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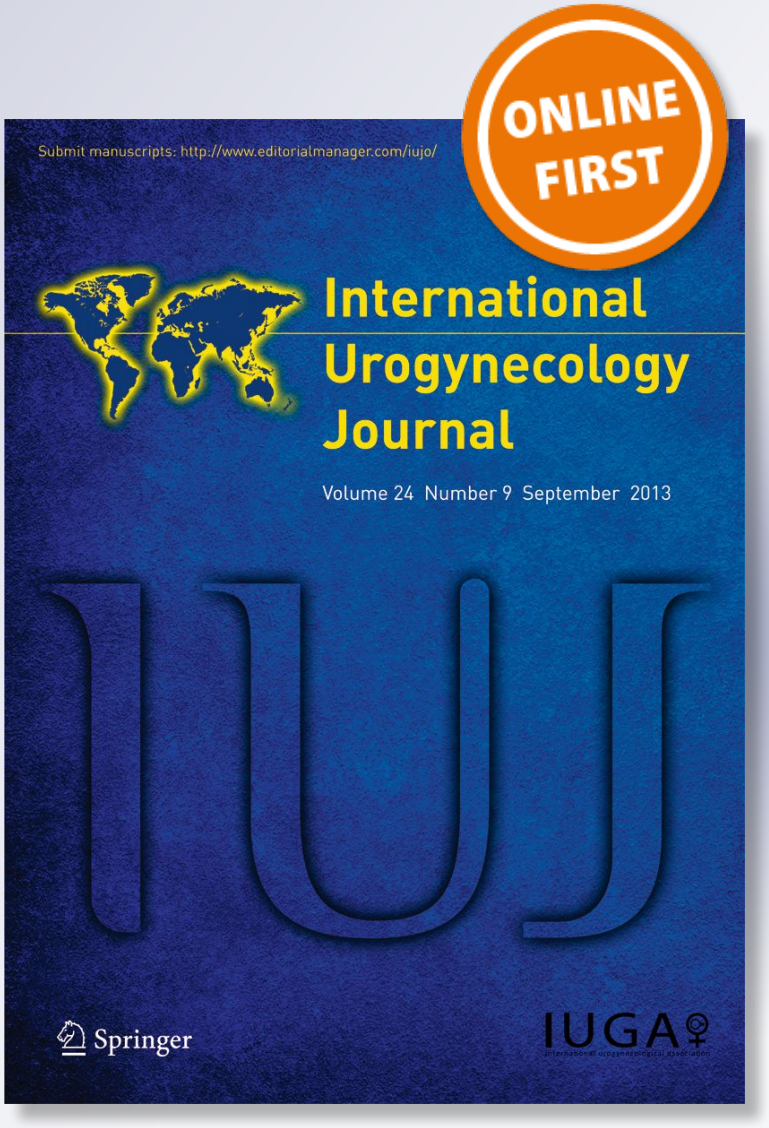

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EDITORIAL

Should surgeons continue to implant mesh sheets behind the vagina?

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Aims of this editorial are to explain how discrete ligament repair using the artificial neoligament principle exactly as used in the highly successful midurethral sling differs substantially from transvaginal mesh sheets that work only by blocking organ descent.

Introduction

In 2011, the US Food and Drug Administration (FDA) warning on transvaginal mesh implantation for pelvic organ prolapse (POP) was the start of a major controversy with seismic manifestations: media stories; government inquiries; legal suits; closure of mesh companies. Expert committees endorsed the midurethral sling (MUS) but expressed caution about mesh implantation for POP. No anatomical reasons were advanced by these experts. Yet anatomical answers are required for the two questions below if a solution is to be found.

1. What is it about MUS that makes it work reasonably well, with manageable complications?
2. What is it about transvaginal mesh sheets that can cause severe quality of life (QOL) complications that are not easily manageable?

On weighing up 2, the answer is not legal, more comprehensive, consent forms, or stating that benefits outweigh risks. The question is ethical. Should surgeons be performing an operation that can have such catastrophic effects on QOL, albeit in a minority of patients? This is the thrust of the hostile media campaign. Going back to native tissue repair is clearly not the answer. The *Lancet* Prolapse Surgery: Pragmatic Evaluation and Randomised Controlled Trials (PROSPECT) [1] proved the futility of surgical intervention to the vagina with >80% failure rate at 6 months and further attrition at 1 year.

The answers to questions 1 and 2 and the alternative ligament-based tape surgery described below can be found in the 1990 publication of the Integral Theory [2]. It states ligament integrity is essential for structure and vaginal elasticity for function:

"Essential to the understanding of this theory is the appreciation that the vagina has two distinct anatomical segments, which are pulled in opposite directions against the pubourethral ligament (PUL) to close the urethra. PUL acts as a fulcrum (Fig. 1). In order to transmit (mediate) these movements, sufficient elasticity is needed in the zone of critical elasticity of the vagina."

The same publication described experimental animal work on which the transvaginal tape (TVT) was based; tapes were implanted in the precise position of the PUL to strengthen it by creating a collagenous neoligament.

Experimental animal and clinical studies between 1986 and 1997 demonstrated that alloplastic strips of tape were essential for long-lasting strengthening of damaged PUL and uterosacral (USL) ligaments. Emphasis was placed on the preservation of vaginal elasticity and avoidance of vaginal scarring: it can cause massive uncontrollable urine loss attributabe to what is known as tethered vagina syndrome [2]. That: "like the intestine, the vagina has an autonomic nerve innervation and crushing or stretching may cause severe

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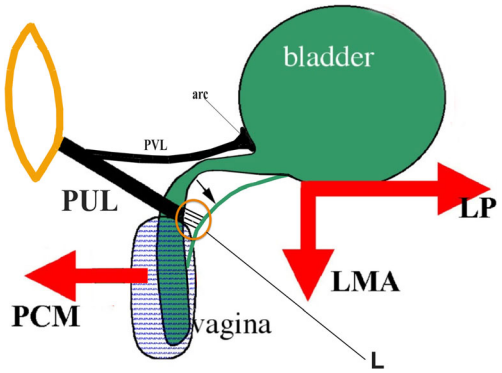

Fig. 1 How a lax pubourethral ligament (PUL) causes urinary stress incontinence. Schematic sagittal view, sitting position. The urethra has two separate closure mechanisms activated by oppositely acting muscle forces (*arrows*). Adequate elasticity in the bladder neck area of the vagina is required for these to function separately [3]. Distal closure: pubococcygeus muscle (PCM) (*arrow*) contracts against competent pubourethral ligaments (PUL). This stretches the suburethral vagina forward to close the distal urethra (3). Bladder-neck closure: levator plate (LP) stretches the urethra backward against the PUL. Conjoint longitudinal muscle of the anus (LMA) (*arrow*) rotates the bladder base down and around the arc of Gil-vernet to close the urethra at the bladder neck. Extension of the PUL to *L* indicates PUL loosening; the PCM weakens; LP/LMA pull open the posterior urethral wall (*small diagonal arrow*). Intraurethral resistance exponentially decreases. The patient loses urine on effort. Surgical restoration of the PUL with tape restores muscle strength for both striated muscle vectors and therefore continence *PVL*pubovesical ligament

pain." All of this was published and therefore known, which begs a third question: Did the developers of the mesh kits who used "substantial equivalence" to TVT and infracoccygeal sacropexy for FDA mesh approvals take account of these clearly enunciated surgical principles for their use? All of which introduced a fourth question raised by mesh lawyers: "Where was the prior experimental work for the use of the prosthesis?" It was there, but its critical importance was not necessarily appreciated.

Major improvements in tape technology have revolutionized surgical repair of POP. These methods apply the discrete ligament repair principles so successful for the MUS [2, 3] combined with site-specific repair of pubocervical, rectovaginal fascia, and extraurethral ligaments, without vaginal excision.

POP studies by Sekiguchi ($n = 60$) [4], Shkapura ($n = 148$) [5], and Wagenlehner ($n = 1420$) [6] reported cure rates >90% at 12 months for 3rd- and 4th-degree POP by discrete ligament repair of cardinal ligament (CL) and USL, with minimal postoperative pain and very low tape erosions. This method can repair other ligaments, dislocated pubovisceral muscles, and the perineal body.

Organ support is by ligaments, not the vagina: breaking strain for ligaments is 300 mg/mm^2 and for the vagina 60 mg/mm^2. These MUS-like tapes create collagenous neoligaments that attach directly to the skeleton, so they have minimal effect on vaginal elasticity. Mesh sheets placed behind the vagina do not restore anatomy; they create a fibrotic barrier. Ultrasound shows a cystocele bulge behind the mesh. Pelvic tissues are innervated by visceral nerves that are sensitive to stretching. Mesh-sheet fibrosis may compress nerves and cause visceral pain, which can be severe. Fibrotic scarring removes the elasticity required for independent closure action by opposite vector forces (Fig. 1) and may result in the tethered vagina syndrome: massive uncontrolled urine loss on rising from a chair or getting out of bed in the morning (which are key diagnostic symptoms). Cure requires dissection of scar tissue and skin graft to the bladder neck area of the vagina. Transvaginal mesh sheets appear to have the potential for long-term complications. Even with no complications, the collagen formed by mesh will stiffen with age, and problems may emerge 20–30 years later. Objective assessment of vaginal elasticity will be helpful in such cases.

Conclusions

Although complications can be severe, albeit infrequent, it is not sufficient to judge risks vs benefits. The public outcry against vaginal mesh has a valid scientific basis: the collagenous scarring that mesh creates is appropriate for nonelastic ligaments; it is contraindicated for an elastic vagina [2, 3]. Ensuring any form of repair that maintains lifetime tissue elasticity is possibly crucial to success. Lightweight mesh sheets are not the answer either; neither are alternative materials. Any mesh sheet will fibrose. Data using 3rd-generation (individually knitted, nonstretch, lightweight) tapes to cure POP by ligament repair only, with minimal tape rejection, is encouraging and may well be the treatment of the future, especially as all damaged ligaments can be repaired. An entirely new direction for pelvic floor science beckons, as high cure rates for pelvic symptoms in addition to prolapse are also achieved.

A better understanding of the differential function of ligaments and vagina is important: how ligament collagen degenerates with age; how mesh is beneficial for ligaments but potentially catastrophic for the vagina. With an aging population, objective biomechanical assessment of tissues will become essential, certainly with previous surgery. Exciting state-of-the art technology is already available (Advanced Tactile Imaging, Inc., NJ, USA), all of which begs a 5th and final question: "What are the lessons learnt from mesh, and where do we go from here?"

1. Ligament-based operations for POP are, like their MUS analogs, a totally different concept from mesh sheets.
2. Adequate surgical training, precise knowledge of ligament location, how a particular operation may affect organ function, are absolute prerequisites before any surgical procedure is undertaken.

3. Understanding that because hitherto unknown problems may only surface years later, longer-term follow-up and notification of complications to statutory bodies is essential.

Compliance with ethical standards

Conflict of interest Peter Petros is the coinventor of the midurethral sling, Integral Theory, inventor of the posterior infracoccygeal sacropexy sling, and Tissue Fixation System (TFS) minisling. No conflicts for the other authors.

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