Original article

Surgical repair of uterosacral/cardinal ligaments in the older female using the Tissue Fixation System improves symptoms of obstructed micturition and residual urine

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Abstract: Background. Previously published flow mechanics and finite element model works demonstrated that the intraurethral resistance to flow in normal micturition was exponentially determined and that the detrusor pressures required for expulsion of urine were by two orders of magnitude beyond normal available voiding pressures. Xray and EMG studies indicated the presence of directional vectors which most likely contacted against the cardinal/uterosacral ligament complex. *Objectives*. A prospective pilot study to test the hypotheses that voiding dysfunction in the female may be caused by lax cardinal/uterosacral ligaments preventing traction of the opening vectors and so is potentially curable by surgical reinforcement of these ligaments. *Patients and Methods*. The mean patient age was 61 yrs., mean BMI 23. Inclusion criteria: symptoms of emptying dysfunction, residual urine >40ml and apical/uterine prolapse to the halfway mark (stage2, Baden Walker). Exclusion criteria: nil. The TFS (Tissue Fixation System), an adjustable tape which shortens and reinforces loose ligaments was applied to the cardinal and uterosacral ligaments for cure of symptomatic uterine/apical prolapse (n=36). The sample size (n=36) was double the number required to give a 95% confidence interval with 1% significance for 50% cure rate of the "obstructed micturition". A two-tailed Student's ttest was used. *Results*. 34/36 patients were reviewed at 12 months. Emptying symptoms were cured or improved beyond a VAS self-assessed >80% level in 76% of patients (p>0.001); mean emptying time improved from 52 to 26 secs. (p.0.001); mean residual volume from 201ml to 39ml (p>0.001). *Strengths of the study*. The results appear to indicate that competent cardinal/uterosacral ligaments may be important for adequate bladder emptying. *Weakness of the study*. Single centre, non-randomized, no control group. *Conclusions*. The surgical methods described appear to have the potential to improve "obstructed micturition", a major as yet insoluble problem in older females. The results are best explained by reference to an external striated muscle mechanism reliant on firm ligamentary insertion points for the vector forces to open the urethral tube. Further more rigorous studies are required.

Key words: Obstructed micturition; Residual urine; TFS surgery; Uterosacral ligament; Cardinal ligament; Urethra.

INTRODUCTION

Inability to adequately evacuate the bladder is a major source of repeated urinary infection and pathology[1]. Catheter-associated UTI is the most common nosocomial infection, accounting for >1 million cases in hospitals and nursing homes. The risk of UTI increases with increasing duration of catheterization. In non-institutionalized elderly populations, UTIs are the second most common form of infection, accounting for nearly 25% of all infections with a cost of 1 billion dollars p.a.[1].

The traditional view of the mechanism of micturition was described by Messelink et al[1]: *"The pelvic floor muscles must relax in order to remove the passive continence mechanisms, thereby favouring normal micturition"*.

A recent Review of voiding dysfunction[2] shed little light on the problem. It stated, *"There remains a lack of consensus regarding a precise diagnosis and definition of voiding abnormalities in women"*. The Review's statement of causation[2] was limited to "*detrusor underactivity and outflow obstruction which could be either physiological or iatrogenic*." Two studies reporting improvement of bladder emptying following cystocele and fascial repair were mentioned, but no anatomical explanations were forwarded as to why[2].

We believe that the answer to these conundra is to be found in urethral resistance to urine flow which is exponentially determined and is instantaneously modified by an external striated muscle mechanism first described in 1990[4]. This mechanism, since validated with EMG and video xray studies[5,6] stretches open the posterior urethral walls during micturition, figs 1&2, and is in turn ultimately dependent on competent posterior suspensory ligaments in the position of the cervix 'CX', fig. 1[5,6].

The external opening mechanism, figs 1&2, was described as follows[4-6]: immediately prior to commencement of voiding, the forward closure vector (m.pubococcygeus) relaxes; relaxation of m.pubococcygeus releases the closure pressure of the hammock on the posterior urethral wall, thereby freeing the posterior vectors (levator plate and the conjoint longitudinal muscle of the anus, arrows, fig. 1, to actively open the urethra prior to detrusor contraction; this causes the urethra to funnel, exponentially lowering the resistance to flow immediately prior to the expulsive action of the detrusor[5,6].

According to[4], the keystone of this mechanism is the requirement for firm anchoring points for the downward opening vector, the uterosacral/cardinal ligaments (CL/USL) at 'CX', fig. 1[5,6]: the downward opening vector (white arrow, Fig. 1) contracts against the CL/USL: if the USL is loose, the vector weakens[7]; the vector cannot open out the posterior urethral wall; the detrusor contracts against an unopened urethra and therefore, a high urethral resistance; a higher detrusor pressure is required for expulsion, fig. 3; the patient will have bladder emptying difficulties because of greatly increased resistance to flow[8]. Resistance to flow is highly sensitive to this opening mechanism, as it is exponentially determined (Poiseuille's Law). For non-laminar flow, it is approximately inversely related to the 5th power of the radius 'r'[8]. With reference to fig. 1, there appears to be almost doubling of the urethral diameter during micturition. The pressure flow relationship as determined by direct laboratory measurement and computer modelling is shown in fig. 3[8]. At a diameter of 3.5 mm, a pressure head of approximately 170 cm H_2O is required to achieve a flow rate of 50 ml/sec, fig. 3. If the urethra can be opened out from 3.5 mm to 6 mm by the proposed external mechanism, the head of pressure required for a 50 ml/sec flow falls to 20 cm H_2O.

The basis of this study is that the cascade of events which leads to these voiding dysfunctions is potentially reversible by surgical strengthening of the uterosacral/cardinal ligament complex by insertion of TFS polypropylene tapes.

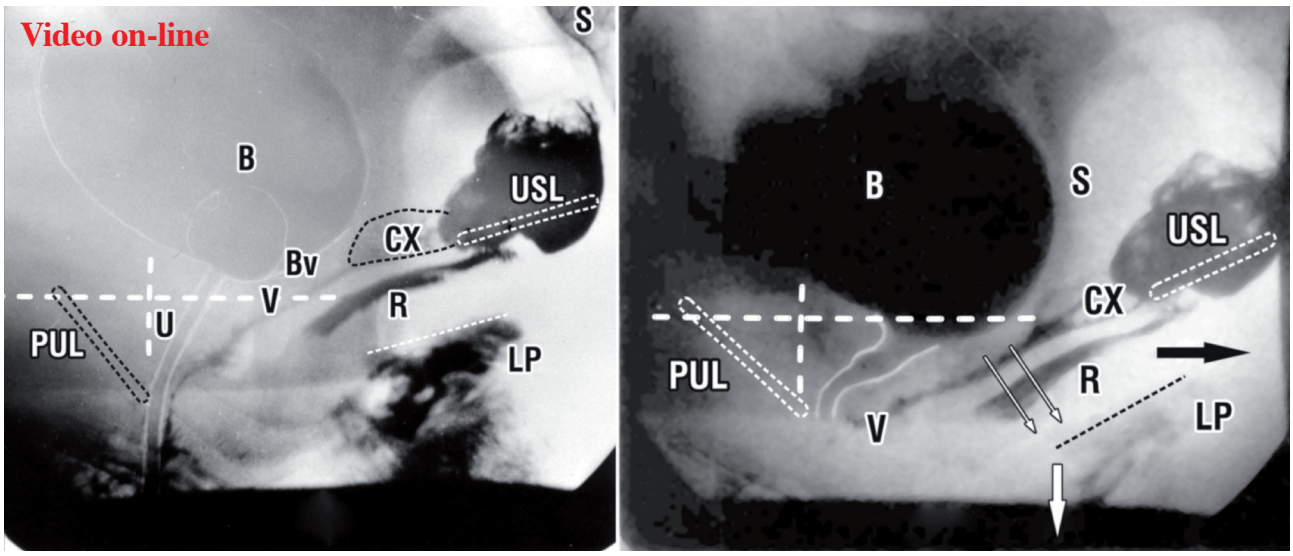


Figure 1. – Normal patient - xrays at rest (left) and during micturition (right), samepatient in sitting position At rest, slow twitch contractions angulate bladder (B), urethra (U), vagina (V) and rectum (R) around the insertion of the pubourethral ligament (PUL) at midurethra. 10ml radioopaque material has been injected into the levator plate (LP) vagina and rectum. Vertical and horizontal broken lines indicate bony co-ordinates. During micturition (right figure), the urethra has moved backwards from the vertical co-ordinate, suggesting relaxation of the forward vector. Vagina and rectum appear to have been stretched backwards by a backward vector (black arrow). The anterior part of LP has been angulated downwards apparently by the downward vector (white arrow) acting against the cervix (CX)/uterosacral ligament (USL) complex. The backward/downward vectors (thin diagonal arrows) create a diagonal vector force which seems to be pulling open the posterior urethral wall. S=sacrum. **Micturition video in the journal online.**

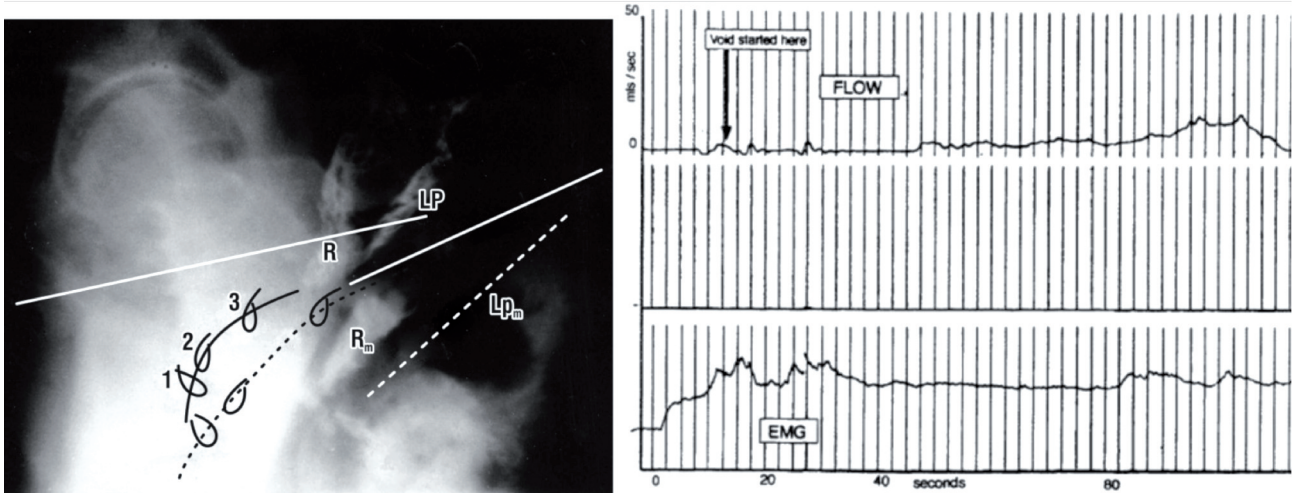


Figure 2. – Micturition x-ray superimposed on resting xray (left side), patient sitting. Vascular clips have been applied to the midurethra '1'. Bladder neck '2' and bladder base '3'. Radio-opaque dye has been injected into the levator plate 'LP', which has been angulated downwards during micturition, as has the rectum 'R', which has 10 ml of barium paste. Broken lines indicate position of organs during micturition. Subscript 'm' indicates the position of rectum 'R' and levator plate 'LP' during micturition.
Surface EMG (right side) Surface EMG cylinder placed in the posterior fornix of the vagina simultaneous with uroflowmetry. EMG shows that muscle contraction preceded urine flow.

The aim of this study was to test the hypotheses that non-surgically induced voiding dysfunction is largely a consequence of loose cardinal/uterosacral ligaments invalidating the external opening mechanism described earlier and as such, is potentially curable surgically by TFS reinforcement of these ligaments.

MATERIALS AND METHODS

We prospectively studied a cohort of 36 patients from a tertiary referral centre who met all the inclusion criteria.

Inclusion criteria.

Patients with a residual urine of 40ml or more, with uterovaginal or apical prolapse at or beyond stage 2 (Baden Walker classification) and who complained of at least one of 4 abnormal emptying symptoms from a validated questionnaire (9).

- Do you feel that your bladder isn't emptying properly?
- Do you ever have difficulty starting off your stream?
- Is it a slow stream?
- Does it stop and start involuntarily?

Exclusion criteria

None

Surgery

All patients had TFS tapes implanted for repair of the cardinal/uterosacral ligaments (Figs 4&5)[10]. The cardinal ligament TFS repaired the high transverse cystocele defect[10] and helped suspend the apex along with the USL TFS[10]. Where required, TFS perineal body repair for recto-

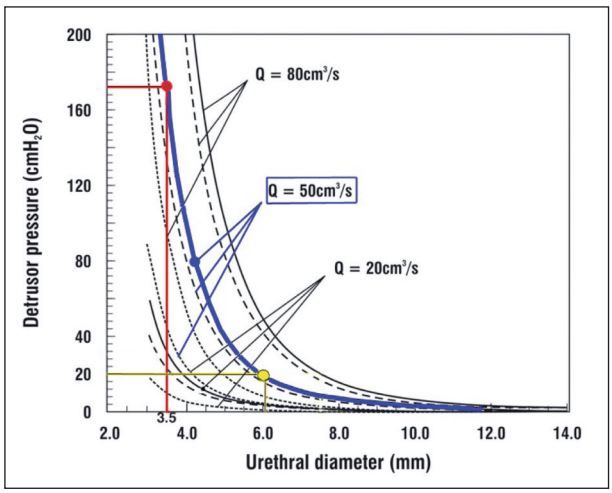


Figure 3. – Pressure flow graph – detrusor pressure as a function of urethral diameter for urethral length of 4 cm at flow rates of 20,50,80 ml/sec (8).
Total resistance to flow (unbroken line) ———————- Frictional component …….. Dynamic component - - - - - -. For a flow rate of 50 ml/sec (blue line), increasing the diameter of the urethra from 3.5 mm to 6 cm, reduces the head of pressure required to empty from approximately 170 cm H_2O to 20 cm H_2O

cele was also performed (n=8). The TFS surgical technique is the same for all ligaments in the pelvis. The ligaments are identified. A tunnel is made with Metzenbaum scissors into or adjacent to the body of the ligaments. The TFS applicator is inserted into each channel in turn and fired to release the anchor. Then the tape is tightened until a resistance is felt, a sign that denotes return of muscle contractility subsequent to return of ligament tension. The one-way tensioning system of the anchors shortens and re-attaches the elongated cardinal and uterosacral ligaments to the cervical ring and pelvic side wall, fig. 5.

Apical/uterine prolapse repair: 34 patients (4th degree n=1; 3rd degree n=10; 2nd degree n=23). All patients had TFS repair of uterosacral and cardinal ligaments, fig. 4.

Cystocele repair: 15 patients (3rd degree n=5; 2nd degree n=10) had a transverse defect repaired by a cardinal TFS sling. 3 patients with central or lateral defect had a native tissue paravaginal re-attachment to the ATFP in addition to a TFS cardinal ligament sling.

Rectocele and perineal body repair: In 8 patients a 3rd degree rectocele was repaired with a TFS perineal body operation plus rectovaginal fascial attachment to the perineal body.

Statistics

Based on results of a previous work[11] which showed a 50% success rate with a posterior sling, a sample size of 18 patients would give sufficient power (95% confidence limit), to detect a 50% success rate in emptying for a 1% significance. A two tailed Students t-test was used to compare the results. The cohort of 36 patients was deemed sufficient for these statistical requirements.

Approval for the TFS surgery was granted by the local Ethics committee. Informed consent was obtained from all patients. The Declaration of Helsinki for Medical Research Involving Human Subjects was followed.

RESULTS

Thirty-four patients attended for review at 12 months. Two patients when contacted declined to return for testing,

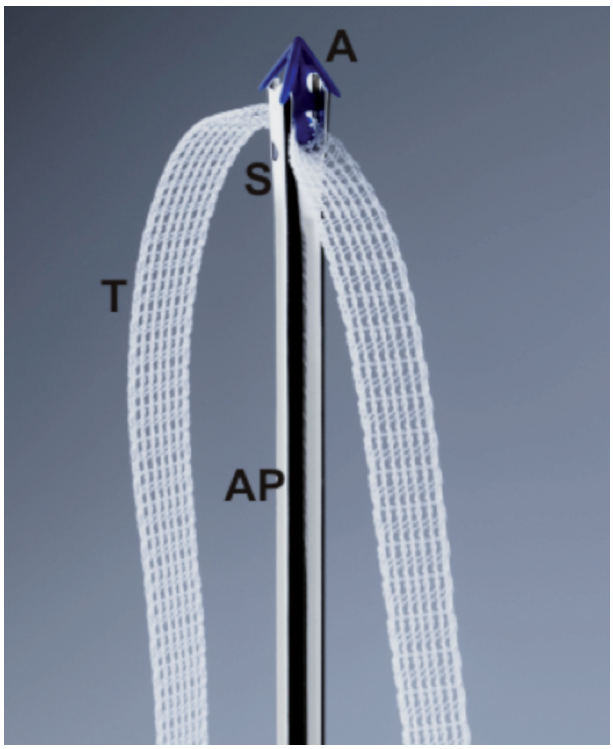


Figure 4. – The TFS system for site-specific re-inforcement of damaged suspensory ligaments. A tunnel is made into the ligament with Metzenbaum scissors; the applicator (AP) is inserted and fired to release the soft tissue anchor (A). This is repeated on the contralateral side and the tape (T) is tightened via the one-way system at the base of the anchor to restore tension and strength to the damaged ligament.

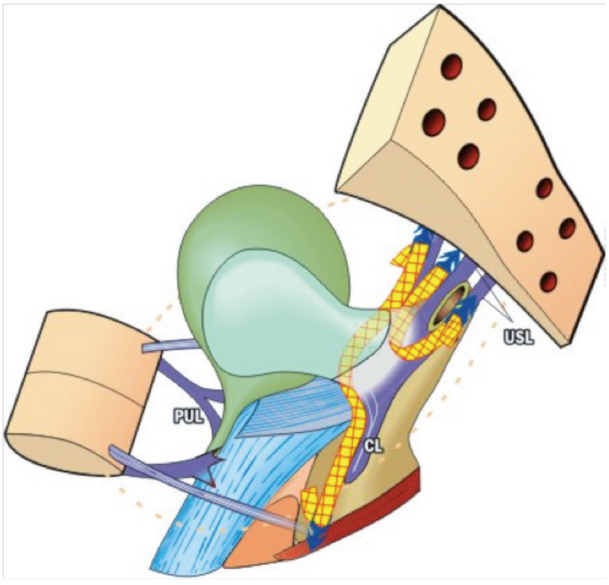
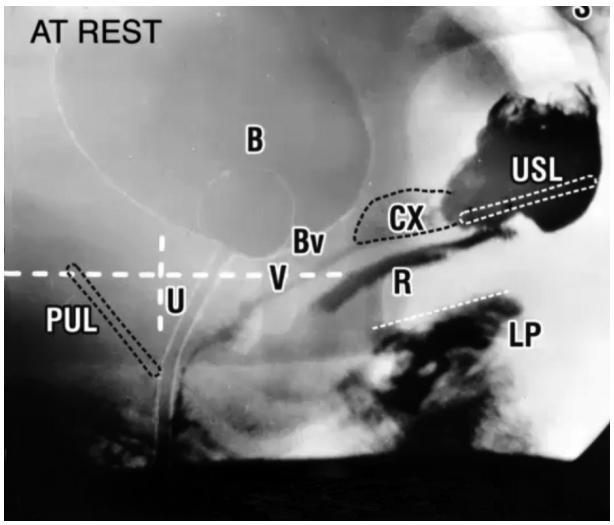


Figure 5. – TFS surgical repair of the cardinal and uterosacral ligaments, patient in standing position. The tape shortens and reinforces the lax ligaments and re-attaches them to the pelvic side wall. With reference to fig 1, the "U" configuration of the uterosacral sling potentially allows the downward movement necessary for the opening mechanism, even when fibrosed from tissue infiltration.

but stated they were happy with their result. The mean age was 61yrs (range 40-82), mean parity 3 (range 0-6), mean BMI 29 (Range 17 to 46). Eight patients had no previous pelvic surgery and 24 had prior hysterectomies. Thirty-four patients had the following TFS surgeries



This is a video xray of a patient taken during micturition in the sitting position. Barium has been inserted into the vagina and rectum and Urografin into the bladder and levator plate. Fig1 has been inserted at the start of the video to orientate the viewer. The process of micturition is clearly active: the anterior border of levator plate is angulated downwards at the commencement of micturition, apparently as a result of muscle contraction which also pulls down rectum, vagina and bladder base prior to detrusor contraction. In the video, there are 4 other observations of note.

1.There is considerable elasticity in the vertical organ movements. This elasticity is necessary for recoil to the resting position and it can only be attributed to elasticity in the suspensory ligaments.

The vector causing downward angulation can only act against the cardinal/uterosacral ligament complex as an insertion point.

In neither the xray (fig1) nor the video, is there any evidence of muscle relaxation. On the contrary, active co-ordinated organ movement is seen.

If abdominal pressure was the motive force for driving the urine to open the urethra, there would have to be indentations in the dome of the bladder and indeed, the anterior rectal wall. There are none. Loops of bowel are seen falling onto the dome of bladder in fig1, but there is no indentation.

At 12 months post-operative review (Baden Walker classification**)

Uterine/vault prolapse (n=34). One patient had 3rd degree prolapse, 3 had 1st degree and 30 had zero degree prolapse. *Cystocele repair (n=15)*. One patient had 3rd degree prolapse, one 2nd degree, four 1st degree and 9 zero degree prolapse.

Rectocele repair (n=8), one patient had 1st degree prolapse and 7 zero degree prolapse.

** 1st degree, prolapse to the mid part of the vaginal length; 2nd degree beyond midpoint; 3rd degree beyond introitus; 4th degree complete eversion.

Surgical complications. There was one tape erosion which was trimmed. There were no haematomas or infections and all patients were discharged the day after surgery.

Post-operative emptying symptoms. The patients used a self-assessed VAS improvement scale of 0-10, with 0 being zero symptoms and 10 being no change. Of 34 patients, 28 reported cure or substantial improvement, (17 reported 100% cure; 9 reported >80% improved; 2 reported >50-60% improvement). There were 6 total symptomatic failures. The improvement in symptoms was significant p>0.001 (Students t-test). Two patients who were self-catheterizing pre-operatively were restored to normal micturition, with postoperative residuals of 50 ml & 32 ml. The former was 87 years old with no cystocele, 3rd degree apical prolapse, 2nd degree rectocele and no cystocele. The latter was 82 years old, with 2nd degree uterine prolapse and 1st degree cystocele.

Objective data. The residual volume decreased from mean 203 ml pre-operative to mean 38.9 ml post-operative (p>0.001) (Students t-test). The change was significant (p>0.001) (Students t-test) as were the changes in emptying times (p>001) (Students t-test).

Pre-operative residual volume ranged from 40-600 ml and post-operative from 0-150 ml.

Thirty-four patients with >40ml residual pre-operatively reduced to 11 patients recording >40ml residual post-operatively.

Pre-operative emptying time ranged from 12-120 seconds and post-operative from 13-78 seconds.

Pre-operative bladder volume ranged from 232-1012 ml and post-operative from 220-1022 ml.

DISCUSSION

The concept of apical prolapse and symptoms of inadequate bladder emptying (12) is not new. Cole et al.[12] found a strong relationship between apical prolapse, and "pure voiding symptoms" (hesitancy, straining, positional voiding).

What was novel in this study was the intervention, repair of the apical prolapse by site-specific reinforcement cardinal/uterosacral ligament complex using the TFS tensioned sling. Bladder evacuation was symptomatically and objectively improved. Of 34 patients, 28 reported cure or substantial improvement in their emptying symptoms. The residual volume decreased from mean 203ml pre-operative to mean 38.9 ml post-operatively, (p>0.001) and the emptying times from 52 seconds to 26 seconds (p>001). Thirty-four patients with >40ml residual pre-operatively reduced to 11 patients recording >40ml residual post-operatively.

Our results cannot be explained by any "passive relaxation" theory. It can only be explained by an external opening mechanism.

The conventional muscle relaxation theory[1] has many flaws. Total relaxation of the pelvic floor would cause reciprocal laxity in the urethral tube, imposing urethral folds into the urethral cavity, further increasing resistance to urine flow, exponentially to the 5th power[8]. Furthermore, total pelvic relaxation does not accord with xray and EMG observations, figs 1&2[5,6], or the video presented as part of this work. All these observations indicate that the posterior urethral wall is actively stretched open by vector forces which are quite visible on the video xray. Active stretching of the organs by the backward/downward vectors, figs 1&2, would stretch out the longitudinal urethral folds, and pull open the urethra, vastly decreasing internal frictional resistance to flow, fig. 3[8]. Nor can the pelvic relaxation theory explain the post-surgical improvement in emptying symptoms and the objective improvements in emptying time and residual urine.

The consequences of a failed external opening mechanism are evident in patients who have a) severance of the spinal cord, b) in Burch colposuspension operations, or c) in very old patients with loose uterosacral ligaments. In a) the external mechanism is paralysed, so the urethra cannot be pulled open. In b), the vagina is sutured to Cooper's ligament; this mechanically prevents opening out of the posterior urethral wall. In c) the loose uterosacral ligaments weaken the downward opening vector. In all 3 examples, for different reasons, the detrusor is forced to contract against a high internal resistance. This is interpreted by the cortex as obstruction to flow, which is exactly what it is, but only in the functional sense, a consequence of the exponen-

tial resistance factor[8], not urethral narrowing. Our results are consistent with the conclusions from a recent finite element model of micturition (FEM)[13]. Using known anatomy, bladder pressures and stiffness of the tissue components of the urethra, it demonstrated that the detrusor pressure would need to be increased by two orders of magnitude beyond normal voiding pressures (i.e., 100 times normal micturition pressures) in order to achieve opening of the tube by detrusor contraction alone[13].

The 82 and 87 year old patients who were restored to spontaneous micturition had no significant cystoceles.

We deduce from our results that repair of the uterosacral/cardinal ligament suspensory mechanism was the key factor in the improvement of the patients' micturition and therefore, it must have a key role in the mechanics of normal and abnormal micturition.

From an anatomical perspective, the surgical cure of patients with voiding dysfunction is explained as follows: the uterosacral/cardinal ligament complex is the effective insertion point of the downward vectors which open out the posterior urethral wall into a funneled shape, figs. 1&2. A loose insertion point effectively lengthens a striated muscle, weakening its contractile force[7]; the TFS tape restored ligament tension and therefore, muscle length and contractility[7].

The basis of this study is the external opening mechanism which precedes detrusor contraction, figs. 1&2.

Using intra-anal ultrasound, Watanabe et al[14] demonstrated a similar active opening mechanism in the male which preceded micturition.

Strengths of the study

The results appear to indicate that competent cardinal/uterosacral ligaments may be important for adequate bladder emptying

Weaknesses of the study

Single centre, non -randomized, no control group.

CONCLUSIONS

The surgical methods described herein have the potential to improve or even cure "obstructed micturition" problems in the elderly female. However, confirmation by other surgeons with larger numbers will be required before these methods can become mainstream.

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Conflicts The senior author PP is the co-inventor of the TVT and the inventor of the TFS. WL and MB have no conflicts.
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Ethical standards

The operations had appropriate ethics committee approval; all patients gave their informed consent prior to the surgery and for use and publication of the results of their surgery; the study was performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments.

Author contributions All authors contributed to analysis and impact of results, writing of paper. Specifically: PP, MB figures, video; MB mathematical analysis of pressure/flow charts; PP, WL surgery.

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