Rescuing failed midurethral sling surgeries by tape repair-assessment and surgical technique.

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# TITLE PAGE

# COMMENTARY

Rescuing failed midurethral sling surgeries by tape repair-assessment and surgical technique.

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# INTRODUCTION

The banning of midurethral slings (MUS) in the United Kingdom (UK) has removed the option of a repeat MUS and has provoked discussions about other, more traumatic options such as Burch Colposuspension, autologous sling, artificial sphincters [1]. The fact that these are major operations aside, after a 20-year dominance of the stress urinary incontinence (SUI) field by the MUS, few surgeons are skilled in such procedures. A less traumatic option which has been discussed by experts for failed MUS surgery [1] is Bulkamid (polyacrylamide hydrogel), which is far inferior to the MUS. An RCT between tension-free vaginal tape (TVT) and Bulkamid [2] gave the following 12-month results: satisfaction score of 80 or greater on a visual analogue scale of 0 to 100 was reached in 95.0% and 59.8% of patients treated with TVT and Bulkamid, respectively. Bulkamid often requires multiple return treatments.

Though the initial midurethral sling surgeries published cure rates regularly exceeding 85%,

more recently, much lower cure rates have been recorded. A Cochrane Review in 2017 recorded a wide cure rate for MUS, between 62% and 98% [3]. The MUS dominance for 20 years indicates most likely, that the major group of failed incontinence operations in the UK currently derive from midurethral slings [3].

My long experience in MUS surgery causes me to believe that most stress urinary incontinence (SUI) failures were caused by a MUS set too loosely. A loose PUL invalidates the distal urethral and bladder neck closure mechanisms, fig.1 [5]. PUL laxity is easily diagnosed by a "simulated" or "virtual operation": a hemostat applied immediately behind the symphysis controls SUI by preventing elongation of a weak PUL, fig.1, VIDEO1 https://youtu.be/0UZuJtajCQU. The anatomy of this "simulated operation" manoevre is exactly reflected in the ultrasound section of Fig1. If the suburethral hammock is loose, please note the VIDEO how a gentle fold of vagina helps continence control. The "fold" in the video improves the distal closure mechanism, fig.1, and indicates it should be repaired in addition to the "tape rescue procedure", VIDEO2.

The aim of this short commentary is to introduce a clinical test (VIDEO1) which can diagnose which of the MUS failures may have been caused by a tape applied too loosely, to introduce a "tape rescue operation" for precise tensioning of the tape and, in addition, reconstitution of the distal urethral closure mechanism, fig.1, which is similar in principle to the two-incision version of the MUS [4,6].

# THE SURGERY

"Tape rescue surgery". The operation needs to be performed under spinal anesthesia, as it permits testing for continence during the procedure. With a No18 Foley catheter in place, a vertical incision is made in the vagina from midurethra to within 0.5cm of external meatus, so the external urethral ligament can be accessed for the vaginal part of the procedure, see VIDEO2. The tape is identified. After preliminary dissection, the suburethral loop of the tape is grasped with two fine mosquito forceps and, under tension, divided in the midline. This facilitates further dissection of each side of the tape from its lateral attachments to the urethra. The bladder is filled with 300ml of saline and the patient is asked to cough. The forceps are moved to each edge of the cut tape. They are approximated while the patient is coughing until there is no urine loss, or preferably, a few small drops which are more indicative of the correct tension. Interrupted non-absorbable sutures are placed into both cut edges, but not immediately tied. The catheter is re-inserted and the sutures are tied over the catheter, taking care to avoid excessive tightness. It needs to be remembered that the urethra is elastic and easily compressed\*[7,8]. The 18gauge Foley catheter acts as an obturator and prevents over-tightening. The catheter is removed and the patient is re-tested.

# Repair of the distal closure mechanism

Next, the distal urethral closure mechanism, fig.1, is surgically restored, VIDEO2. https://youtu.be/QM0rEtQ7i8w. Taking the midline incision to within 0.5 cm of the external urethral meatus (EUM) allows access to the external urethral ligament (EUL) which is sited immediately lateral to the EUM. As per the VIDEO, a 00 vicryl suture is inserted into the left EUL, then into the smooth muscle layer of the vagina on the same side, then on the right side and finally, the right EUL. The suture is lightly tied.

If the patient is continent on coughing with 300 ml in the bladder at the end of the operation, it is highly likely she will remain cured. The immediate post-operative treatment is as per a standard MUS operation.

\* Compression of 0.5 millimetre beyond the normal urethral diameter, fig2, requires a far higher detrusor pressure to evacuate the urine from the detrusor, as the pressure change is exponentially determined, being the inverse of the 4<sup>th</sup> power of the radius (Poiseuille's Law).

# CONCLUSIONS

The foregoing discussions bring up some not insignificant ethical questions for surgeons faced with failed MUS operations. If tape "rescue surgery" restores continence in the manner of the MUS, which it does, is it ethical to perform a lesser procedure? The tape rescue operation restores the natural closure mechanisms much in the same way as the hemostat test restores closure and continence, fig.1. In contrast, Bulkamid

works by compression of the urethra. By definition it reduces urethral diameter, laying the patients open to all the consequences of exponentially reduced urine flow as per fig.2. Its action is not physiological, and this is reflected in the poor results of the Itkonen RCT, 59% vs 95% patient satisfaction [2]. Suggestions for a return to largely discarded operations such as fascial bladder neck slings and Burch Colposuspension for cure of SUI [1] is a more serious ethical problem. These are major operations which require a high level of skill which only comes after years of practice. The "rescue operation" is well within the skill set of surgeons who are familiar with the MUS. It is worth serious consideration as a first-choice operation for failed MUS.

### Ethics NA

# Financial assistance NA

#### Conflicts NIL

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# **FIGURES**

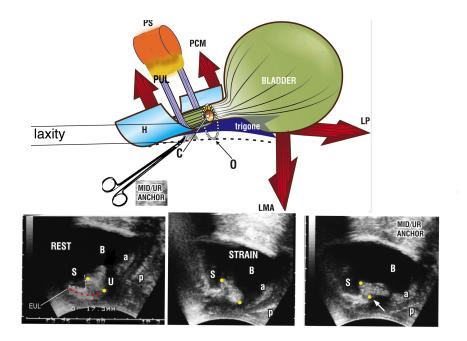


Figure 1 How the hemostat test mimics normal control of SUI.

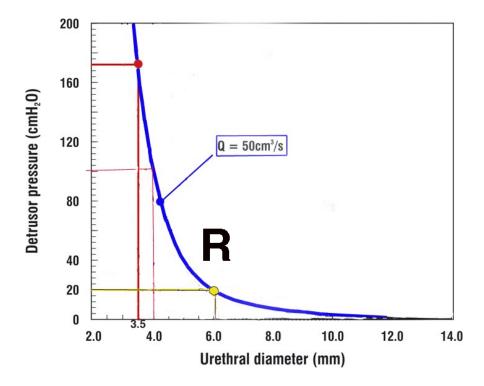
**Upper figure** A firm pubourethral (PUL) attaches to the lateral part of urethra, pubococcygeus muscle (PCM) and vagina [6]. It prevents the posterior reflex closure forces LP (levator plate) and conjoint longitudinal muscle of the anus (LMA) acting on the trigone to pull open the posterior urethra during effort [5]. Likewise, in SUI women, transverse and retropubic tapes create new collagen below the midurethra to prevent elongation of a loose or weakened PUL during effort.

Normal urethral closure Three reflex directional muscles forces close urethra: pubococcygeus (PCM) contracts forwards against PUL to close distal urethra; levator plate (LP), contracts backwards to tension PUL, and to stretch bladder base and trigone backwards for LMA (conjoint longitudinal muscle of the anus), to pull the anterior tip of LP downwards https://www.youtube.com/watch?v=3vJx2OvUYe0

This downward action rotates bladder base around PUL and pubovesical insertion into the arc of Gilvernet (not shown) to close urethra at bladder neck [5].

Stress urinary incontinence If PUL is weak or loose, it cannot sustain the powerful posterior forces LP/LMA on effort; it lengthens, the anterior vaginal and trigone are pulled downwards; urethra is opened from "C" closed to "O" open; urine is lost on effort [5]. The hemostat mechanically supports PUL, prevents lengthening and controls SUI, as in the VIDEO and right ultrasound frame.

Lower figure The ultrasound figures show typical geometry of SUI caused by loose PUL [9]. Left frame: REST. Urethra closed. Structures in normal anatomical position, S=symphysis;U=urethra; B=bladder; "a" & "p" = anterior and posterior walls of vagina; red broken lines mark a whitish continuum which represents distal ligamentous support of the urethra from EUL=external urethral ligament to the yellow dots which mark another thickening, the pubourethral ligament. Middle frame: STRAINING. Pubourethral ligament (yellow dots) lengthens and cannot sustain the posterior forces acting on the anterior ("a') and posterior ("p") walls of the vagina are tensioned and pulled backwards/downwards. The urethra is opened along its length; urine is lost on effort. Right frame; MID/UR ANCHOR A hemostat placed at midurethra as in the video mechanically supports PUL (yellow dots), prevents lengthening and restores continence, as in VIDEO1.



**Figure 2**. Exponential nature of urine flow is related to urethral diameter [7,8]. For a flow rate of 50 ml/sec (thick blue line), closing the urethral diameter from 4 mm to 3.5 mm (for example, by an overtight tape) increases the head of pressure required by the detrusor to expel urine from the bladder from 100 cm to 172 cm water. Expanding urethral diameter to 6 mm (yellow lines), reduces the head of pressure to 20 cm water. The blue line represents the total urethral resistance to flow.

