Sounding Board

SOUNDING BOARD - CURRENT OPINION

NEUROUROLOGY & URODYNAMICS

WHAT IF THERE WERE NO TAPES?¹

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Abstract

It is possible that the controversy involving prostheses implanted into women with pelvic floor problems might result in the majority of, or even all such products being restricted, banned or withdrawn in certain jurisdictions. A clear distinction between “tapes” for urinary incontinence and “mesh” for prolapse has been made in the enquiries and subsequent rulings in Australia and New Zealand. Transvaginal “mesh” will be unavailable with the range of “tapes” much more restricted in those countries from January 2018. The Chair of the all-party parliamentary group on surgical mesh implants in the United Kingdom was reported as describing the New Zealand announcement as “hugely significant” and “it’s precisely what we’ve been calling for the UK”. The title of this article has changed from a hypothetical piece to a potential reality review.

Where does that leave the clinicians treating stress urinary incontinence (SUI) and the large number of female sufferers? “Tapes” (synthetic midurethral slings - MUS) have become very popular over the last 20 years since their original development and introduction in Scandanavia. Evidence-based medicine has shown their advantages over previous surgeries, in terms of ease of use, safety and efficacy.

This article outlines the options which countries potentially rejecting the use of tapes, must now resort to for women with SUI. Those countries considering such action need the note of caution that none of the options are as good as tapes.

Keywords: female urinary incontinence, stress urinary incontinence,
midurethral slings, suburethral tapes

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Introduction

It is possible that the controversy involving prostheses implanted into women with pelvic floor problems might result in the majority or even all such products being restricted, banned or withdrawn in certain jurisdictions. A clear distinction has been made between “tapes” for stress urinary incontinence (SUI) and “mesh” for pelvic organ prolapse (POP) in the enquiries and subsequent rulings in Australia and New Zealand. Transvaginal mesh will be

unavailable whilst the range of “tapes” will be much more restricted from January 2018^{1,2}. The Chair of the all-party parliamentary group on surgical mesh implants in the United Kingdom was reported as describing the New Zealand announcement as “hugely significant” and “it’s the first major country to effectively ban mesh for all pelvic operations. It’s precisely what we’ve been calling for in the UK”.³

The title of this article, which started as a hypothetical argument, becomes a potential reality review, given the timing on the Australian and New Zealand announcements^{1,2}. New Zealand Health spokesperson in December 2017 was reported as stating “we now believe the risks associated with use of these products in the pelvis for prolapse and stress incontinence far outweighs the benefits”^{2,3}. This follows an announcement from the Australian Therapeutic Goods Administration (TGA) on the 28th November, 2017¹, banning transvaginal surgical mesh devices in urogynaecological surgery and certain products used for SUI with subsequent clarification on January 17, 2018¹, where “minislings” were excluded from future use. From that same date, a leading manufacturer of tapes has chosen, in Australia and New Zealand, to voluntarily withdraw all their tape range for an unspecified period. This leaves a large number of clinicians effectively without their preferred device.

The International Continence Society (ICS) and the International Urogynecological Association (IUGA) were proactive in defining all the terminology related to the insertion of prostheses and grafts in female pelvic floor surgery⁴. **Prosthesis** is defined as a “fabricated substitute to assist a damaged body part or to augment or stabilize a hypoplastic structure”⁴.

The two related key definitions are:

Tapes (Slings): A flat strip of synthetic material. The use of this term would be for *incontinence surgeries using synthetic materials*.

Mesh: A (prosthetic) network, fabric or structure. Open spaces or interstices between the strands of the net. The use of this term would be for *prolapse surgeries with synthetic materials*.

The major differences are (i) the volume of synthetic material (relatively small in the case of tapes) and (ii) the much more defined positioning of the tapes. Specifically, tapes are placed in a mid- and sub-urethral location whereas mesh use for prolapse can be at variable anterior or posterior vaginal locations using a vastly greater amount of synthetic prosthesis.

Conservative options for female stress urinary incontinence

Female stress urinary incontinence is not only a common, but also burdensome and costly diagnosis with a negative impact on a women's quality of life⁵. Several treatment options are available, including non-surgical options.

Pelvic floor muscle training (PFMT) is recognised as a valid first line conservative treatment of urinary incontinence, supported by evidence derived from systematic reviews of available randomised controlled trials. Despite an overall cure rate of 55% over 12 weeks, the same review also emphasised the lack of long term data and only a modest immediate response^{6,7}. This should not be surprising, given PFMT require ongoing exercise and thus runs a risk of decline in compliance over time. Combining PFMT with a continence device did not show superior results compared with PFMT alone, in a recent RCT⁸.

Many women proceed to surgery when conservative measures fail. For women with moderate to severe SUI, initial surgery with tapes have a higher objective and subjective cure compared with women undergoing initial PFMT⁹.

Continence surgery – looking for the ideal option.

There are three main clinical scenarios for continence surgery: (i) primary stress incontinence surgery; (ii) stress incontinence surgery in combination with prolapse surgery; (iii) revision (re-do) stress incontinence surgery. It is worthwhile considering the “ideal qualities” for stress incontinence surgeries. We propose the following:

- **Quality A:** Success rates around 80% - 90% (significantly improved or cured of SUI)
- **Quality B:** Minimally invasive.
- **Quality C:** Minimal prolapse creation.
- **Quality D:** Voiding dysfunction potential can be minimized.
- **Quality E:** Urgency creation can be minimized.
- **Quality F:** Suitable for use with difficult (particularly scarred) anatomy.
- **Quality G:** Suitable for re-do continence surgery.
- **Quality H:** Low rate of intraoperative complications.

An analysis of the different stress incontinence surgical options.

Numerous surgical techniques have been described for cure of female SUI. However, majority of these operations were variants upon the following themes, listed in historical order:

- Bladder buttress operations (Kelly 1914)^{10,11} (Figure 1).
- Marshall Marchetti Krantz (MMK - 1949) retropubic suspension¹² (Figure 2)
- Needle suspension^{13,14} (Pereyra, Stamey - 1959) (Figure 3)
- Colposuspension^{15,16} (Burch 1961) (Figure 4)
- Artificial urinary sphincter^{17,18} (Brantley Scott 1973) (Figure 5)
- Autologous rectus fascial sling¹⁹ (McGuire 1978) (Figure 6 A & B)

- Periurethral bulking^{20,21} (1991) (Figure 7)
- Mid-urethral synthetic tape²² (sling) (Figure 8 A & B)

A comprehensive historical overview of these traditional surgical techniques is beyond the scope of this document. An interested reader may find these reviews to be of interest²³⁻²⁵.

Figure 1: Anterior Repair^{10,11,26}

Figure 2: Retropubic suspension¹²

Figure 3: Needle suspension^{13,14}

Figures 4: Colposuspension^{15,16}

Figure 5: Artificial urinary sphincter^{17,18}

Figures 6: Fascial Sling¹⁹

Figure 7: Bladder Neck Injectable^{20,21}

Figure 8: Mid-urethral sling²² (MUS – “tape”) (a) retropubic (b) transobturator

Efficacy and safety of the different procedures:

It was already well known in early 1990s that (i) some operations (slings, colposuspension) have better cure rates than others (anterior vaginal repair, injectables) and (ii) the primary operation tends to have better results than the subsequent operation, as shown in Table 1. [Leach et al, 1997²⁷]

Table 1: Results of traditional SUI operations (Leach et al 1997²⁷)

Compared to open retropubic procedures, transvaginal needle suspensions are minimally invasive, have shorter operating time and quicker recovery. While the overall success rate is reported as 85% in the published literature (range 40-100%), these are subjective rather than objective cures. They fell into disuse, given their poor long term efficacy^{13,14,27,28} and not insignificant risk of nerve entrapment of up to 16%²⁸. Overall complications include 20-50% incidence of postoperative voiding dysfunction, risk of internal organ injury during blind

passage of the needle device through the retropubic space, significant haemorrhage, poor intraoperative visualisation and infection²⁸.

Colposuspension, a popular choice, was shown by a systematic review²⁹ to have superior efficacy compared to conservative management, anterior vaginal repair, needle suspension and MMK. A subsequent systematic review^{29,30} showed no difference in the comparison between laparoscopic or open colposuspension, although it is generally acknowledged laparoscopic colposuspension require greater technical skill.

The *autologous rectus fascial sling* was also popular especially amongst urologists. A direct comparison with colposuspension was evaluated in the SISTER trial³¹. Despite a significantly higher efficacy rate, fascial sling has higher morbidity including urgency incontinence, voiding dysfunction and urinary tract infections.

Some words on the less popular options:

- (i) *Anterior Repair/Kelly Plication*^{10,11}: Anterior repair and Kelly plication aims to reduce the cystourethrocele and reinforce the pubovesical fascial support of the urethra and the bladder. It is minimally invasive, easy to perform, avoids a retropubic dissection and has a low rate of complications. However, long term cure rates are poor and risk of reoperation for incontinence is higher compared with open abdominal approach.
- (ii) *Marshall-Marchetti Krantz (MMK)*: This procedure, also known as a cystourethropexy, aims to suspend and stabilise the anterior vaginal wall, thereby restoring the proximal urethra and bladder neck to a retropubic intra-abdominal position. It has a lower cure rate compared with the colposuspension. Overall

complication rates are reported as 21% including urethral obstruction, voiding dysfunction and osteitis pubis¹².

(iii) *Artificial Urethral Sphincter*^{17,18}: Due to the invasive surgery and high revision rate, this procedure is not considered first-line therapy. It is more of an end-stage procedure, rarely used currently. Complications reported include mechanical failure (3-33%), early infection/erosion (exposure) (5-67%), late erosion (exposure) (15%), delayed recurrent incontinence (7%).

(iv) *Periurethral injection therapies*^{20,21}: These are rarely used as primary treatments for SUI due to their relatively poor efficacy. From 1991 to 2011, periurethral collagen provided reasonable success rates for previous colposuspension cases and other cases with scarred anatomy where the bladder neck is well-supported but open (type 3)^{20,21}.

The introduction of the mid-urethral tapes/slings (MUS) has revolutionised female continence surgery³². Studies have demonstrated its efficacy, minimal complications and its minimally invasive nature lends itself for day case surgery and greater access to the elderly.

Several systematic reviews evaluated the efficacy, complications and re-intervention rates of the MUS, demonstrating its comparable or higher overall objective cure rates when compared with colposuspension. MUS also has shorter operative time, less post-operative de novo voiding issues or overactive bladder symptoms.^{33,34} However it is associated with significantly more bladder injuries. When compared with open retropubic colpopexy, MUS has more return to operation room for retention, exposure, overactive bladder symptoms and groin pain. Urinary tract infection rates were higher compared with fascial slings³⁵. Fascial

slings, despite having similar success rates to MUS, have longer operative time and higher rates of adverse events including voiding dysfunction and overactive bladder symptoms.^{33,34}

MUS is the most extensively researched surgical treatment for SUI in women and has a good safety profile, a sentiment echoed by Cochrane reviewers³⁴. It has been the operation of choice for female SUI in UK³⁵, USA³⁶ & Australia³⁷.

Comparison of all the Surgical options for “ideal” qualities:

As highlighted in Table 2, the MUS clearly has more “ideal” qualities compared with other stress incontinence operations. We have relied on the literature assessment as well as the over 30-year experience of the first author in having used all procedures with the exception of the artificial urinary sphincter.

Table 2: Characteristics of female SUI operations

Clinical versus Medico-legal approach to MUS

The disconnect between evidence based medicine and the medico-legal system is well documented³⁸. Despite the consistent differentiation between tapes/slings for stress incontinence and transvaginal mesh for prolapse by FDA and other international scientific associations⁴, litigation and plaintiff lawyers, and probably the general public, do not make a distinction between these two significantly different products, placed in a different anatomical location to treat different pelvic floor problems.

Despite firm position statements from several specialty colleges and learned societies³⁹ stating evidence based support for the MUS, some government jurisdictions are moving towards severe restrictions or a ban for these tapes. It is not only a retrograde step; it would

also mean resorting to more traditional operations that have less efficacy, more voiding dysfunction or postoperative overactive bladder symptoms. It could significantly limit access to an efficacious treatment for a common, burdensome and costly condition for women.

Conclusion:

In the haste for some countries to severely restrict or abandon the use of tapes for SUI, authorities should be cognizant that they are leaving their incontinence sufferers and the clinicians who treat them with overall inferior surgical treatment options. The experience of many clinicians with any of these alternate options might be little or none. The inherent danger to patients with surgeons returning to these options would be far greater than leaving in use, tapes of proven efficacy and safety.

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Figures:

Figure 1: Anterior repair

Figure 2: Retropubic suspension (below)

Figure 3: Needle suspension

Figure 4: Colposuspension

Figure 5: Artificial urinary sphincter

Figure 6: Fascial sling

Figure 7: Bladder neck injectables

Figure 8a: Midurethral sling – retropubic

Figure 8b: Midurethral sling – transobturator

Tables:

Table 1A: Female Stress Urinary Incontinence Clinical Guidelines. Panel summary report on surgical management of female stress urinary incontinence. The American Urological Association. Results of traditional SUI operations (AUA, 1997) ²⁷

Table 1B: Female Stress Urinary Incontinence Clinical Guidelines. Panel summary report on surgical management of female stress urinary incontinence. The American Urological Association. Results of traditional SUI operations (AUA,1997)²⁷

Table 2: Table 2: Characteristics of female SUI operations

****An “X” indicates a positive quality (A-H) for the different surgical procedures***

Table 1a: Results of traditional SUI operations (Leach 1997²⁷)

Outcomes	Retropubic Suspensions		Transvaginal Suspensions		Anterior Repairs		Sling Procedures	
Cure/Dry	G/P ²	Median CI ³ (2.5 - 97.5)%	G/P ²	Median CI ³ (2.5 - 97.5)%	G/P ²	Median CI ³ (2.5 - 97.5)%	G/P ²	Median CI ³ (2.5 - 97.5)%
12 - 23 months	15 / 943	84% (77 - 89)%	13 / 700	79% (71 - 86)%	6 / 310	68% (55 - 80)%	5 / 135	82% (73 - 89)%
24 - 47 months	23 / 1,870	84% (80 - 88)%	8 / 424	65% (50 - 77)%	3 / 113	85% (69 - 95)%	7 / 341	82% (73 - 89)%
48 months and longer	17 / 2,195	84% (79 - 88)%	4 / 292	67% (53 - 79)%	5 / 1,088	61% (47 - 72)%	7 / 477	83% (75 - 88)%
Cure/Dry/Improved								
12 - 23 months	16 / 961	86% (80 - 90)%	13 / 700	82% (74 - 87)%	6 / 310	78% (65 - 88)%	5 / 135	91% (84 - 96)%
24 - 47 months	24 / 1,941	88% (85 - 91)%	8 / 424	78% (71 - 83)%	3 / 113	95% (89 - 98)%	7 / 344	85% (77 - 91)%
48 months and longer	18 / 2,204	90% (87 - 92)%	4 / 292	82% (73 - 89)%	6 / 1,101	73% (70 - 76)%	7 / 473	87% (80 - 92)%
Postoperative Urgency								
For Patients with Urgency and DI ¹ Preop	6 / 78	66% (50 - 79)%	6 / 33	64% (35 - 73)%			4 / 45	46% (24 - 68)%
For Patients with Urgency and No DI ¹ Preop	6 / 319	36% (22 - 52)%					5 / 110	34% (13 - 61)%
For Patients with No Urgency but with DI ¹ Preop	1 / 6	4% (0 - 33)%	1 / 3	7% (0 - 54)%			4 / 36	20% (5 - 45)%
For Patients with No Urgency and No DI ¹ Preop	8 / 241	11% (6 - 16)%	6 / 150	5% (3 - 10)%			7 / 140	7% (3 - 11)%
Retention								
Longer than 4 weeks	5 / 340	5% (3 - 7)%	6 / 479	5% (4 - 8)%			7 / 578	8% (6 - 11)%
Permanent	Less than 6%							
Days in the Hospital (Panel Survey)	From 0 to 5 days							
Resumption of Normal Activities	Typically six weeks for all treatment modalities							
Death	Death rate for all procedures presumed to be no different than for other types of elective vaginal/abdominal surgery: approximately 5 out of 10,000							
Transfusion	9 / 1,131	5% (3 - 8)%	10 / 1,083	3% (1 - 6)%	3 / 857	3% (1 - 9)%	6 / 279	4% (2 - 7)%
General Medical Complications								
Significant	21 / 3,135	2% (2 - 3)%	10 / 805	2% (1 - 3)%	5 / 1,005	2% (1 - 3)%	14 / 1,127	4% (2 - 5)%
Not Significant	7 / 1,549	2% (1 - 4)%	7 / 646	4% (1 - 9)%	3 / 650	8% (2 - 17)%	2 / 258	6% (3 - 10)%
Intraoperative Complications								
Significant	13 / 1,992	2% (1 - 3)%	5 / 532	2% (1 - 5)%	1 / 294	1% (0 - 2)%	6 / 326	3% (1 - 6)%
Not Significant	16 / 2,284	3% (1 - 4)%	25 / 1,835	5% (4 - 8)%	1 / 313	0% (0 - 1)%	19 / 1,077	8% (5 - 12)%
Perioperative Complications								
Significant	40 / 3,598	4% (3 - 5)%	40 / 2,814	7% (5 - 9)%	5 / 970	2% (1 - 5)%	20 / 1,723	7% (5 - 10)%
Not Significant	64 / 5,044	14% (14 - 15)%	54 / 3,330	12% (9 - 15)%	13 / 2,322	16% (10 - 23)%	26 / 1,916	12% (8 - 17)%
Subjective Complications	13 / 1,001	9% (5 - 15)%	24 / 1,412	11% (8 - 15)%	3 / 341	2% (1 - 6)%	4 / 301	6% (2 - 13)%
Complications Requiring Surgery	15 / 2,718	2% (1 - 3)%	15 / 1,575	2% (1 - 4)%	2 / 1,074	0% (0 - 1)%	11 / 1,119	3% (2 - 5)%

¹ Detrusor instability² G = Number of Groups/Treatment arms extracted / P = Number of Patients in those groups³ Confidence intervalTable 1b: Results of traditional SUI operations (Leach 1997²⁷)

Outcomes	Retropubic Suspensions		Transvaginal Suspensions		Anterior Repairs		Sling Procedures	
General Medical Complications	G/P ¹	Median CI ² (2.5 - 97.5)%	G/P ¹	Median CI ² (2.5 - 97.5)%	G/P ¹	Median CI ² (2.5 - 97.5)%	G/P ¹	Median CI ² (2.5 - 97.5)%
Abdominal Complication	1 / 19	6% (1 - 22)%			1 / 519	0% (0 - 1)%	1 / 88	1% (0 - 5)%
Cardiovascular	21 / 3,136	3% (2 - 3)%	10 / 805	2% (1 - 3)%	5 / 1,005	2% (1 - 3)%	14 / 1,127	4% (2 - 5)%
Pulmonary	6 / 1,000	2% (1 - 3)%	5 / 516	4% (1 - 11)%	3 / 650	8% (2 - 17)%	2 / 258	6% (3 - 10)%
Intraoperative Complications								
Bladder Complication	16 / 2,284	3% (2 - 4)%	25 / 1,835	5% (4 - 8)%	1 / 313	0% (0 - 1)%	19 / 1,077	8% (5 - 12)%
Ureteral Complication	6 / 730	2% (1 - 4)%	1 / 255	1% (0 - 2)%				
Urethral Complication	5 / 1,003	1% (0 - 3)%	2 / 128	3% (1 - 8)%			6 / 326	3% (1 - 6)%
Perioperative Complications								
Bleeding	19 / 1,608	5% (3 - 7)%	21 / 1,392	4% (3 - 5)%	3 / 889	3% (1 - 6)%	4 / 500	3% (1 - 6)%
UTI	46 / 4,141	13% (12 - 14)%	33 / 1,598	10% (7 - 13)%	11 / 1,743	9% (5 - 16)%	14 / 984	12% (7 - 19)%
Wound Complication	57 / 5,633	7% (5 - 8)%	61 / 4,096	7% (6 - 8)%	7 / 1,806	10% (6 - 17)%	30 / 2,499	9% (6 - 12)%
Subjective Complications								
Dysuria	3 / 175	13% (6 - 24)%	4 / 119	16% (6 - 32)%			2 / 178	8% (1 - 25)%
Pain	5 / 349	6% (3 - 10)%	16 / 1,151	10% (7 - 14)%			1 / 54	4% (1 - 11)%
Sexual Dysfunction	9 / 766	6% (3 - 12)%	10 / 609	8% (6 - 11)%	3 / 341	2% (1 - 6)%	1 / 69	2% (0 - 7)%
Complications Requiring Surgery								
Fistula	15 / 2,718	1% (1 - 2)%	14 / 1,568	2% (1 - 3)%	2 / 1,074	1% (0 - 1)%	10 / 829	3% (1 - 5)%
Stone Formation	4 / 744	2% (1 - 4)%	1 / 7	16% (2 - 50)%			2 / 417	3% (1 - 7)%

¹ G = Number of Groups/Treatment arms extracted / P = Number of Patients in those groups² Confidence interval

Table 2: Characteristics of female SUI operations

**An “X” indicates a positive quality (A-H) for the different surgical procedures*

	Efficacy 80- 90% (sig improved or cured)	Minimally invasive	Minimal de novo prolapse	Minimal voiding dysfunction	Minimal de novo urgency	Difficult anatomy suitable	Repeat surgery suitable	Low intraoperative complications rate
Ant Repair		X	X	X	X			X
MMK	X							
Needle suspension		X	X					
Colpo suspension	X					X	X	
Fascial suspension	X		X			X	X	
Artificial sphincter	X		X			X	X	
Urethral bulking		X	X	X	X	X	X	X
MUS	X	X	X	X	X	X	X	X

Figure 1

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Figure 2

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Figure 3

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Figure 4

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Figure 5

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Figure 6

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Figure 7

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Figure 8

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