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The mechanics of urethral closure, incontinence, and midurethral sling repair Part 3 surgical applications (1990-2016)

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Part 3 briefly summarizes further development in midurethral sling (MUS) instruments and technique following the 1990 prototype operations, then critically examines the whole MUS surgical methodology, 1990 to present day. The aim is to identify positive and negative aspects of these methodologies which can be usefully applied to improve current MUS surgery.

Animal Experiments: 1987-1988 proved that a collagenous neoligament could be formed by implantation of a tape. There was a wide variation in tissue reaction to implanted tapes. Inflamamatory tissue reaction was very different from bacterial infection and was safe even when a sinus is formed.

MUS Methodology: The key factor in avoiding major vessel and nerve injuries is to penetrate the perianal membrane with scissors, insert the applicator. Importantly, this reveals any bleeding which could otherwise accumulate in the Space of Retzius and only be controlled by digital pressure. The balance between too tight (retention) and too loose (incontinence) is analyzed in terms of the exponential relationship between urethral diameter and urine flow; why elastic tapes are more likely to cause post-operative urinary retention; how to minimize retention by tightening against an indwelling No18 Foley catheter; the importance of routinely repairing the distal closure mechanism with purse string suture to external ligaments, fascial layer of vagina; why minislings avoid most of the serious MUS complication; why a tensioned minisling allows greater precision when tightening the sling and how anchors and individually knitted tapes give hope that tape erosions may decrease.

KEYWORDS
midurethral sling, minisling, neoligament, pubourethral ligament, pubovesical ligament, stress incontinence

1 | INTRODUCTION

The aim of parts 1 and 2 was to describe, validate and analyze the musculoelastic urethral closure mechanisms as described by the Integral Theory, how a lax PUL can cause urinary stress incontinence (USI) and reversal thereof by a midurethral sling operation (MUS).

The aim of Part 3 is to briefly summarize further development in MUS instruments and technique following the 1990 prototype operations, then to critically examine the whole MUS surgical methodology, 1990 to the present day, with a singular aim, identifying positive and negative aspects of these methodologies which can be usefully applied to improve current MUS surgery.

Roger Dmochowski led the peer-review process as the Associate Editor responsible for the paper.

1.1 | Further development of the MUS 1990-1996

The 1990 prototype operations had a 50% failure by 3 months.[1] Between 1990 and 1993, the 1st author worked closely with the late Ulf Ulmsten to further develop the MUS. By 1993, it was concluded that a permanent tape was required for the MUS with polypropylene the preferred material for the tape. The original MUS surgeries were all performed with the IVS tunneller until 1994, Figure 1, when the IVS tunneller was re-engineered to create the TVT instrument, Figure 1.[2]

The IVS tunneller was a lightweight instrument, with a 90° curve and plastic delta wing handle. The IVS design made it a tactile extension of the surgeon's hand. It allowed the surgeon to know the exact position of the instrument tip in three dimensions. There was a plastic insert with a blunt plastic wedge shaped head. The tape was non-stretch Amid type 3, later proven to have more problems than the Amid type 1. The TVT instrument had identical dimensions, but was different in some important areas. There were two solid stainless steel ends with sharp tips joined by an elastic polypropylene tape, Figure 1. Their angle was about 120°, which meant that the surgeon could not know exactly where the tip was situated in the vertical plane. Each end was attached to a heavy screw-on handle for insertion. The TVT tape was elastic Amid type 1.

1.2 | The surgical methodology in 1996

The final surgical technique as described in the 1996 publications by both Ulmsten et al[3] and Petros[4] were based on applying a midurethral tape to restore the distal and proximal closure mechanisms.[1] The technique for the two instruments was almost identical to that of the final 1993 prototype operation using a permanent sling[5]: local anaesthesia, a stiff insert in the Foley catheter to divert the bladder, a hole in the perineal membrane prior to instrument insertion, "hugging" the posterior surface of the pubic bone, tape sited exactly at midurethra, elevation of the two ends tape until urine loss ceased on coughing with 300 mL saline in the bladder, tightening the suburethral vagina.

There were two major differences in methodology. The TVT instrument used an elastic Amid type 1 tape elevated against an empty urethra; a No8 Hegar dilator was inserted at the end of the operation to ensure no constriction of urethra, Figure 2. The IVS instrument initially used a denser non-stretch Amid type 3 tape applied to touch but not indent a urethra distended by an indwelling No18 silicon Foley catheter, over which the tape tightening was performed, Figure 2.

1.3 | Application of MUS to other operations for USI

The transobturator "TOT" midurethral sling[6] in 2001 was a significant advance. It avoided almost all life-threatening complications associated with the TVT. Cure rates were equivalent for USI, though possibly less effective in ISD (Intrinsic sphincter defect) and perhaps associated with up to 15 times more repeat surgeries than the retropubic operations.[7]

The first minisling was the TFS tensioned minisling in 2005.[8] Minislings utilize only small tape strips, without the risk of arterial, nerve small bowel perforation and the retropubic hemorrhagic complications in the Space of Retzius associated with the TVT. Unlike the TVT and TOT which have long lengths of tape, "minislings" rely on the anchor "grip" to resist restorative forces from tissues they compress. Anchor grip varies with different "kits" as do results reported. In general, achieving the correct tension is difficult with untensioned minislings, as insertion and tightening are done simultaneously. They compress the periurethral tissue and so are subject to restorative tissue elastic forces post-operatively

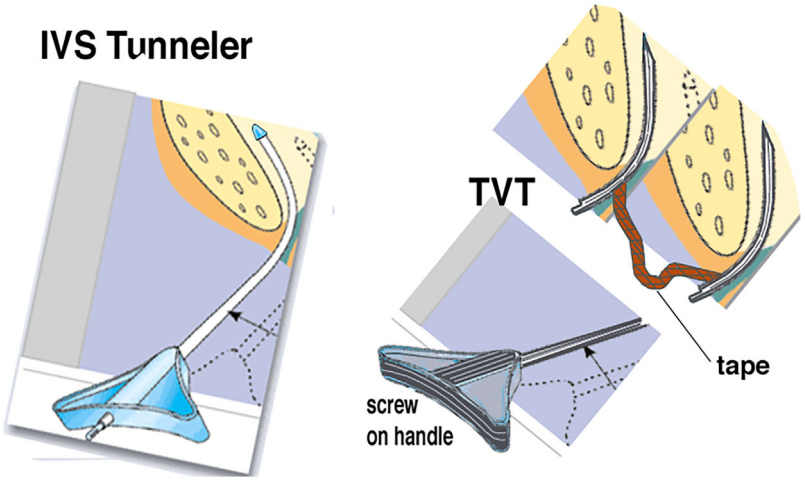

FIGURE 1 Original MUS instruments Left IVS tunneller. Right TVT

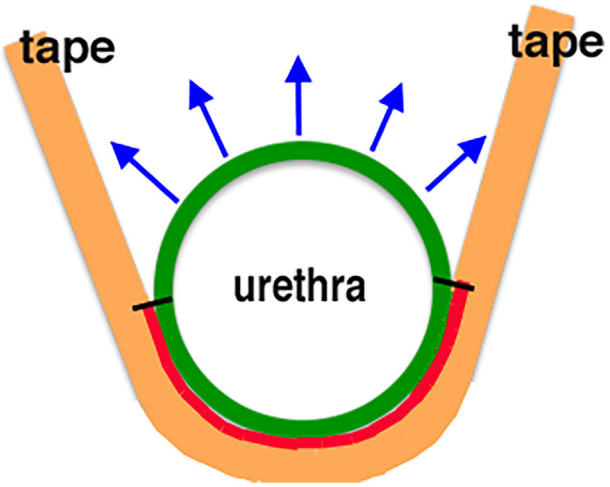

FIGURE 2 Tissue mechanics of MUS tape placement. The tape grips the inferior wall of the urethra (red line) and proceeds along the length of the midurethral limb of PUL. If the tape is elastic, as it is pulled upwards to stem urine loss on coughing, it will also stretch the inferior part of the tape. Elastic restoration may then constrict the urethra and on rare occasions transect it. Inserting a No8 Hegar dilator after tape adjustment with the cough test will only expand the point of least resistance, the anterior urethral wall (blue arrows). Tightening over a rigid No18 silicon catheter vastly limits urethral constriction with a non-stretch tape. Use of a Foley catheter with an elastic tape and tip of scissors between the urethra and tape gives an extra layer of certainty against overtightening and more accuracy

which tend to loosen the tape. Tensioned minislings work on a different principle. Soft-tissue anchors with high pullout strength are inserted and the tape is tightened as a separate movement. Five year RCT data,[9] 3 year data,[10] and high cure rates for ISD[11] using retropubic tensioned midurethral slings have been reported the latter with no tape erosions. Such reports indicate that this type of tensioned MUS has at least equivalent cure rates to the original retropubic techniques.

2 | CRITICAL ANALYSIS

2.1 | Lessons from the animal studies 1987—For MUS surgery

1. Implanted tapes cause foreign body reaction (FBR). This varies from individual to individual. Radioactive Gallium studies[12] demonstrated very low grade inflammation. FBR is different from infection. It is characterized clinically by an afebrile state, normal white cell count (WCC), histologically by giant cells and sometimes, sterile pus*, which like a splinter, may distend the tissues to cause pain. FBRs are clinically benign, and quite different from those of infection, which are not. FBR sinus formation in some dogs was safe and not bothersome.

   * **Note** Pus is only the liquefactive necrosis of granulocytes and the tissue in which they have invaded—bacteria are not necessarily involved.
2. Bacterial growth on the tape, where present, was of "mixed" nature, with low counts. There was no infective inflammation in the dogs. With human MUS erosions, infection is very uncommon. When it occurs, it is generally caused by an infected hematoma accompanied by pyrexia, raised WCC and isolation of pathogenic bacteria.
3. In the dogs, sinuses were present, but only in some animals. This indicated individual immunological variation in tissue reaction. The animal data explains why some patients develop a tissue reaction and others do not.
4. The collagenous neoligament when tested on an Instron Tensiometer pulled out of the grips at 0.64 megapascals, indicating that the collagenous neoligament formed is enormously strong, indicating that large meshes are not required to support a uterine or vaginal prolapse. An implanted tape is sufficient.
5. The inflammatory reaction from the tape glued it to anything it touched, indicating a tape could be used for "tissue welding."

2.2 | Methodology—Lessons from the early MUS operations (1990-1996)

1. A hole* in the urogenital diaphragm preceding insertion of the instrument gave greater control of the instrument (especially the heavy TVT). Once in the hole, the instrument could be turned in a vertical direction to "hug" the posterior aspect of the pubic bone. It is our view that this is the single most important step in preventing damage to the external iliac vessels and obturator nerves and vessels. It also exposes any bleeding from the venous sinuses below the inferior border of the pubic bone. Unnoticed, this bleeding may collect in the low pressure Space of Retzius and track right up to the liver. The only way to control this low pressure bleeding is with digital pressure, repeated if required, pressing the vagina against the posterior surface of the pubic bone, with or without insertion of a hemostatic agent such as Surgicel.

   * Though Ulmsten and Petros explicitly stated in their 1996 papers[4,5] that a hole is a required step for inserting the TVT, the marketing departments from some of the companies eliminated that step as it often caused major bleeding by puncturing the venous sinuses, a "bad look" for marketing. Elimination of this one step could have hidden low pressure venous bleeding which accumulated in the Space of Retzius.
2. The staged technique for tightening the tape under LA was accurate and effective. The optimal technique is to ALWAYS tighten over a No18 silicon Foley catheter

(rubber can be compressed). Figure 2 demonstrates the difference between the two techniques.[4,5]

3. The Tape must always be fixed at midurethra, the site of PUL insertion, so as to balance the opposite muscle forces (see Parts 1 and 2).
4. In patients with USI and urge symptoms, ("mixed" incontinence) the urge component can be cured in 50% of the patients.[16] No anticholinergics are required pre-operatively.

2.3 | Lessons learnt from tapes and tape placement

2.3.1 | The ideal tape

It is our view that lightweight non *stretch individually knitted* macropore Amid type 1 polypropylene is the best material for implantation. Though the Amid type 3 IVS tape had far fewer urethral transections and urinary retention, it also had significantly higher erosion rates and tissue reaction than Amid type 1. The original TVT and all other tapes at the time were all cut to size either by heat or laser from a large knitted mesh sheet. This methodology inevitably leads to microscopic splintering, resulting in the persistent presence of splinter particles which create extra inflammation which does not contribute to the linear deposition of collagen required for neoligament formation. Only individually knitted tapes can avoid splintering with any certainty.

2.3.2 | Pore size

Macrophages were found in the interstices of the original 1990 animal Mersilene tapes,[12] indicating that whatever the cause of the sinuses in the animal experiments, it was not absence of macrophages because of "75 micron spaces." Macrophages can negotiate even one micron vessels by developing lamellopedia.[13] However, it is well known that the greater the density and volume of the implant, the greater the tissue reaction and the more the erosions. Densely knit tapes and large mesh sheets are more likely to cause tissue reaction, surfacing, and erosions than the thin strips of lightweight tapes developed over the past few years.

2.3.3 | Stretch or non-stretch?

The early TVT Amid type 1 tapes used in the TVT and other devices were elastic. Initially, the elastic TVT tape was applied directly onto the wall of the urethra and a No8 Hegar dilator inserted after the cough elevation test,[3] Figure 2. This could not counteract what happened when a tape had been overtstretched when pulled upwards, sometimes to the point of acting like a narrow cutting wire to transect the urethra. Less dramatic consequences such as post-operative urinary retention could be caused by the restoration of tape elasticity in the subsequent 24 h. Placed under stretch the diamond-shaped tapes stretch like a steel wire, sometimes transecting the urethra to cause fistula. A space left between tape and urethra has helped this problem, but this method remains imprecise: too tight-retention; too loose-incontinence. The question is "How much space to leave." Clearly a longer tape will create more elastic restoration (and more risk of retention) in a 120 kg woman than in a 45 kg woman.

The non-stretch Amid Type 3 "multifilament" tape was the only truly non-stretch tape available in the mid 1990s to mid 2000s. Applied to the wall of urethra with a No18 Foley catheter in situ, there was no post-operative tape retraction, few retentions, and no reports of transection. Nevertheless, the higher concentration of polypropylene per unit volume had the potential to provoke larger FBRs around the tapes with greater likelihood of slippage, surfacing, and erosions and if the foreign body reaction (FBR) was sufficient, also pain. Though infrequent, florid FBRs were distressing to the patient.

In spite of the benign histology (granulomas), benign clinical characteristics, delayed time frame (24 months duration) being indicative of a FBR, many such cases were described as "infection," especially when presenting months or years later with red painful implant sites. We emphasize the importance of understanding the difference between foreign body induced inflammation (benign) and infection (not benign). This differentiation becomes especially important in the context of medico-legal suits. Though entrapped pus from a foreign body reaction may cause pain, it is sterile, and like a splinter, non life threatening. The patient has pain but does not look ill. The symptoms settle immediately on tape removal. In contrast, an infected tape is a potentially serious matter. The patient is febrile and looks ill. Pus contains heavy concentrations of pathogenic bacterial species.

2.4 | Why repair a defective distal urethral closure mechanism?—A critical analysis

The three structures comprising the distal closure mechanism are the external urethral ligament, suburethral vagina, and pubourethral ligament. Basic science studies in Part 2 indicated this mechanism does play a role in urethral closure, albeit a minor one. Its minor role in continence closure was unintentionally confirmed by Lapides' some 60 years ago, who stated that patients can remain continent even after excision of the distal part of their urethra.[15] A practical proof that the proximal (bladder neck) closure mechanism is key to continence control is to apply the midurethral test with a hemostat[14] (VIDEO 1). It is our view that the distal closure mechanism mainly acts to seal the urethra. The anatomical appearance of loose structures is detailed in Figure 3. The

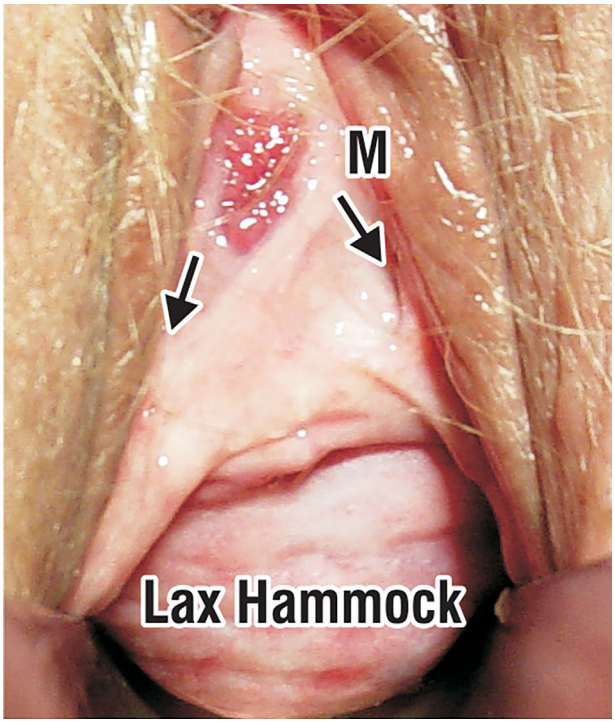

FIGURE 3 Diagnosis of damaged distal closure mechanism. The urethral meatus (M) is lax, and the urethral mucosa is everted. The lateral EUL supports are seen "drooping" downwards (arrows). The suburethral vagina ("hammock") is lax and angulated downwards. The everting urethral mucosa restores following repair, Figure 4

clinical symptoms are sudden loss of small amounts of urine on moving quickly, getting off a chair. Sometimes the urine loss can be considerable, for example constant slow leaking during a long walk. Often the patient says the leak is "like a bubble of air escaping."

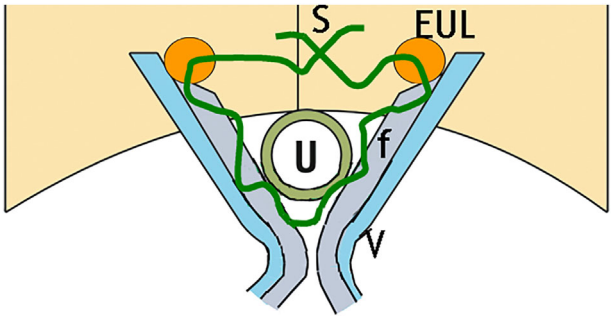

FIGURE 4 Repair of the distal closure mechanism. The midline MUS incision is extended to within 0.5 cm of the urethral meatus. A purse-string type suture "S" is inserted into one external urethral ligament "EUL," then into the ipsilateral fascial layer "F" of the vagina "V," then into the opposite fascia, into the opposite EUL. The suture is tightened sufficiently to remove laxity and tied fairly loosely, always over a No18 Foley catheter. S, anterior surface of the symphysis; U, urethra

The distal closure mechanism is best restored by combining vaginal tightening with repair of the external urethral ligament, Figure 4, *performed routinely at the time of a midurethral sling*. Unfortunately the diagnosis of this condition often occurs post MUS surgery. Our experience is that native tissue repair post MUS does not work. In a small number of cases we have inserted a pre-pubic sling, usually a tension free unanchored tape with mixed results.

2.5 | Intrinsic sphincter defect ISD

Nakamura et al reported 90.9% for patients with maximum urethral closure pressure $<20\,cm\,H_2O$ using retropubic tensioned minislings without any erosions ($n = 96$). These are very high cure rates for a condition many experts previously considered to be incurable.

These results compare favorably with those achieved by Rezapour and Ulmsten[16] (74%) using TVT and Schierlitz et al[7] (79%) also using TVT. Nakamura et al[11] gave a concise description for both ISD cure and why urinary retention may occur after MUS

> *An adequately tightened PUL is required to restore this (closure) mechanism. However, the exponential effect (urethral resistance) works both ways. It means that the tightening of the sling has to be very precise. With any sling operation, excessive tension on the sling will constrict the urethra and cause urinary retention. In contrast, excessive looseness of the sling will cause ongoing SUI. The local anesthesia methodology and non-stretch tape meant that we did not need to make any allowance for postoperative rectus muscle contractions or tape elasticity (eg, by placing scissors between the tape and the urethra during tightening). It is our view that the main reason for our high cure rate in patients with ISD is that we were able to precisely tighten the tape millimeter by millimeter after its insertion, thereby avoiding the exponential effects on the urethral lumen of an over-tight or over-loose sling. We consider that one extra step, (routinely) tightening the external ligament, and suburethral vagina (see Figure 4), was an important contribution to our surgical methodology, as it restored the distal closure mechanism.*
>
> *These mechanics appear to explain the poor results reported in non-ISD patients. A non-tensioned mini-sling is inherently imprecise. It has to insert and tighten a loose PUL in one movement. Great skill is required to do this. The*

retropubic nature of the tensioned TFS minisling appears an optimal methodology for treating ISD. At 3-year review, Schierlitz et al[7] showed that the risk for re-operation in TOT patients with ISD was 15-fold greater than the TVT. The authors recommended that only a retropubic sling should be used for patients with ISD.

2.6 | Is it possible for MUS to be performed without subsequent erosions?

The main studies of MUS operations to date, whether retropubic or TOT, have almost without exception reported a percentage incidence of erosions. The explanation may lie in the unattached "tension free" sling which relies on the friction of the tape to stay in place. Immediately following implantation of the tape, there is an initial influx of fluid exudate at the site of injury, followed by inflammatory cells such as neutrophils and macrophages. It was observed in the original animal studies[12] that the FBR (exudate) varied greatly among the individual animals. Excessive exudate could loosen the adherence of the tape to cause surfacing, the commonest type of erosion. In a series of papers using the tensioned retropubic-type minisling system for MUS and POP, Sekiguchi et al report zero erosions.[10,11,17,18] The explanation may lie in the strong anchoring system of the device which may prevent surfacing: each anchor can hold 2.3-3 kg.

However, a misplaced anchor can slip to cause an erosion and this has been reported by Sivalsioglu in his 5 year RCT of the tensioned retropubic minisling MUS against TOT, where the minisling MUS was superior, 84% versus 75% at 5 year review. It is our view, based on the FBR variation noted in the experimental animal work, that even with no slippage, there must, at least in some cases, be an immunological reaction sufficiently severe to require tape removal.

2.7 | What to do with USI and "mixed symptoms"

It is our experience, that USI, if present, should be treated with an MUS, whatever the associated symptoms, urge (mixed incontinence) fecal (double incontinence) or emptying difficulties. It is not within the remit of this paper to discuss the pathogenesis of these accompanying symptoms.

Rezapour et al demonstrated that USI and urge symptoms ("mixed incontinence") can both be cured by a midurethral sling[19] confirming findings from the 1990 prototype operations.[1]

Hocking demonstrated cure of both USI and fecal incontinence ("double incontinence") with a midurethral sling.[20] USI with associated emptying problems may require both an MUS and a posterior sling.[21] The first pre and post-op urodynamic study to demonstrate cure of USI and emptying symptoms (including high residual urines) was in 1997.[21]

2.8 | Application of the MUS ligament repair methodology to other ligaments

Again, this is outside the remit of this work. Interested readers are referred to a large study by Inoue et al[22] ($n = 278$) where total ligament repair of the five main suspensory ligaments, PUL, cardinal, uterosacral, ATFP, and the suspensory ligaments of the perineal body were repaired using only ligament repair.

3 | CONCLUSIONS

The past 28 years have seen a progression from the coarse prototype MUS to the sophisticated local anesthetic minisling methods. The MUS has become what Thomas Kuhn calls "normal science."[23] A tensioned anchoring system promises greater precision, greater safety with fewer erosions than the traditional "tension-free" method. The next major step forward, in our view, is a less reactive material for the tape.

CONFLICTS OF INTEREST

The 1st author PP is the co-inventor of the MUS, Integral Theory, and TFS. BA has previously acted as a teacher for the MUS.

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SUPPORTING INFORMATION

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