive bladder (OAB) symptoms (urge, frequency, and nocturia) (6). Similar symptom reductions have been achieved with vaginal tampons, not only for OAB symptoms, but also, urinary emptying symptoms, CPP and, as seen in *Figures 4,5*, reduction of anterior rectal wall intussusception.

SO assessing USL causation of rectal intussusception with a tampon

A tampon pushed up into the posterior vaginal fornix

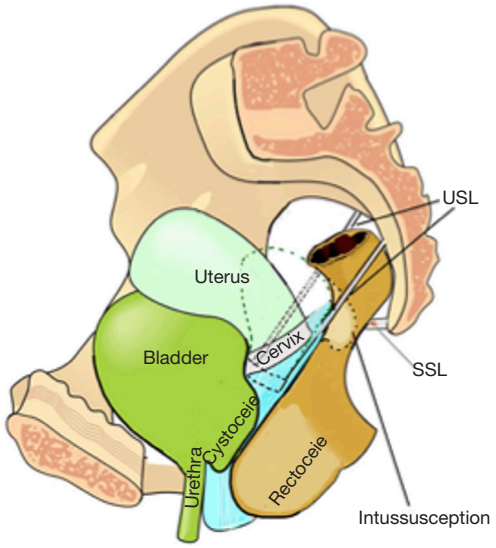

Figure 5 Uterine prolapse caused by damage during childbirth and elongation of the USLs. "USLs" attach loosely to the lateral wall of the rectum. As the "USLs" lengthen to cause uterine prolapse, the anterior rectal wall elongates forwards and laterally, weakening it structurally. The anterior rectal wall widens, slackens, loses its shape, and prolapses inwards to cause intussusception. Reused from Petros P. The female pelvic floor function, dysfunction and management according to the Integral Theory. 3rd ed. Heidelberg: Springer Berlin; 2010. With permission from Peter Petros; retains ownership of the copyright. USL, uterosacral ligament; SSL, sacrospinous ligament.

restores anterior rectal wall intussusception (19). With reference to *Figure 4A*, anterior rectal wall intussusception "I" was seen during straining. After insertion of a 3 cm × 3 cm × 6 cm vaginal pessary into the posterior fornix (*Figure 4B*), the pessary elevates the posterior vaginal fornix and, with it, the intussusception (white arrow) even during straining, to (almost) restore normal anatomy (19).

Anatomical rationale for the SO intussusception tampon test

From an anatomical perspective, the close attachment of suspensory USLs to the lateral wall of the rectum means that if the ligaments are loose, both rectum and vaginal apex may prolapse simultaneously, leading sometimes to anterior rectal wall intussusception (*Figures 4,5*).

SO testing USL laxity as cause for enterocele and apical prolapse

Figure 6 shows an enterocele in a woman years after a hysterectomy. USLs have elongated and become laterally displaced. Approximation of USLs in the OR reduced the enterocele. This test could be painful in the clinic, unless performed with extreme care.

SO testing for CL causation of cystocele

CL weakness is the main cause of transverse defect cyctocele (*Figure 7*). With reference to *Figure 7*, the CL SO

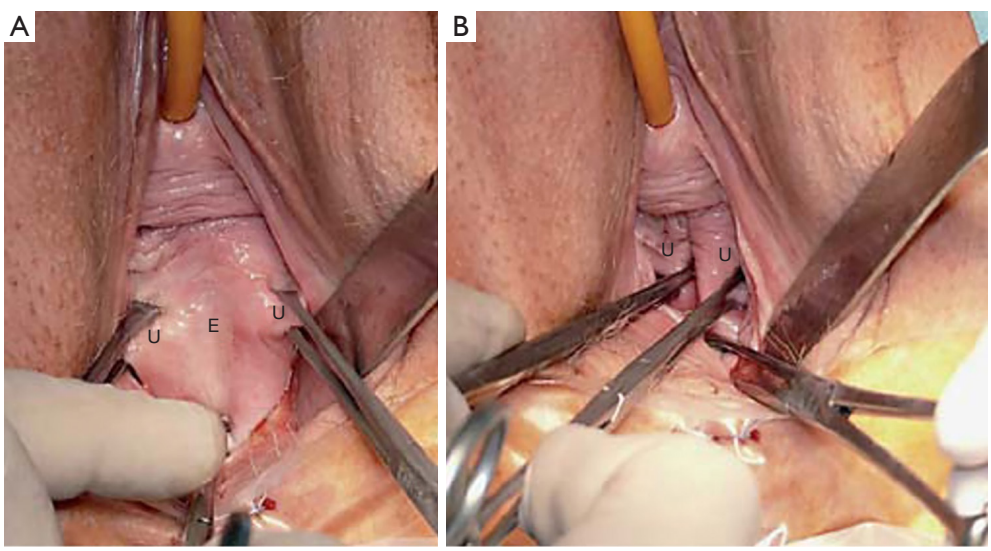

Figure 6 USL SOs performed in operating room (circle 3). (A) Posterior vaginal wall prior to SO. (B) Allis forceps approximate USLs. Enterocele disappears. Reused from Petros P. The female pelvic floor function, dysfunction and management according to the Integral Theory. 3rd ed. Heidelberg: Springer Berlin; 2010. With permission from Peter Petros; retains ownership of the copyright. U, USLs grasped by Allis forceps; USL, uterosacral ligament; E, bulging enterocele; SO, simulated operation.

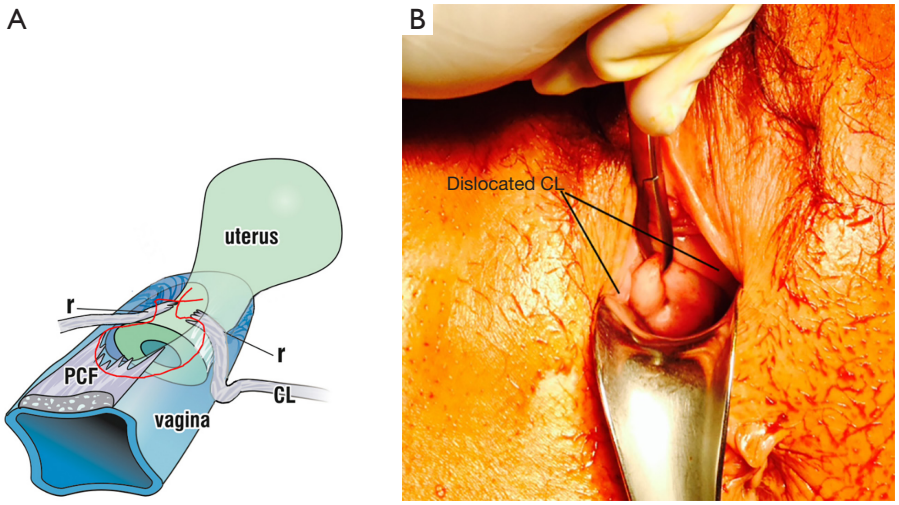

Figure 7 Pathogenesis of transverse defect cystocele. (A) CLs "r" from the cervix and become displaced laterally. The torn "PCF" layer of the proximal anterior vagina is also torn. It cannot support the bladder above it, and the vagina prolapses downwards like a trapdoor to form a cystocele, which can be repaired by suturing the displaced "CL" back onto the anterior surface of the cervix, then re-attaching the "PCF" onto the now-repaired "CLs" (*Figure 8*), preferably with wide-bore No. 2 polyester sutures. (B) The dislocated "CL" prolapses down on the lateral aspect of the cervix. Reused from Petros P. The female pelvic floor function, dysfunction and management according to the Integral Theory. 3rd ed. Heidelberg: Springer Berlin; 2010. With permission from Peter Petros; retains ownership of the copyright. r, rupture; PCF, pubocervical fascia; CL, cardinal ligament.

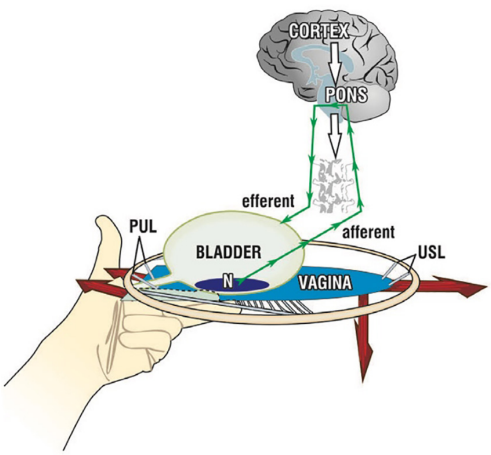

Figure 8 Gentle digital support of the anterior vaginal wall supports the urothelial stretch receptors "N", reducing afferent impulses, and preventing activation of the micturition reflex which is interpreted as "urge" (16). Excessive pressure on "N" may stimulate more afferents to cause urge (Video S2). Reused from Petros P. The female pelvic floor function, dysfunction and management according to the Integral Theory. 3rd ed. Heidelberg: Springer Berlin; 2010. With permission from Peter Petros; retains ownership of the copyright. PUL, pubourethral ligament; N, urothelial stretch receptors; USL, uterosacral ligament.

is based on grasping the prolapsed vagina at the site of the two dislocated CLs (*Figure 7B*), and approximating them to the anterior lip of the cervix, as in Video S3. The cystocele disappears. If, however, there is also a central cystocele (which happens about 20% of the time), only the proximal cystocele is reduced, as seen in Video S3, and a partial cystocele protrusion remains distally.

SO digital support of bladder can reduce urge symptoms

Digital support of the bladder base (*Figures 8,9*), can be explained by support of the urothelial stretch receptors. It reduced urge symptoms in 18 of the 20 patients (16). The urge disappeared between 3 and 8 seconds (mean, 5.4 seconds) and returned on removal of the digital support in a comparable period of time. The same test reversed a urodynamic tracing of "Detrusor overactivity" in 6/20 women (16) (*Figure 9*). The SO in Video S2, controlled an activated micturition reflex with urine loss by digital pressure on the bladder base by supporting the bladder base stretch receptors "N". Control of urine loss by mechanical support of PUL worked differently. It restored the contractile strength of the forward vector to stretch the

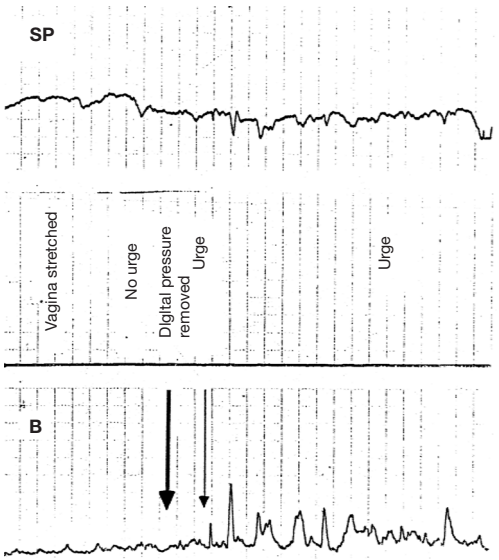

Figure 9 Digital suppression of detrusor overactivity. Increased vaginal tension by digital vaginal stretching (left side of graph to large arrow) prevented bladder instability (16). Note phasic variation of urethral pressure commencing after digital support was removed (large arrow). Large arrow indicates removal of the bladder base support. Small arrow indicates commencement of urgency. Reused from Petros P. The female pelvic floor function, dysfunction and management according to the Integral Theory. 3rd ed. Heidelberg: Springer Berlin; 2010. With permission from Peter Petros; retains ownership of the copyright. SP, subtracted pressure; B, bladder pressure.

vagina more tightly to support the stretch receptors "N" from below.

Palpating the bladder base digitally

Palpating the bladder base can, in some severe cases of OAB, activate the micturition reflex sufficiently for urine to seep out. It fits the hypothesis that "N" (*Figure 8*), is pressure sensitive to the hydrostatic pressure of the urine above, and digital pressure below. Clearly, this manoeuvre is not recommended unless very well explained. (See Video S4 by permission of Dr. Abranches Monteiro).

Unmasking prolapse as cause of latent SUI

Video S5 demonstrates how the reduction of the cystocele prolapse unmasked SUI, so urine loss was noted during coughing. The coughing was controlled by mechanical pressure at the site of PUL insertion into the midurethra. (See Video S5 by permission of Professor Paolo Palma).

Conclusions

SOs take very little time to perform, provide much information and should be part of a standard vaginal examination. The most useful SOs are for confirming symptom causation by PUL and USL laxity. Unilateral support of the PUL at the midurethra with a hemostat can prevent urine loss on coughing (SUI); USL support in the posterior fornix with a speculum can relieve pain and urge symptoms.

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Footnote

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Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. All clinical procedures described in this study were performed in accordance with the ethical standards of the institutional and/or national research committee(s) and with the Helsinki Declaration (as revised in 2013). Written informed consent was obtained from the patients for the publication of this

article and accompanying images. Human participation in the video was by patient permission on the basis that it was deidentified.

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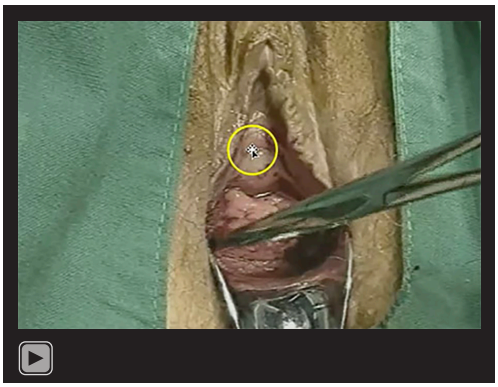
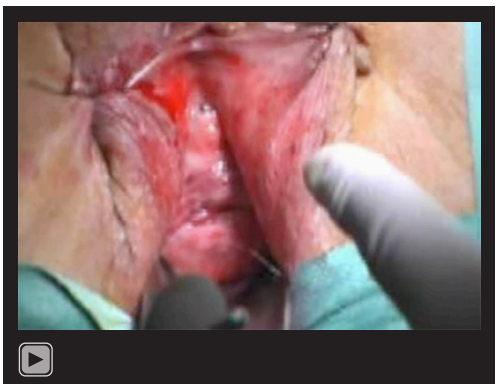
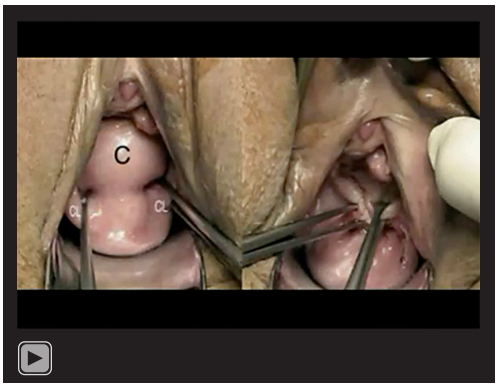
Supplementary



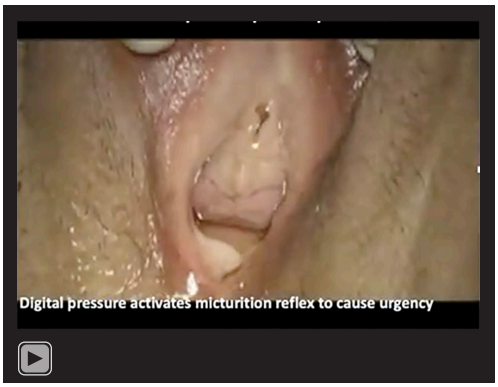
Video S1 Original 1990 video. SO PUL support with a hemostat reduces most of the urine loss on coughing. Plication of the suburethral vagina restores the distal urethral closure mechanism, and completes continence control. The video shows why the distal vagina should also be repaired during a midurethral sling. SO, simulated operation; PUL, pubourethral ligament.



Video S2 The patient had a full bladder which activated urine loss without coughing or other stimulus. "SO" digital support of the bladder bases and PUL controlled urine loss. By permission of Dr. Lius Abranches Monteiro. (1 min). SO, simulated operation; PUL, pubourethral ligament.



Video S3 SO re-approximation of CLs as in *Figure 8*, reduced the major part of the cystocele. SO, simulated operation; CL, cardinal ligament.



Video S4 SO stimulation of the bladder base has apparently activated the micturition reflex with demonstrated urine loss. This video supports the hypothesis of pressure stimulation of urothelial stretch receptors as the originators of the micturition reflex. By permission of Dr. Luis Abranches Monteiro. (0.34 min). SO, simulated operation.

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Video S5 Latent SUI because of prolapse. SOs reduction of the prolapse allowed urine loss on coughing. SOs mechanical support of PUL controlled the urine loss. By permission of Prof. Paolo Palma. SUI, stress urinary incontinence; SO, simulated operation; PUL, pubourethral ligament.

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