



Tension-free artisan tape: a low-cost option for cure of pelvic organ prolapse and stress incontinence

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Abstract: The Lancet PROSPECT Trial has shown that vaginal repair has dismal cure rates of some 20% at 12 months. Meanwhile 10-year data from collagen creating ligament repair methods (implanted mini-sling tapes), with no vaginal excision, report very high, long-term cure rates. The reason for conserving the vagina, is that the vagina's main function is to transmit the muscle forces for external urethral closure or opening. Ligaments provide the main structural support for the organs, much like a suspension bridge. Collagen is the key structural component of the ligaments which structurally support the organs. However, collagen breaks down after the menopause and is excreted as hydroxyproline. If sufficient collagen breaks down, the ligaments weaken, and this explains the 80% failure rates for native ligament in the Lancet PROSPECT Trial. Whereas satisfactory results for pelvic organ prolapse (POP) and symptoms have been obtained with native ligament repair in premenopausal women, it has been shown that collagen-creating ligament repair method, for example, precisely inserted tapes, is required in older women. "Tension-free" artisan tapes work in the same way as commercial tape kits which have been used to cure stress urinary incontinence (SUI) and POP. The "tension-free" artisan tape results for POP at three years were encouraging, but were applied only in a small number of cases. Very recently, long-term (5.7 years) tension-free artisan tape data has become available from artisan SUI surgery. Results from 93 women using an artisan transobturator tape (TOT) achieved a cure rate of 91.3% at a mean of 5.7 years postoperatively. The only significant complication was a 4.3% erosion rate. The implications are that tension-free artisan tape for POP is also likely to be long-lasting. Another implication is the cost, which, for each tape, is a few Euros. The low cost allows the artisan method to be applied even in the poorest nations.

Keywords: Artisan tape; prolapse; stress urinary incontinence (SUI); neoligament; collagen

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Introduction

The key points of the article are summarized in the video abstract ([Videos S1,S2](#)).

The banning of all mesh kits for prolapse surgery in many parts of the world [and in the UK, the midurethral sling (MUS) also], has left few surgical options for women with major prolapse other than native tissue repair. The low cure rates for pelvic organ prolapse (POP) at 12 months (20%), from the Lancet PROSPECT Trial (1) and from the ligament-based Shkarupa *et al.* trial in postmenopausal women (2) demonstrate that at least for postmenopausal women, any native ligament repair without restoring collagen to collagen-deficient ligaments, doomed to failure. The 20% cure rate for native tissue surgery stands in stark contrast to the 79% 5-year cure rates for prolapse using tapes to repair major 3rd and 4th degree prolapse, for Tissue Fixation System (TFS) commercial kits by Inoue *et al.* (3) or the 12-month data for artisan tapes (4).

The artisan tape

The Food and Drug Administration (FDA) and UK bans affect only commercial kits. It has always been legal for an individual surgeon to use any FDA or Conformité Européenne (CE) approved mesh tape, cut for an individual condition (e.g., prolapse or incontinence), in an individual patient. This is a low-cost option which applies especially to the older group of women most in need of collagen creation methodology (2).

The artisan methodology is very close to the TFS mini-sling technique used by Inoue *et al.* (3) for stress urinary incontinence (SUI) and POP, minus the anchor. The

surgeon relies on the friction of the inserted tape to hold it in place. The same mesh as a commercial midurethral and other slings is used, except that the tape is cut from an FDA approved mesh sheet with scissors. The techniques for SUI and POP described are those used by Piñango-Luna *et al.* (4), and are summarized in [Video S3](#).

Methods

The surgical methodology quoted below is as performed by Piñango-Luna *et al.* (4).

Retropubic artisan MUS technique

With an 18 French Foley catheter in place, a full thickness 1.5 cm midline vaginal incision is made at the midurethra. Using Metzenbaum scissors, a tunnel is made to the perineal membrane which is penetrated to 1.5 cm as in a standard MUS. Both ends of a 1 cm wide × 8–10 cm long tape are grasped with a Crile forceps and directed upwards through the tunnel, one at a time, with sufficient tension for the base of the tape to firmly touch, but not indent a urethra distended by an 18 French Foley catheter. The tape is left *in situ*, and the vagina is sutured with 00 vicryl, taking care to approximate loose suburethral vaginal fascia (See [Videos S3,S4](#)).

Artisan sling reconstruction of cardinal ligaments (cystocele) and uterosacral ligaments (uterine prolapse)

The original surgery Silvia Piñango-Luna *et al.* (4), used a 10 cm tape (See [Video S3](#)). The tape was prepared from a polypropylene sheet used for hernia repair. The cervix was grasped with a Pozzi forceps. A full thickness transverse incision was made in the anterior wall of the vagina at the juncture of the bladder to the cervix, about 2–3 cm distal to the cervical os or vaginal vault. The bladder was dissected off the cervix.

The cardinal ligaments (CLs) were located by palpation, prolapsed laterally, 2–3 cm inferior and lateral to the cervix. They were grasped with Allis forceps and a suture was placed in each to bring them to the midline, fixing them to the anterior aspect of the cervix. Following plication, and under tension, right and left tunnels were made laterally in the anatomical position of the CL, with Metzenbaum scissors, for the introduction of the tape, with equal lengths on each side. One end of the tape was grasped with a Crile forceps and inserted into the tunnel made in the fascia. A second Crile forceps grasped the tape at its other end and

Highlight box

Key findings

- Low cost 1 cm × 10 cm artisan tapes from mesh sheets give good results for stress urinary incontinence and pelvic organ prolapse.

What is known and what is new?

- Native vaginal repairs for prolapse had an 80% failure rate at 12 months (*Lancet*). Repair of prolapse requires repair of its structural component (ligaments).

What is the implication, and what should change now?

- Collagen breakdown in ligaments causes prolapse and pelvic symptoms. Collagen-creating methods are needed to repair damaged ligaments.

the tape was stretched, inserted and its middle part fixed to the cervix. The fascia of the vagina was sutured as a purse string and attached to the cervix with 00 vicryl.

Reconstruction of uterosacral ligaments (USLs) for uterine prolapse

A 1 cm × 10 cm tape was created from a hernia sheet. A

full thickness, 5 cm transverse incision was made in the posterior wall of the vagina at the apex of the enterocele bulge, about 4 cm distal to the cervix or vaginal vault. Blunt dissection and closure of the posterior cul-de-sac or enterocele was made without opening it. The USLs were identified by palpation at hours 4 and 8 o'clock in relation to the cervix. Both USLs were grasped with Allis forceps and approximated with 00 vicryl sutures.

The USLs were plicated with vicryl sutures. Then, two 1 cm diameter tunnels were made in the direction of the cervix between the vaginal skin and the USLs by dissection backwards along the direction of both USLs. Both ends of the tape were grasped with a Crile forceps and inserted one by one into the tunnels and stretched upwards towards the cervix. The vaginal wall was closed with a running 00 vicryl sutures.

Results

Table 1 shows the dysfunctions and surgical treatment of the patients (4). *Table 2* shows 12-month results for 40 tape insertions (4).

Eight patients out of the initial 15 were evaluated at three years. Their preoperative symptoms were: pelvic pain in four patients, vulvodynia in two patients, SUI in six patients, urinary urgency in eight patients, Pelvic Organ Prolapse Quantification System (POPQ) grade I, in one patient (surgery for vulvodynia with minimal POP), POPQ grade II, in three patients, POPQ grade III, in four patients. Interventions were: reconstruction of uterosacral and CL in all eight patients and reconstruction of pubourethral ligament in six patients. Symptom cure at three years were: pelvic pain: 2/4, vulvodynia 2/2, SUI 4/6; urinary urgency 6/8. Anatomic findings: POPQ grade I: six patients, POPQ grade II: zero patients, POPQ grade III: two patients. It is

Table 1 Pre-surgical dysfunctions and surgical treatments

Variables	Statistics
n	15
Age (years), median ± SD	64±12
Clinical record	
Pelvic pain	6 (40%)
Vulvodynia	2 (13.3%)
SUI	9 (66.6%)
Nocturia	11 (73.3%)
POPQ	
POPQ I	2 (13.3%)
POPQ II	6 (40.0%)
POPQ III	7 (46.7%)
Technique	
Uterosacral	15 (100.0%)
Cardinal	15 (100.0%)
Pubourethral	10 (66%)

Reused with permissions from *Central European Journal of Urology* (4). SD, standard deviation; SUI, stress urinary incontinence; POPQ, Pelvic Organ Prolapse Quantification System.

Table 2 Symptom resolution after the procedure

Symptoms	Preoperative presence of initial symptoms		Postoperative absence of initial symptoms		% of resolution	P
	n	%	n	%		
Pain	6	40.0	2	13.3	66.6	0.033
Vulvodynia	2	13.3	2	13.3	100.0	N/A
SUI	10	66.6	7	46.6	70.0	0.033
Nocturia	11	73.3	9	60.0	81.8	0.002
Prolapse	13	86.7	11	73.3	84.6	0.001

Reused with permissions from *Central European Journal of Urology* (4). N/A, not applicable; SUI, stress urinary incontinence.

important to note that one of the patients with symptoms of severe SUI requiring the use of large daily towels was entirely cured, suggesting, perhaps, that the “tension-free” tape approach as performed for SUI may be valid even for very severe symptomatic cases.

Discussion

Sections of this discussion are reproduced from the original paper (4), by permission from the *Central European Journal of Urology*. The 40 tape surgeries were performed by Piñango-Luna *et al.* (SP) in Venezuela using the artisan tape method (4). Given this *proviso*, that the surgeries were part of SP’s learning curve, the results are not so far inferior to more sophisticated and expensive tape methods (3). Because of the collapse of the economy and the health system in Venezuela, no more surgeries were able to be performed to fulfill the original target of a much larger series of patients.

This is a low-cost method which can create the new collagen essential for POP and incontinence in older women in poor countries, no more than EUR 3–4 per sling instead of up to EUR 1000 for a commercial kit. Furthermore, the anatomical and symptom cure results, albeit in small numbers, were not so far inferior to those of more sophisticated (and far more expensive) single incision kits (3).

It is unfortunate that after completion of operations on the 40 surgeries (15 patients) reported here, no further surgery was possible because of the collapse of the Venezuelan economy, the health system itself, and finally, the onset of coronavirus disease (COVID). Nevertheless, the 3-year data, albeit limited, indicates the artisan surgery, in expert hands, would most likely achieve satisfactory results.

How easily learnt is this method?

The data presented in fact constitutes SP’s (4) learning curve in its entirety. The view of the authors is that the artisan methodology is easily performed by any competent vaginal surgeon. It is a matter of locating CLs and USLs, plicating them and laying, without tension, an artisan tape across the anatomical position of the repaired ligaments.

Is a tape necessary?

The short answer for postmenopausal women is “yes”. The poor results of the Lancet PROSPECT Trial, 80% failure

at 12 months (1) after vaginal repair, can be explained by the very different strength of vaginal tissue *versus* the ligament tissues repaired by slings, artisan or otherwise. The breaking strain of the vagina is 60 mg/mm². and of ligaments, 300 mg/mm² (5). Ligaments weaken after the menopause (5), probably due to collagen break down after the menopause, as evidenced by the ongoing excretion as hydroxyproline during the duration of the menopause (6). In contrast, CL/USL slings create new collagen and achieve high anatomical and symptom cure rates, even 10 years after surgery (3).

The recent banning of all mesh kits (including tape sling kits) for prolapse surgery has seemingly deprived the American, European and other surgeons of any possibility to help older women with major symptoms and prolapse with ligament-based surgery. We believe that the “tension-free” tape can provide a safe, easily learnt, legal alternative to help the older group of women most in need of this methodology. The artisan tape method uses similar quality mesh to that of commercial slings (3), except that the tape was cut from a US FDA approved mesh sheet with scissors. Though the FDA ban is only on commercial kits, it has always been within the province of an individual surgeon to use any approved product for an individual condition (e.g., prolapse or incontinence), in an individual patient, for specific indications.

Ethics and safety

The surgical methodology for USL repair, is virtually identical with that of the MUS, literally a “reverse vaginal tape procedure (TVT)”. Absence of erosions or mesh complications was attributed to the mesh itself (3rd generation lightweight macroporous mesh), the very small amount of mesh implanted, (a 1 cm × 10 cm strip of tape), but, also, importantly, to the fact that no significant amount of mesh was inserted behind the vaginal membrane. All tapes were transversely placed, so the amount of mesh in contact with the vagina was minuscule.

Mesh sheets may cause major problems from shrinkage, pain from trapping of the nerve in contracting scar tissue from the mesh. The scar from the mesh greatly interferes with the vaginal elasticity necessary for normal bladder function. Such scarring may result in massive uncontrollable urine loss from the Tethered Vagina Syndrome (7). Such complications are rarely if ever seen with slings, as the mesh implanted by slings by comparison, small in area, has very little contact with the vagina, and so has minimal effect on

vaginal elasticity. The main problem with slings is erosions, usually minor, which occur in 1–5% of operations.

Worthy of comment were two patients with severe vulvodynia cured by CL/USL plication and tension-free tapes (4). In both cases, the pain was relieved by the speculum test reported by Wu *et al.* (8). They had only slight prolapse, hardly 1st degree. Though not definitive, relief of pain and urge by the speculum test (8) serves as confirmation of an important Integral Theory prediction: symptoms of bladder, bowel and pain dysfunction may occur with minimal prolapse.

Can an artisan tape replace the tapes from commercial kits?

The data from the Piñango-Luna *et al.* study for prolapse at 3 years is small (4). There seems no other data for artisan tape prolapse surgery. The only long-term artisan tape data available is from artisan SUI surgery (9). Uysal *et al.* (9) recently presented results from 93 women using an artisan transobturator tape (TOT). The cure rate was 91.3% at a mean of 5.7 years postoperatively. The only significant complication was a 4.3% erosion rate. By comparison, Uysal *et al.*'s data compares well with that of Nilsson *et al.* reported objective 90% SUI cure in 78% of 70 women, 17 years after MUS using the TVT commercial kit (10).

Collagen is the main structural component of ligaments (11). A tape, any tape, creates a neocollagenous ligament in exactly the same way (12): it harnesses the wound reaction in a positive way to create, first collagen 3, and in 6–12 weeks, collagen 1 (12). This method of collagen creation was central to the excellent 12-month results from posterior sling studies (13–16), the 10-year data from the Inoue *et al.* studies (16) and Uysal *et al.* study (9). In contrast, the Lancet PROSPECT Trial (1), reported only 20% cure for prolapse at 12 months postoperatively.

Conclusions

An artisan tape provides a strong, low-cost structural method for POP and SUI surgery, for any surgeon who wishes to provide an individual patient with a stronger surgical alternative to native vaginal repair with its catastrophically high failure rates (1). It may be the only option available in some countries where commercial slings are banned.

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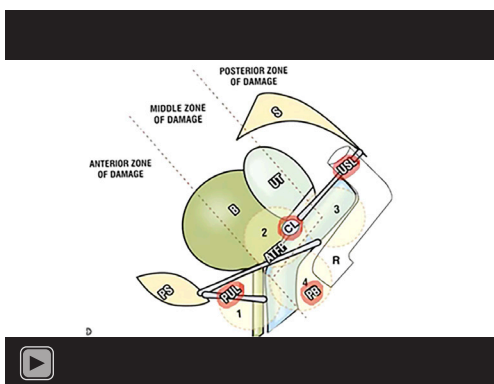
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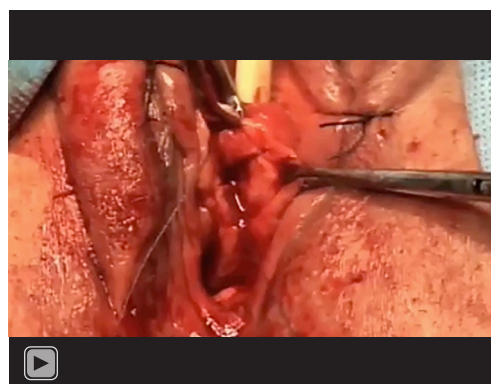
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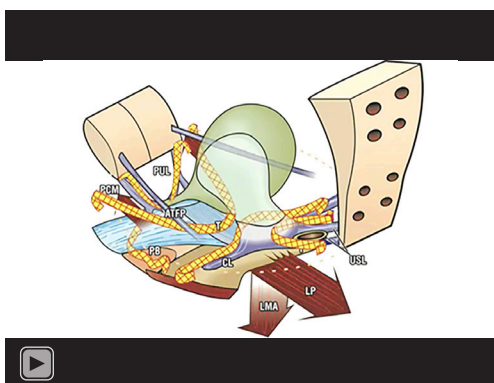
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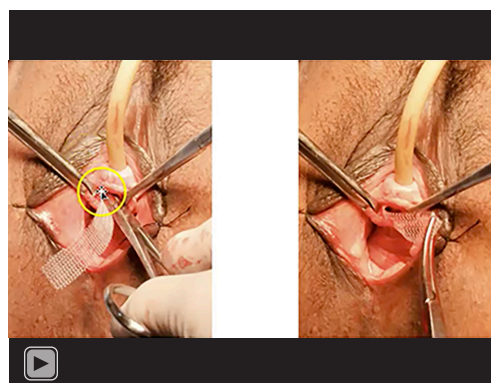
Video S1 Video abstract of structure, collagen, and pathogenesis surgery.



Video S3 Artisan tape surgical technique. Source: Piñango-Luna (4).



Video S2 Video abstract of artisan tape 12-month data.



Video S4 Repair of the suburethral vaginal hammock after midurethral tape placement. Source: Piñango-Luna (4).