

## Tension free vaginal tape underneath bladder base: does it prevent cystocele recurrence?

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### Abstract:

**Objective:** The target of the current prospective study was to assess the effectiveness of the polypropylene tapes in preventing recurrence of cystocele formation when placed underneath the bladder base.

**Materials and Methods:** Twenty-two Caucasian women, predominantly postmenopausal with marked descent of the anterior, middle and/or posterior pelvic segment, participated in the study. Vaginal reconstructive surgery including anterior colporrhaphy and Kelly placation, posterior colpoperineorrhaphy and/or hysterectomy, was undertaken in all subjects. The polypropylene tape was placed not under the midurethra, as often performed in stress urine incontinence (SUI) cases, but underneath the bladder base as an adjunct to the anterior colporrhaphy sutures. The postoperative follow up lasted 2 years and was carried out every 4 months. The assessment of the anatomic result included evaluation of the operated sites and the position of the tapes inserted on clinical grounds and after perineal sonography. Urodynamic assessment was performed in the presence of urinary incontinence.

**Results:** In all patients the postoperative correction of the anterior vaginal wall was sufficient, 14 subjects did not present genitourinary symptoms and therefore were considered as cured; three patients were designated as improved because despite sufficient anatomic correction of the anterior vaginal segment they reported urinary incontinence symptoms. Retro-pubic haematoma occurred in 1 patient, transient urge incontinence in 1, transient stress incontinence in 1, and persistent stress incontinence also in 1. There was no erosion of the tape noticed. Mean residual urine was 30 ml, mean bladder base distance to the inferior edge of the symphysis pubis was 1.2 cm and the mean total vaginal length was 7 cm.

**Conclusion:** Despite the relative short follow up period and the limited number of patients enrolled, we conclude from our study that the use of polypropylene tapes as an adjunct for fortification of the anterior pelvic segment could provide an option in preventing recurrence of cystocele formation. Hippokratia 2008; 12 (2): 108-112

**Key words:** cystocele, tension free vaginal tapes, urinary incontinence

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Vaginal reconstructive surgery for pelvic organ prolapse is one of the most challenging aspects of surgical gynecology and recurrence is particularly troublesome in the anterior vagina<sup>1,2</sup>. Anterior vaginal prolapse may re-occur after standard anterior colporrhaphy in up to 40% of patients<sup>2-5</sup>. This high rate of recurrence has led to the addition of synthetic materials such as absorbable or permanent synthetic mesh following the introduction of the tension free vaginal tape procedure for the correction of female urinary stress incontinence by Ulmsten et al in 1996<sup>6,7</sup>.

In keeping with the theory of Petros<sup>8</sup> and Delancy<sup>9,10</sup>, it became evident that, in order to hinder the anterior vaginal wall from descending, one should look for fixing points in the pelvic floor. The idea came up as the polypropylene tapes used for urethra support and the concept adhered to their technique could provide the tools for sufficient support for another "locus minoris resistentiae"; that is the anterior vaginal wall and the overlying bladder base. Therefore, it was set as a target of the current prospective study to assess the effectiveness of the polypropylene

tapes in preventing recurrence of cystocele formation when placed underneath the bladder base as an adjunct to the anterior colporrhaphy sutures.

### Materials and Methods

Twenty-two Caucasian women planning to undergo pelvic reconstructive surgery were invited to participate in this prospective study after giving informed consent. The ethics committee of our Institution approved the study. The inclusive criteria were the following: significant loss of support and descent of the anterior, middle and posterior pelvic segment, no prior surgery for incontinence or genitourinary prolapse and no coexistent pelvic pathology. All the women of this group had at least one of the following additional risk factors for recurrence: obesity, older age, chronic pulmonary disorder, chronic constipation, heavy domestic work (Table 1). Routine preoperative evaluation included detailed history, physical and laboratory evaluation, perineal sonography and urogynaecological assessment. Physical examination and perineal ultrasound were performed in both the lithotomy

**Table 1.** Demographic characteristics

<b>Age (mean – range)</b>	66.6 (50-77)
<b>Weight [kg] (mean – range)</b>	85.3 (72-108)
Parity (mean – range)	2.57 (2-4)
<b>Menopausal status</b>	
- Premenopausal	2
- Postmenopausal	20
<b>HRT (Hormonal Replacement Therapy)</b>	0
<b>Previous abdominal hysterectomy</b>	1
<b>Additional risk factors</b>	
- Chronic pulmonary disorder	7
- Heavy domestic work	9
- Chronic constipation	6

and the erect position at rest and under strain. All data were recorded and assessed by a senior consultant, the same one who performed the operations. The extend of uterine prolapse in accordance to Baden's halfway system<sup>11,12</sup>, was graded as follows: A score of 1 indicated descent of the relevant portion of the vaginal wall half way to the hymen; grade 2 descent indicated support loss that did not extend beyond the hymen, grade 3 prolapse existed when the prolapsing segment protruded beyond the hymen but was not completely everted and grade 4 prolapse was diagnosed when the segment was completely everted. Cystocele location was diagnosed by repositioning the anterior compartment by supporting both sulci. Supplementary, the measurements were also made by the Pelvic Organ Prolapse Quantification System (POPQ)<sup>13,14</sup> (Table 2).

All operations were performed under epidural anesthesia (Table 3). The patient was placed in the dorsal lithotomy position and a full thickness midline incision was made in the anterior vaginal wall from the vaginal

apex to the level of the urethrovesical angle. The vagina was dissected off the bladder as laterally as possible separating the vaginal epithelium from the underlying muscularis, so that the tape placement could be possible in full view. Transvaginal hysterectomy was performed with the standard manner in all cases with severe uterine prolapse. In accordance to the technique for vaginal apex support proposed by Shull et al<sup>15</sup>, the uterosacral ligament pedicles were sutured on each side. One arm of each suture was placed in the transverse position of the pubocervical and the rectovaginal fascia. The sutures were tied bringing the transverse portions of pubocervical and rectovaginal fascia together at the apex. The placement of TVT (Tension free vaginal tape) was performed under cystoscopic control or TOT (Transobturator tape) (both, Johnson & Johnson Ethicon Gyneacare, Somerville, NJ, USA) in standard manner. Then the sutures for anterior colporrhaphy were placed including Kelly stitches and as an additional reinforcement, the slope of the tape was placed not underneath the midurethra but more posteriorly underneath the bladder base and was fixed there in place. There was not any specific indication to our group of patients for choosing between TVT or TOT. In case of prolapse of the posterior vaginal segment posterior colporrhaphy was performed with or without placement of posterior IVS (infracoccygeal sacropexy tape) (Tyco, Healthcare, Mansfield, MA, USA), (Figure 1, 2).

In all cases antibiotics (coamoxyclav) were administered intra- and postoperatively for 24 hours and the bladder was catheterized for 72 hours, following surgery.

First postoperative visit was scheduled as early as 10 days after dismissal for guiding purposes; further follow up lasted two years and consisted of regular examinations every 3-4 months including laboratory, clinical and sonographic assessment via perineal sonography. The clinical evaluation was particularly focused on the operated sites of the anterior, middle and posterior vaginal compartment in order to exclude recurrence of protrusion or erosion of the tapes used. Perineal sonography was used as a means for evaluation of the outline of bladder base and urethro-

vesical junction as well as the position of the tapes, as already described by other authors<sup>16,17</sup>. Further on, the distance of the bladder base to the interior edge of the symphysis pubis was also measured. Additional notice was given to postoperative symptoms and quality of life of the patients in comparison with their preoperative condition by using a specific questionnaire<sup>18</sup>. Urodynamic assessment was performed in the subjects with urinary incontinence symptoms. The condition was defined as "cure" when patients showed postoperatively evidence of sufficiently restored anatomic interrelations of the pelvic floor particularly of the anterior vaginal wall and had no genitourinary symptoms.

**Table 2.** Measurements made by the Pelvic Organ Prolapse Quantification System – preoperative and postoperative evaluation

	<b>Aa</b>	<b>Ba</b>	<b>C</b>	<b>D</b>	<b>Ap</b>	<b>Bp</b>	<b>TVL</b>	<b>GH</b>	<b>PB</b>
<b>Postoperative</b>	-2.6	-2.6	-0.3	-5.3	-2.1	-2.1	5.5	3	3
<b>Evaluation</b>	(-2 to	(-2 to	(-3 to	(-5 to	(-3 to	(-3 to	(4 to	(2.5 to	(1.5 to
<b>(Mean values)</b>	-3)	-3)	0)	-6.5)	-1)	-1)	6.5)	3.5)	4)
<b>Preoperative</b>	+1.8	+3.4	-0.6	-2.3	-1.5	+0.6	6.5	3.2	2.8
<b>Evaluation</b>	(-2 to	(-1 to	(-4 to	(-5 to	(-3 to	(-3 to	(4.5 to	(2 to	(1.5 to
<b>(Mean values)</b>	+4.5)	+8)	+2)	0)	+2)	+4)	8)	4.5)	4)

Measurements were recorded as a simple line of numbers for points Aa, Ba, C, D, Ap, Bp, total vaginal length (TVL), genital hiatus (GH) and perineal body (PB) resp. All measurements were obtained in keeping with the Pelvic Organ Prolapse Quantification System for evaluation of pelvic organ support defects.

**Table 3.** Operative management

Pat. No	
1	TVT, anterior colporrhaphy, vaginal hysterectomy
2	TVT, anterior colporrhaphy, posterior IVS
3	TOT, anterior colporrhaphy, vaginal hysterectomy, posterior IVS
4	TOT, anterior colporrhaphy, vaginal hysterectomy
5	TVT, anterior colporrhaphy, vaginal hysterectomy
6	TVT, anterior colporrhaphy, posterior IVS vaginal hysterectomy
7	TOT, anterior colporrhaphy, vaginal hysterectomy
8	TVT, anterior colporrhaphy, vaginal hysterectomy
9	TVT, anterior colporrhaphy
10	TVT, anterior colporrhaphy, vaginal hysterectomy, posterior colporrhaphy
11	TOT, anterior colporrhaphy, vaginal hysterectomy, posterior colporrhaphy
12	TVT, anterior colporrhaphy, vaginal hysterectomy, posterior colporrhaphy
13	TVT, anterior colporrhaphy, vaginal hysterectomy, posterior colporrhaphy
14	TOT, anterior colporrhaphy, vaginal hysterectomy
15	TVT, anterior colporrhaphy, vaginal hysterectomy, posterior colporrhaphy
16	TOT, anterior colporrhaphy, vaginal hysterectomy, posterior colporrhaphy
17	TOT, anterior & posterior colporrhaphy
18	TOT, anterior colporrhaphy
19	TOT, anterior colporrhaphy, vaginal hysterectomy
20	TOT, anterior & posterior colporrhaphy
21	TVT, anterior colporrhaphy, vaginal hysterectomy, posterior colporrhaphy
22	TVT, anterior colporrhaphy

A condition was designated as “improved but not cured” when despite the sufficient anatomic correction, of the anterior vaginal segment the patients reported urinary symptoms.

### Results

There have been no intra- and postoperative complications recorded in all but one patient; on the day after TVT placement she had a large retropubic hematoma requiring blood transfusion. There has been no voiding difficulties and no erosion of tape. The anterior vaginal wall including the bladder base appeared in a distance to the inferior edge of symphysis pubis, as measured by perineal ultrasound, of 1.2 cm (1-2.2). The total vaginal length was 7 cm (6.2-8.4 cm). Upon dismissal from the clinic (mean stay 5 days postoperatively) all patients were given specific instructions. One patient presented transient stress incontinence, one transient urge incontinence and one persistent stress incontinence up to date. The postoperative evaluation showed that all patients were anatomically cured and that the anterior vaginal segment was satisfactory restored. There has been no recurrence of cystocele formation after two years follow up (Table 2). The incidence of stress urinary incontinence in two patients was considered to be associated with inappropriate placement of the Kelly stitches.

Patient No 2 had been operated on one year before presenting herself to our clinic. The uterus was removed on

gynecological grounds; upon admission she was found to have a large cystocele Grade III and a rectocele Grade II whereas the vaginal cuff was in good support. TVT placement was carried out along with anterior colporrhaphy as well as posterior colporrhaphy and IVS placement. She presented herself one month after the operation we performed with stress incontinence, therefore Duloxetine treatment was initiated for six months. Re-examination indicated that the patient was dry after a year's follow up; clinical and sonographic evaluation failed to reveal any recurrent descent of the vaginal walls.

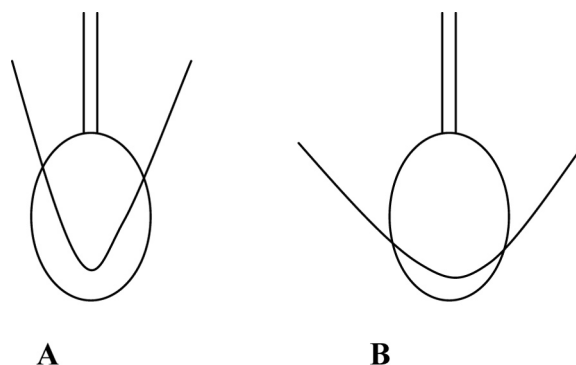
Patient No 5 appeared two months after the operation with urge incontinence; vaginal hysterectomy, TOT placement and anterior colporrhaphy had been carried out. Treatment with anticholinergic drugs was prescribed for five months.

Patient No 6 presented in the first place with severe cysto- and rectocele, thus only TVT placement, anterior colporrhaphy and posterior colporrhaphy with concomitant IVS placement were performed. Apart from failing to attend in the follow up clinic, she took no care of avoiding lifting heavy weights. Presently she appeared with a loss of middle segment support but with no significant damage to the anterior and posterior compartments. A vaginal hysterectomy was performed whereas the TVT and IVS tapes were left in place; upon a follow up, sixteen months after the hysterectomy, the patient was considered as cured.

Finally, patient No 17 presented five months after surgery with stress incontinence. Duloxetine treatment was initiated; she is on that medication until now, claiming that the symptoms have improved.

### Discussion

Genital prolapse is a common problem with an especially high prevalence among parous women. Olsen et



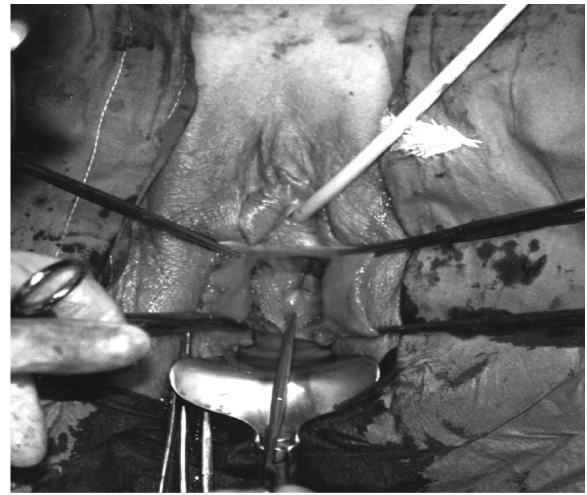
**Figure 1.** Diagrammatic representation of the course of the tape placed underneath the bladder base. A: placement of TVT, B: placement of TOT.

al found a correlated risk of 11.1% following anti-incontinence and / or genital prolapse surgery by the age 80 years. In 29% of these cases the problem was a recurrence<sup>1,19</sup>. From these data it becomes clear that genital prolapse is a frequent problem, particularly in the aging population, and the prolapse of the anterior wall is the most common. When prolapse is treated surgically, the specific defects in support must be carefully addressed to ensure an optimal outcome. Anterior colporrhaphy corrects anterior vaginal wall prolapse by plicating paravaginal tissue in order to reduce the protrusion of the bladder and anterior vaginal wall. As there are no transverse ligaments in the middle, the pubocervical fascia is the main supporting structure. This is generally considered as the most difficult part of the vaginal repair because it has an inherent tendency to prolapse due to intra-abdominal pressure from above in combination with the gravity. Dissection in anterior colporrhaphy involves a variable splitting of the muscular layer of the vagina, with some smooth muscle remaining in the mucosal layer and some overlying the bladder. The smooth muscle of the vagina over the bladder along with the adventitial layer gives the appearance of a fascia, hence its name: paravesical or pubocervical fascia. When this layer is plicated, the cystocele is reduced; however normal support of the vagina and bladder has not been restored. The components of the vagina that are plicated respond dynamically (smooth muscle, collagen, elastin) to the forces placed on them. Subjected to the same forces that resulted in prolapse in the first place, those tissues may stretch or break again in time and prolapse will recur<sup>3,20</sup>.

Failure rates for operative repair of a cystocele may range from 20% to 30%, even when experienced surgeons, such as Shull and Sze, carefully consider these defects. Shull et al found 24% of recurrent cystocele after vaginal and paravaginal repair along with concurrent vaginal reconstructive surgery in 62 women<sup>15</sup>. Sze et al reported 24% recurrence for anterior vaginal wall prolapse<sup>21</sup>.

Numerous surgeons have introduced different techniques aiming to improve the outcome of anterior vaginal wall prolapse. Particularly, the surgical techniques developed by the integral theory focus on reinforcing damaged ligaments and fascia with polypropylene tapes<sup>8,15</sup>. In search for additional tools providing support to the damaged structures, particularly of the anterior compartment, it was appealing to use the polypropylene tapes adjusted in a way to meet the needs for preventing cystocele recurrence.

Our study had set as a goal to assess the use of such tapes as TVT or TOT not for bladder neck support as originally described<sup>7,22</sup> but to provide additional support to the bladder base after placement of the anterior colporrhaphy sutures in an effort to prevent cystocele recurrence. The tape was therefore placed higher, that is underneath the bladder base, towards the vaginal apex. There, it is meant, to additionally reinforce the vaginal mucosa plicating sutures. The study group included patients with mean age of 66.6 years, mean weight of 85.3 kg and



**Figure 2.** Adjustment and fixation of the tape underneath the bladder base.

mean parity of 2.57. As previously mentioned, additional risk factors such as obesity or heavy domestic work were also taken into account. Regarding the clinical condition, the mean preoperative POPQ rating was increased. As a whole, the study group consisted of individuals at risk for recurrence, especially of the anterior vaginal wall. The postoperative follow up was 2 years. In all subjects the bladder base was clinically and sonographically elevated to a satisfactory degree and no recurrence of a cystocele was noticed. Additionally, there was no evidence of erosion of the tape and no dyspareunia noted in all patients. Residual urine was minimal in all subjects and transient urinary symptoms such as stress or urge incontinence occurred each in two different patients treated medically. One patient is still on medication with Duloxetine for persistent stress incontinence.

The technique described was thought to act as reinforcement to the anterior colporrhaphy sutures. That technique was before newer techniques involving meshes like eg. Prolift (Gynecare, Johnson & Johnson) were introduced for holding the anterior vaginal wall in place<sup>23-26</sup>. Therefore, the technique of our study could be considered as an additional tool or operative option to these meshes<sup>27,28</sup>. Indeed there are some limitations to our study since it is a small cohort study with a relatively short follow up assessment. Even though, it is obvious according to our findings that, during pelvic floor repair the polypropylene tapes could be used as an additional reinforcement of the anterior vaginal segment complementary to the anterior colporrhaphy in order to prevent cystocele recurrence. This technique as described could be a reliable solution for young patients less than 50 years old, since prolift-meshes have a higher risk in causing dyspareunia in this age group.

## Conclusions

The use of polypropylene tapes used for stress urinary incontinence in women could be expanded in such



a manner as described in our study: it becomes apparent that this technique could serve as an additional reinforcement to the anterior colporrhaphy, preventing the anterior vaginal wall from recurrent prolapse. Therefore, it could be considered as a further option besides the newly introduced techniques using meshes with arms for holding the anterior vaginal wall in place.

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