

The International Continence Society and Integral Theory Systems for management of the incontinent female. A comparative analysis

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Summary: This work critically examines the recommendations of two rival systems for management of pelvic floor dysfunction, those of the International Continence Society (ICS) and the Integral Theory.

The ICS system, is based on the concept that urodynamics findings are “objective” and therefore “reliable”. Unstable bladder symptoms are said to be unreliable, not surgically curable, and require drug therapy. Only patients with “Genuine Stress Incontinence” (GSI) are surgically curable, and patients with “mixed” incontinence, stress and urge, should not be operated on if urodynamics demonstrated “detrusor instability” (DI), now known as “overactive bladder” (OAB). Rather, anticholinergic therapy is prescribed.

The Integral System is a holistic anatomically based system which encompasses all three pelvic organs, bladder, vagina and ano-rectum. It is based on the Integral Theory, a musculoelastic theory which states that connective tissue damage to the 3 zones of the vagina is the ultimate cause of prolapse and dysfunction in these organs. From this theory has evolved a 3 zone diagnostic system, and a minimally invasive surgical system which uses polypropylene tapes to reinforce damaged ligaments or fascia in 3 zones of the vagina. In the context of this theory, DI, or OAB, and all abnormal urodynamic parameters such as low urethral pressure, intrinsic sphincter deficiency (ISD), low flow, residual urine etc. are not separate entities or clinical conditions. Rather than symptoms, they are considered to be mainly secondary manifestations of connective tissue damage.

The Integral System’s treatment recommendations differ markedly from those of the International Continence Society, in that symptoms of bladder instability and abnormal emptying in the female are considered for the most part surgically curable.

Key words: Urodynamics; Detrusor instability; Integral theory.

INTRODUCTION

Origins of urodynamics

Bladder pressure measurement commenced more than 100 years ago. In 1933 Denny-Brown¹ measured urethral and bladder pressures simultaneously. He observed spontaneous “all or none contraction” of the bladder, and voluntary muscular control of involuntary micturition initiated by bladder filling. Denny-Brown could explain none of these findings by reference to the smooth muscle anatomy of the bladder.¹ “All or none contraction” of the bladder has been subsequently explained by the work of Creed,² who demonstrated muscle to muscle transmission of electrical impulses”. Denny-Brown drew no clinical conclusions from his urodynamic studies.

It is generally accepted that the work of Patrick Bates³ was a key element in the genesis of the ICS urodynamics system. Using combined cini/pressure/flow studies, Bates et al.,⁴ objectively demonstrated that many patients who lost urine on coughing also initiated a detrusor contraction, and that coughing could stimulate detrusor contraction per se. Two thirds of patients with recurrent symptoms of incontinence after surgery were found to have unstable bladders. Many patients with unstable bladders operated on pre-operatively showed no improvement in symptoms after repair operation. Based on this evidence, Bates and others claimed that the distinction between stress and urge incontinence may be difficult or impossible based on the symptoms and examination alone. For example, a history of leakage on rising from a chair or walking may be particularly difficult to interpret when not associated with urgency. The purpose of urodynamics (‘objective’) studies was to isolate that group of patients unlikely to respond to surgery who had bladder instability. This viewpoint has been reinforced by many investigators including Stanton et al.,⁵ Cardozo et al.⁶ However, not all studies reported low surgical success rate with pre-existing detrusor instability. McGuire et al.⁷ and Meyhoff et al.⁸ demonstrated a high

success rate with incontinence surgery in patients with pre-existing detrusor instability, as did Petros in 1997.⁹ It is worth noting that Stanton, Cardozo et al performed a Burch colposuspension, which exerts tension on the stretch receptors of bladder base. McGuire performed a bladder neck fascial sling, and Petros a midurethral ‘tension-free’ sling. These do not greatly tension the bladder base.

The First ICS Report on the Standardisation of Terminology of Lower Urinary Tract Function.¹⁰ This was a major step in pelvic floor science. For the first time, a common language was established. Furthermore, the definitions were stated in such a way as to allow testing for truth or falsity.

All known nomenclature such as frequency, nocturia etc. was defined; also, the methods and interpretations of the emerging science of urodynamics. It was assumed that symptoms were unreliable, but urodynamics was reliable, as it was ‘objective’, and therefore, scientific. The first definition of detrusor instability (DI) specified a rise in bladder pressure of 15cm H₂O for the diagnosis of ‘detrusor instability’, subsequently, some definitions were later found to be too limiting. The 15cm limit was removed in 1988,¹¹ and replaced by a description of an ‘unstable pattern’. This replaced the former ‘objectivity’ with an entirely subjective assessment. The Expert Committee¹¹ stated that, be-

* NOTE 1: these ‘definitions’ and ‘recommendations’ are but one ‘expert committee’s’ opinion. Another ‘expert committee’ may have given different ‘definitions’ and ‘recommendations’. Despite the inherent fallibility of this process, the ICS ‘recommendations’ were published as an official document, a rigid scientific declaration, with no allowance for alternatives. Such rigid definitions cannot be reconciled with what was being described, the irregular and unpredictable manifestations of a non-linear biological system, the bladder. The physical principles such as urethral resistance¹² p 176 and connective tissue stretch-extension curves,¹² pp 39, 70 which regulate these manifestations are complex, exponentially derived, and not given to simplification by definition.

NOTE 2: References to specific pages in the textbook “The Female Pelvic Floor”, reference,¹² have been made for readers desiring further information.

cause DI was observed in normal women, it was recommended that only patients with urge symptoms could be defined as having “DI”. Put another way, urodynamics was required because symptoms were unreliable, and symptoms because urodynamics was unreliable. Unlike the first consultation¹⁰ this recommendation did not allow testing for truth or falsity.

UNEXPECTED CONSEQUENCES OF ICS MANAGEMENT GUIDELINES

Only patients with “genuine stress incontinence” (GSI) were recommended for treatment. Bladder symptoms of urgency were considered unreliable, requiring urodynamics.¹¹ In patients with both SI and urodynamically diagnosed “detrusor instability” (DI), surgery was said to be contraindicated.

To surgeons who had repeatedly observed clinical cure of urgency symptoms following cystocele repair and incontinence surgery, such ‘definitions’ and ‘recommendations’ were contradictory and confusing. Many patients with severe urge incontinence who did not demonstrate an unstable pattern on urodynamics, were told by their physicians that their symptoms were not organic, but psychological in origin. This was an unintended consequence of rigid definitions. Others who sought to follow the ICS recommendations, treated the patient initially with anticholinergics, and performed surgery when the symptoms improved. This was logically invalid, as the drug therapy addressed symptoms, not causation. Anticholinergic drugs, provided temporary relief for some, but were discontinued by most, because of their complications. Even the proscription of surgery in patients with DI (OAB) has been invalidated, Duckworth,¹³ Neuman,¹⁴ Petros.⁹

In conclusion only stress incontinence is recognized as being curable by the ICS paradigm. Surgery for urgency, frequency and nocturia is contraindicated, and these symptoms are treated with anticholinergic drugs. No concept exists for surgical treatment of pelvic pain, abnormal emptying or idiopathic fecal incontinence.

THE INTEGRAL SYSTEM

The Integral System has 4 parts.

1. A holistic anatomical theory of normal pelvic organ function,^{15, 16, 12, pp 14-33} each component of which, organs, ligaments, muscles, central and peripheral neurological control contributes interactively to normal function, figure 1.
2. A theory of dysfunction which states that symptoms and prolapse are linked, and both are mainly caused by connective tissue damage in the vagina or its suspensory ligaments.^{12, pp 34-50} Deriving directly from this is a 3 zone diagnostic system (figures 1, 2, 3).
3. Non-surgical treatment using pelvic muscle exercises which mimic the 3 directional muscle forces.^{12, pp 168-172}
4. Minimally invasive surgical treatment (figure 4), for cure of prolapse and abnormal symptoms.^{12, pp 83-167} Special instruments apply knitted tapes to damaged pelvic ligaments in 3 zones of the vagina, guided by the diagnostic system (figures 2, 3).

In the context of this theory, ‘detrusor instability’, or ‘overactive bladder’ (OAB), and all other abnormal urodynamic parameters such as low urethral pressure, intrinsic sphincter defect (ISD), low flow, residual urine etc. are not separate entities or clinical conditions. Rather like symptoms, they are considered to be mainly secondary manifestations of connective tissue damage.^{6, pp. 174-192}

ORIGINS AND DEVELOPMENT

The Integral Theory evolved from the investigation of a series of discordant findings following the prototype intravaginal slingplasty operations performed at Royal Perth Hospital in 1986-9.¹⁵ Patients were cured with xray evidence of no bladder base elevation, an obvious contradiction of the ‘Pressure Equalization Theory’. Abdominal ultrasound and dynamic xray studies indicated that urethral closure was activated by a musculo-elastic mechanism.¹⁵

Bladder instability in the non-neurological patient was defined as a premature activation of the micturition reflex.^{17, 18} Urodynamic studies²⁰ (figure 5), demonstrated the identical sequence of events seen in a normal micturition reflex, first, sensory urgency, then fall in urethral pressure “X”, then detrusor contraction “Y”, then urine loss. The small arrows denote identical spikes in the bladder and urethra, indicative of repeated fast-twitch contractions of PCM (fig. 1) attempting to close the urethra.

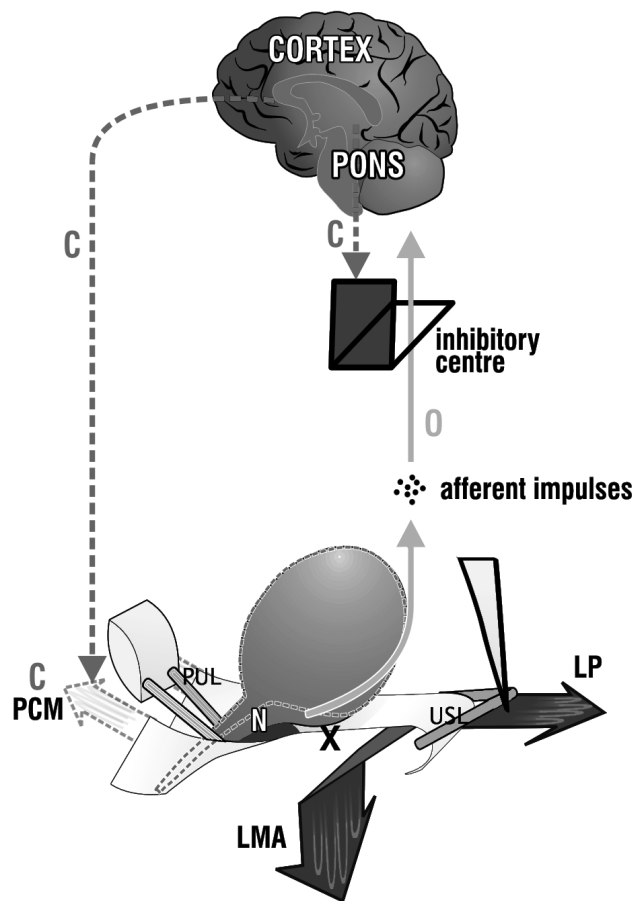


Fig. 1. – Neuro-musculo-elastic bladder control
Bladder in ‘open’(micturition) position. The closed phase ‘C’ is indicated by broken lines and the open phase ‘O’ by unbroken lines. Micturition Afferent impulses ‘O’ activate the cascade of events for micturition: relaxation of the PCM and de-activation of the inhibitory centre and closure reflex ‘C’. LP/LMA vectors actively open out the posterior urethral wall. Urethrovesical closure ‘C’ activates the cascade of events for closure: activation of the inhibitory centres and contraction of PCM to close the urethra from behind. LP/LMA vectors stretch the bladder base backwards/downwards around the pubourethral ligament (PUL) to close the proximal urethra. Note the identical position of LP and LMA in closure and micturition. N = stretch receptors, PCM = pubococcygeus muscle, LMA = longitudinal muscle of the anus, LP = levator plate, X= fascial attachment of bladder base to vagina, USL=uterosacral ligament.

The second (1993) publication of the Integral Theory¹⁶ presented radiological and urodynamic studies and brought a higher level of proof. The ‘posterior fornix syndrome’ was described (1993 Integral Theory), a symptom complex resulting from laxity in the uterosacral ligaments, “posterior zone” (figure 2). Reconstruction of the posterior ligaments improved symptoms of urge, nocturia, abnormal emptying and pelvic pain.^{19, 13} These findings were seminal in the construction of the Pictorial Diagnostic Algorithm (figure 2).

The years 1994 to 2007 have seen a consolidation and international acceptance of many parts of the Integral Theory, in particular, the treatment of stress incontinence with a midurethral sling. The Theory framework has expanded to include fecal incontinence,^{12 pp 211-221} abnormal bladder emptying,^{12 pp 175-176} and some types of pelvic pain^{12 p 73} (figure 2).

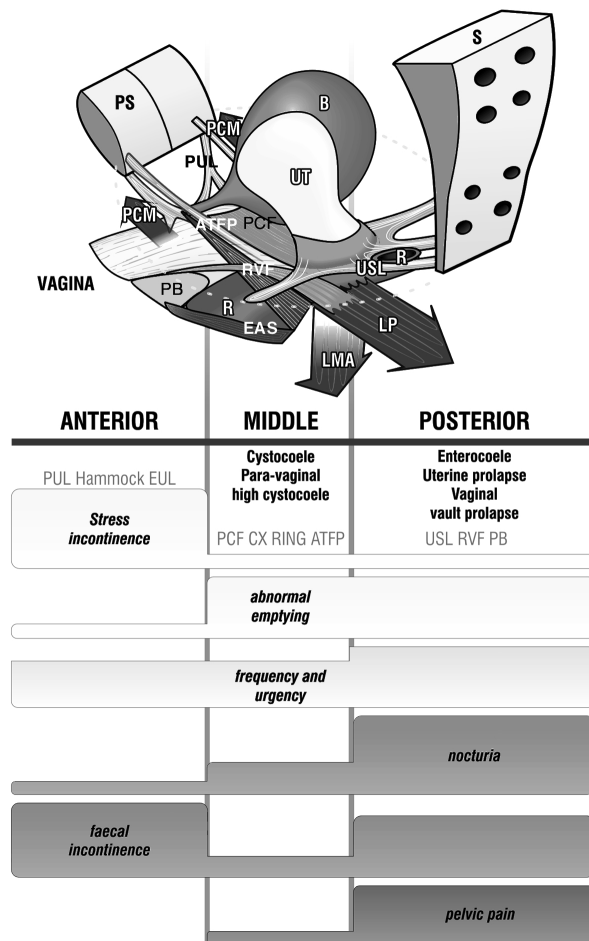


Fig. 2 – The Integral Pictorial Diagnostic Algorithm is designed to be copied and used by the clinician as a record. It summarizes the relationships between structural damage and pelvic floor symptoms in the three zones. The size of the bar gives an approximate indication of the prevalence (probability) of the symptom. The same connective tissue structures in each zone (red lettering) may cause prolapse and abnormal symptoms.
 Anterior zone: External urethral meatus to bladder neck.
 Middle zone: bladder neck to cervix.
 Posterior zone: vaginal apex, posterior vaginal wall and perineal body.
 Arrows= directional muscle forces; LP=m.levator plate; LMA= m.longitudinal muscle of the anus; PCM = m.pubococcygeus; PRM=m.puborectalis; PUL =pubourethral ligament; USL=uterosacral ligament; PCF=pubocervical fascia; cx ring = cervical ring; ATFP=arcus tendineus fascia pelvis; EAS = external anal sphincter. R=rectum; RVF=rectovaginal fascia; PB=perineal body.

Validation of these symptoms by more objective data, and by other investigators is slowly emerging, but more proof is required.

With conceptual advances in the bladder’s control system, symptoms are the brain’s interpretation of the complex interaction between all the different anatomical structures (figure 1). A major problem in attempting to define bladder function, is that all biological control mechanisms are non-linear and often exponentially determined.^{19, 6, pp 188-192} This means that every patient is uniquely different, and there are huge variations, even within the same patient. Even a temporary hormonal alteration in an apparently unrelated structure, the uterus, may significantly alter the balance of the whole system, and this may cause significant variation in symptoms. For example, perimenstrual urgency can be explained as follows:^{12 p 72} in the days preceding a menstrual period, the cervix softens to facilitate the egress of menstrual blood. This may also cause laxity of the uterosacral ligaments in some women, leading to inability of the muscle forces to stretch the vaginal membrane (figure 6), so that the bladder base stretch receptors fire off prematurely. The

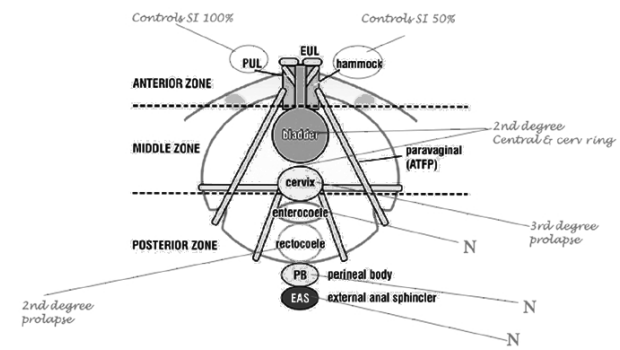


Fig. 3 – The Integral Surgical 3 zone clinical examination sheet is designed to be copied and used by the clinician as a record. Findings in a patient with stress incontinence and prolapse. Each structure is assessed and notated, if possible as 1st, 2nd or 3rd degree prolapse. PUL, EUL, hammock, PB., EAS, are designated ‘normal’ or ‘lax’. The % figures in the anterior zone refer to perceived % reduction in urine loss on anchoring each structure sequentially during coughing. Labelling as in figure 2.

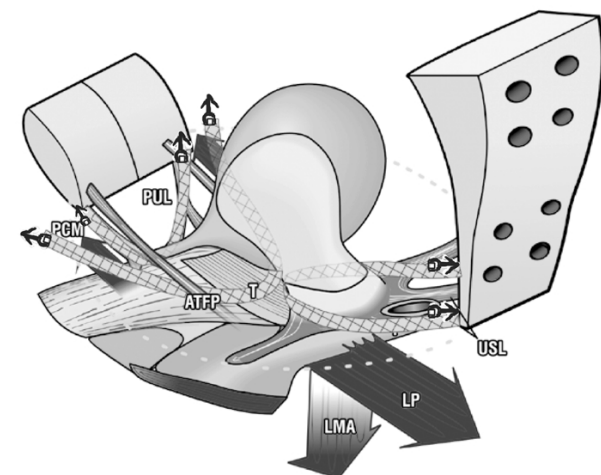


Figure 4 – The Integral Surgical System –a site-specific method for pelvic floor repair.
 This is a 3D figure of the pelvis seen from above and behind. Polypropylene mesh slings, in this instance, TFS (Tissue Fixation System), have been applied to correct ligamentous/fascial defects in the 3 zones of the vagina: anterior zone (midurethral sling for stress incontinence), middle zone (central and lateral cystocele) and posterior zone (vault prolapse). Labelling as in figure 2.

brain interprets the afferent nerve impulses as symptoms of urgency, frequency and nocturia.

Suppression of urgency and DI by digital support of bladder base: In patients examined with a full bladder who have urgency, it is possible to temporarily diminish these symptoms with contraction of the pelvic floor, or digital support of the anterior vaginal wall at bladder base, 'simulated operation'^{12 63-67} (figure 6). It is even possible sometimes to suppress abnormal urodynamically demonstrated detrusor contractions,¹⁹ either with pelvic floor "squeezing" or digital support (figure 6). These experiments are consistent with the Theory's statement that there may be two important causative components of the unstable bladder in the female: a) capacity for musculoelastic stretching of tissues to provide support for the stretch receptors at bladder base, and b) the sensitivity of the nerve endings 'N' (figure 1). Connective tissue laxity is a key determining factor in the former. Neither a) nor b) can be objectively assessed at the present moment.

The voluntary control of a detrusor contraction mentioned by Denny-Brown is explained by vaginal stretching from an external musculoskeletal mechanism, and the "trampoline analogy" (figure 6).

Further surgical advances: Improvements in surgical methodology⁹ have been running on a parallel path with the expansion of the Integral Theory. These new methods were developed because traditional vaginal surgery methods of excision and approximation were unable to restore tissue strength sufficiently to restore structure. To overcome this deficiency, techniques such as the posterior sling, were developed.^{12, pp 83-167} Further developments include mesh at-

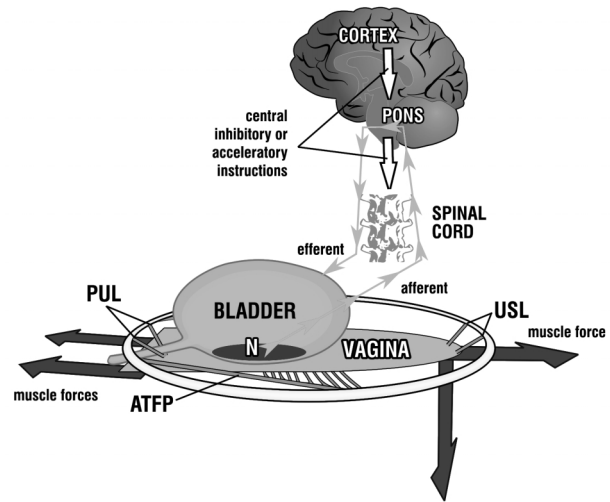


Figure 6 – Peripheral neurological control of micturition – ‘trampoline analogy’.

Lax ligaments may unbalance the system to cause urge incontinence. Like a trampoline, the vaginal membrane cannot be stretched by the muscle forces (arrows) to support the stretch receptors 'N'; these fire off at a low bladder volume: 'premature activation of the micturition reflex'. The cortex perceives the afferent impulses as 'urgency' symptoms. Gentle digital support of the anterior vaginal wall at 'N', may suppress urgency by decreasing the afferents to the brain. PUL = pubourethral ligament; USL = uterosacral/cardinal ligament;

ATFP = arcus tendineus fascia pelvis; N = stretch receptors.

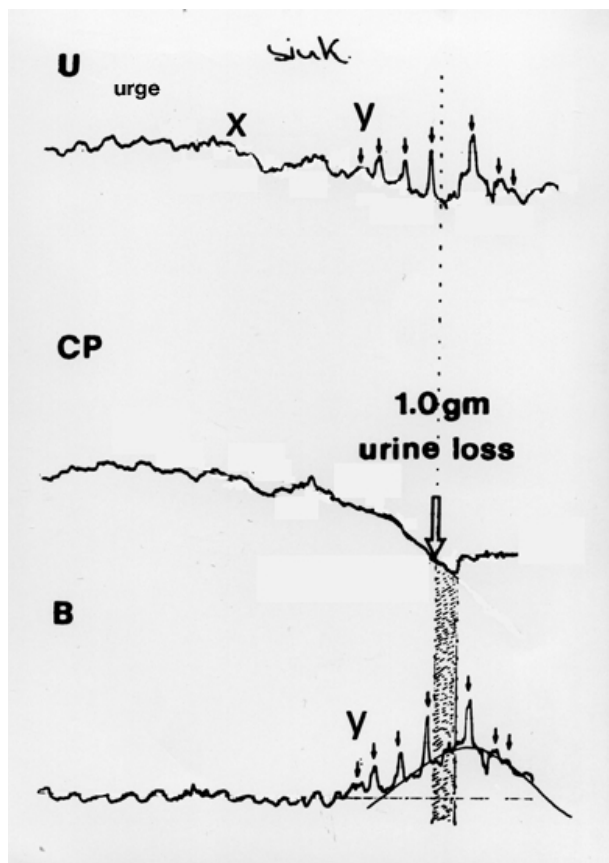


Figure 5 – Urodynamic bladder instability - premature activation of the micturition reflex. Microtransducers in bladder (B) and midurethra (U). CP=closure pressure (U-B). Note how urgency precedes urethral relaxation (x) which precedes detrusor contraction (y).

tachments with suspensory "arms", and more recently, the new tissue fixation system (TFS) The TFS is applied entirely per vaginam as an anterior or posterior sling,^{20, 21} for repair of cystocele,²² rectocele and perineal body.^{12, pp 83-167} It provides a new structural method which can entirely replace large mesh. Strips of tape (figure 4), act much like ceiling beams, the vagina being the plasterboard.

CONCLUSIONS

Vaginal prolapse and symptoms (figure 2) are linked, and both can be addressed by surgically reinforcing damaged ligaments with knitted polypropylene tapes in 3 zones of the vagina (figure 4). It is possible to achieve a cure rate up to 80% for stress, urge, frequency, nocturia, abnormal bladder emptying, pelvic pain and idiopathic fecal incontinence after such surgery.

DISCUSSION

There is no conflict between the science of urodynamics and the Integral Theory System. Any perceived conflict the ICS interpretations and 'recommendations' of urodynamic test results disappears if urodynamic readings are interpreted anatomically. Looked at from the perspective of a prematurely activated, but otherwise normal micturition reflex,^{18, 19} it is perfectly acceptable for up to 70% of normal women²³ to have evidence of DI ("OAB"). Even the prime reason for performing urodynamics, prediction of surgical failure can be explained by figure 6. Stanton, Cardozo et al in performing Burch colposuspension, needed to stretch the vaginal membrane upwards towards the pelvic brim.^{5, 6} This may place undue pressure on the stretch receptors "N", causing neo-urgency. This statement can be directly tested by examining a patient who has urge symptoms with a full bladder. Digitally stretching the vaginal membrane at bladder base upwards and forwards invariably intensifies the urge symptoms. In contrast, McGuire et al.⁷ in positioning

a fascial sling carefully at bladder neck, would normally leave a 1cm gap. This methodology would tend to protect against overstretching and neourgency.

Existing urodynamic parameters such as "DI" (detrusor instability) and "CTR" (cough transmission ratio) can be reinterpreted anatomically using "simulated operations":^{19, 24} anchoring specific connective tissue structures during urodynamic testing. This manoeuvre may temporarily suppress a DI contraction on a graph,¹⁹ or radically change a cough transmission ratio (CTR) reading.²⁴

Finite element models: Using computer simulation and fluid dynamic models, Bush, Petros and others from the School of Mechanical Engineering and Fluid Dynamics at the University of Western Australia have identified urethral resistance as a key physical factor in urodynamic pressure measurement.^{25, 12 pp 175-176}

Another major physical factor is the biomechanics and neurological control of bladder opening and closure (figure 1). In the future, it is envisaged that this can be reduced to a finite element model (FEM).²⁶ But first, we will need to measure the strength and elasticity of tissues, sensitivity of stretch receptors, and potential muscle strength. More accurate and more sophisticated ultrasound imaging, urethral and bladder pressure measurement, and more accurate application of the "simulated operation" technique are required. A small beginning has been made in the FEM field by Bush et al.,²⁵ an on-going development of a computer-based FEM of micturition. Results of work to date may be found on www.integraltheory.org.

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