

1-4) continence procedures. The numbers of the women who had one, two or three injections are outlined in table 1.

Table 1: Numbers of women injected

Type	Injection 1 (n)	Injection 2 (n)	Injection 3 (n)
Gax collagen	26	7	1
Macroplastique	34	12	3

Table 2: Objective outcomes of injectables

	Cured n (%)	Improved n (%)	Fail n (%)
Gax collagen (injection 1)	3 (11)	7 (27)	16 (62)
Macroplastique (injection 1)	6 (18)	6 (18)	22 (64)
Gax collagen (injection 2)	0 (0)	4 (57)	3 (43)
Macroplastique (injection 2)	2 (16)	5 (42)	5 (42)
Gax collagen (injection 3)	0 (0)	1 (33)	2 (67)
Macroplastique (injection 3)	1 (100)	0 (0)	0 (0)

Subjective analysis of QoL showed no significant difference between the two groups either pre or post treatment. QoL did improve significantly in all women following treatment ($p < 0.05$). The only difference between the two groups was the Gax collagen group had a significantly larger urinary loss on pre treatment pad weight test. There was no significant objective difference between the two groups comparing the pad weight loss post treatment at one, six and 12 months (table 3).

Table 3: Median Pad Test loss (ml) for both groups (Inter Quartile Range)

	Pretreatment	1 months	6 months	12 months
Gax collagen	55.2 (18.0 - 80.2) n=26	3.8 (0.6 - 38.2) n=24	9.0 (0.9 - 51.0) n=13	8.4 (1.6 - 34.0) n=10
Macroplastique	22.0 (7.9 - 52.3) n=34	3.7 (0.5 - 24.6) n=34	9.8 (0.4 - 70.7) n=29	0.7 (0.275-6.025) n=10

On the first injection, the mean volume of Macroplastique injected was 5.1mls and 9.2mls in the Gax collagen group which was significant ($p < 0.001$).

Conclusion: This prospective randomised study does not show any difference in objective efficacy between GAX collagen and Macroplastique. The injected volume of Macroplastique was significantly lower than the volume of GAX collagen used. The initial pad test loss did not predict outcome.

Financial interests: The injectable substances were provided by the companies.

45

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Tissue replacement by tension-free insertion of prolene tape (TVT technique according to Ulmsten) in urinary incontinence (UI): technical details, indications, specifications, results

Aims of study

Stress incontinence in women is frequently caused by a constitutional or age-dependent slackening of connective tissue. Surgical methods using body tissue for reconstruction are therefore doomed to failure in the

long run. The results of tissue replacement using synthetic implants have so far likewise been unsatisfactory due to tissue intolerance or persisting postoperative urge symptoms. The TVT (tension-free vaginal tape) technique uses a novel (prolene) synthetic tape which, in contrast to conventional sling procedures, can be inserted in a tension-free manner under the middle segment of the urethra by means of a minimally invasive intervention. (1)

What are the results of this new surgical technique and is it possible to objectify the changed surgical intentions by urodynamic testing and ultrasound? What are the indications for TVT insertion that can be derived from these results?

Methods

134 women (mean 54, SD ± 11 years) were operated on after clinical and urodynamic clarification of urinary incontinence and sonographic assessment of the mobility of the bladder neck (45.5 % stress UI, 45.5 mixed UI; 9 % masked UI, 13.4 % grade I [masked UI included], 71.6 % grade II, and 15 % grade III UI). Retropubic and paraurethral local anesthesia, tension-free suburethral insertion of the vaginal tape through the urogenital diaphragm, between levator muscle and arcus tendineus fasciae pelvis, retropubic space, abdominal wall. Monitoring by cystoscopy with indwelling needles. Cough test with full bladder.

TVT insertion was performed under local anesthesia (n = 91, 67.9%) and under general anesthesia as an additional procedure in combined UI and prolapse surgery (n = 43, 32.1%), among them 12 cases of masked UI.

Results

The results of postoperative follow-up after 6 months, 1 and 2 years are given in the table. Postoperative examinations yielded the following results: unchanged urethral closure pressure at rest (pre-op 39 ± 24 , post-op 39 ± 22 cm H₂O); stabilization of the continence zone in the area of the middle urethral segment; no funneling (preoperative: n = 58);

significant reduction of the inclination angle during pressing (pre-op 70 ± 21 , post-op 8 ± 5 degree), unchanged vesicourethral angle (pre-op 117 ± 35 , post-op 122 ± 33 degree), lowering of the vesicourethral orifice during pressing lowered from a mean of 17 to 6 mm. Spontaneous micturition without residual urine on the day of surgery in 74.6%, on the first postoperative day in 19.4%, and on the 5th postoperative day in 6% (transurethral drainage of urine after bladder perforation). Seven women (7.4%) complained of postoperative dysuria, none reported dyspareunia. Complications comprised 8 bladder perforations (6%), 1 retromyophyseal hematoma (0.7%), 2 obturator nerve irritations (1.5%), and 1 pelvic vein thrombosis (0.7%).

Outcome after	6 months (n=94)	1 year (n=51)	2 years (n=15)
Cure	81 (86.2%)	44 (86.2%)	13 (86.6%)
Stress incontinence	35	21	6
Mixed incontinence	34	23	7
Masked UI	12	0	0
Improvement	11 (11.8%)	6 (11.8%)	2 (13.4%)
Stress incontinence	3	1	0
Mixed incontinence	8	5	2
Failure	2 (2.0%)	1 (2.0%)	0
Stress incontinence	0	0	0
Mixed incontinence	2	1	0

Conclusions

TVT insertion is a promising alternative to other UI interventions, especially as a primary procedure in pure stress UI, but also in mixed UI, or when used for recurrence or as an additional procedure. The surgical intentions were confirmed by urometry and ultrasound. Indications for the TVT technique are a slack anterior vaginal wall, a hypermobile urethra, funneling of the upper urethra, and a low urethral closure pressure.

Comment: Postoperative follow-up demonstrates that cure rates remain stable, suggesting that similar late results can be expected but these remain to be confirmed.

References

- 1) Scand J Urol Nephrol 1995;29:75-82