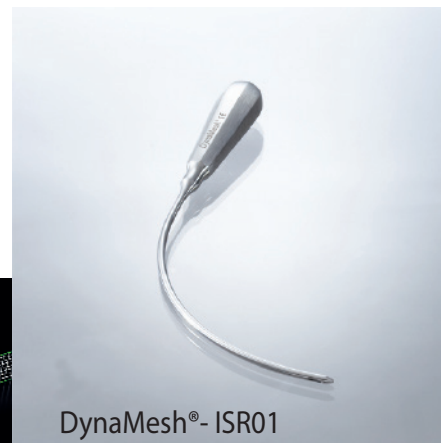
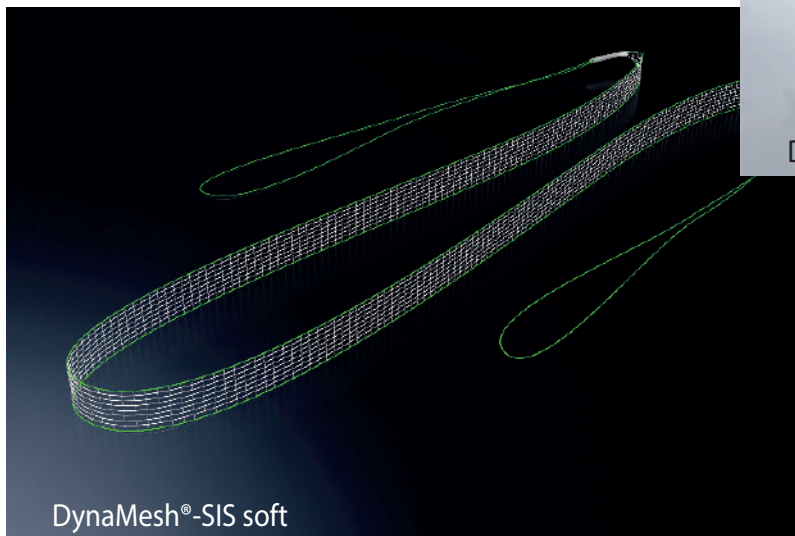


Dr. Stefan Bettin

**Surgical treatment of stress urinary incontinence
arising from a hypermobile urethra and urethral
funnelling when pressing**





DynaMesh®-SIS soft+DynaMesh®-ISR01 - OR video:
Surgical Treatment of Stress UI - TVT Technique (en)
<https://de.dyna-mesh.com/Vi105en01>



Introduction

For the past 25 years, periurethral closure insufficiency in women has been successfully treated through suburethral, tension-free tape insertion (retropubic, TVT technique). TVT-plasty is also used here and with correct implantation has shown very good results to date.

With the proper indication, correct execution and compliance with local oestrogen treatment, the healing and improvement rates are more than 90%. Urinary incontinence is caused by weaknesses in the connective tissue, which manifest in different degrees of intensity in the pubourethral ligaments, the lateral connections of the anterior vaginal wall to the anterior levator ani muscle, and in the urethrovaginal septum.

A number of surgical urinary incontinence and prolapse procedures only improve the after-effects, the funnelling of the bladder neck or the cell formation in the urogenital organs. In these cases, the condition of the tissue is not improved in a sustained manner.

By using a long-lasting tissue reinforcement (artificial ligament replacement) in the form of a DynaMesh®-SIS soft implant made of polyvinyl fluoride (PVDF), the closure insufficiency can be corrected and the stress incontinence can thus be remedied.

With a correct diagnosis and execution, the rate of complications is extremely low.



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Indication

In our own patient population, we use this procedure on patients between 24 and 100 years of age. Nevertheless it is vital, as with all surgical interventions, to have first applied and exhausted all options for conservative treatment prior to the operation. This especially applies to women younger than 40 years of age.

Among patients older than 70 years, our so-called risk population (10-year results with TVT, Falconer et al.) with hypotonic urethra and vertical urethral descent, an alternative, conservative and surgical therapy must be offered.

The Ulmsten technique, in which the mesh tape for the TVT technique is placed below the midurethra, has proven itself to be completely appropriate. The so-called PSR zone (pain-stretch-receptor zone) at the urethrovesical junction is deliberately avoided in order to prevent later miction problems or a renewed urge component.

With the suburethral tape insertion at the height of the midurethra, the urethra is stabilised and stretched, the funnelling is rectified, and the urethral pressure is improved. As already published in the "Gynäkologische Praxis" journal (2nd quarter 2000/volume 24/issue 2/pages305-320/Hans Marseille Verlag GmbH Munich), correct tape insertion allows for preservation of mobility of the urethra. This is easy to confirm nowadays postoperatively, by localising the tape suburethrally and pressing to observe that the mobility of the urethra is preserved (also called a "swing effect", see below).

We avoid using the term "sling operation" as the tension-free tape insertion circumvents any kind of urethral suspension or tape fixation. It can certainly be made very clear to patients that the tape insertion leads to stabilisation of the poor connective tissue structure that already exists.

Patient selection

1. Conservative therapy conducted and exhausted.
 2. Local peri- and post-menopausal oestrogen treatment.
 3. Age-independent, with observance of the critical ages younger than 40 and older than 70 years.
 4. Caution with vertical urethral descent.
 5. Exclusion of urogenital prolapse.
- Adherence to the "Urinary incontinence operation checklist".
 - Written documentation that a suburethral tape insertion will be performed using a tissue replacement made of PVDF (polyvinyl fluoride), in order to treat the periurethral closure insufficiency.

Diagnostics

- Medical history
- Questionnaire
- Introitus/perineal sonography
- Urodynamics

At the slightest indication of an existing urgency component, a urogenital prolapse must be ruled out, a motor/sensory urgency must be verified urodynamically and the absence of post-void residual urine must be documented.

In the event of recurrent urinary incontinence, the use of flowmetry will be imperative. The introitus or perineal/introitus sonography allows for determination of the position of the bladder neck in relation to the bottom edge of the symphysis and is performed dynamically, at rest, while pinching and while pressing. This procedure allows for documentation of the patient's ability to control the pelvic floor muscles. The funnelling of the urethra can also be captured sonographically, as the expression of a pronounced loosening of the ventral fixation of the urethra.

Sonography is used for postoperative control of the tape position, the preserved mobility of the urethra and also the absence of post-void residual urine.

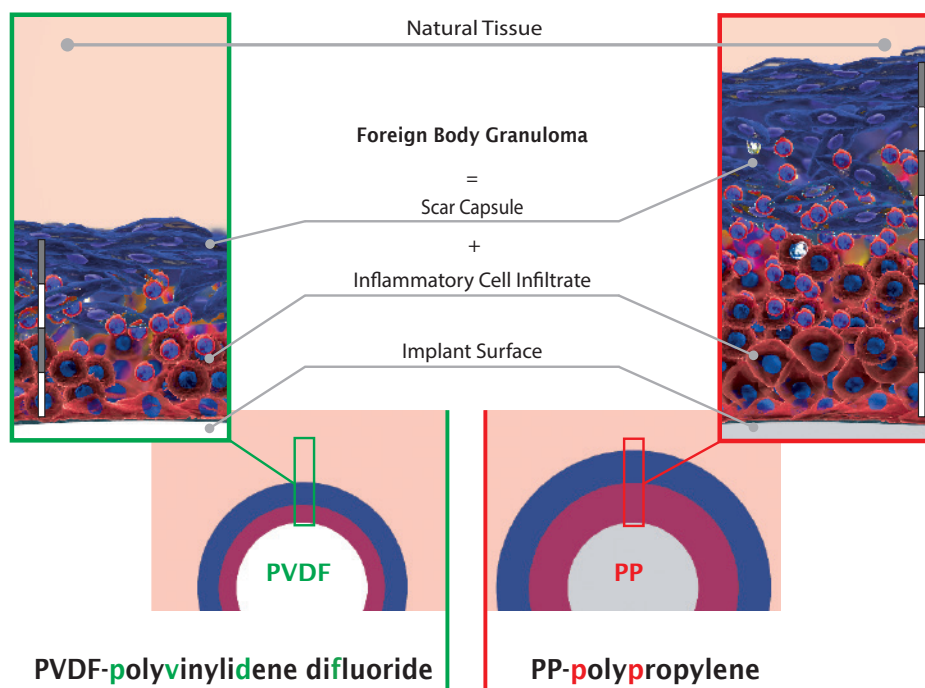
Choice of implant

The quality of the implant in terms of material, dimensional stability, and resistance to ageing has a great influence on the results of surgical treatment of stress incontinence.

Implants made of polyvinyl fluoride (PVDF) exhibit good biocompatibility (assessed according to ISO 10993) and show significantly lower granuloma formation (scar tissue).

Cross-Sectional View

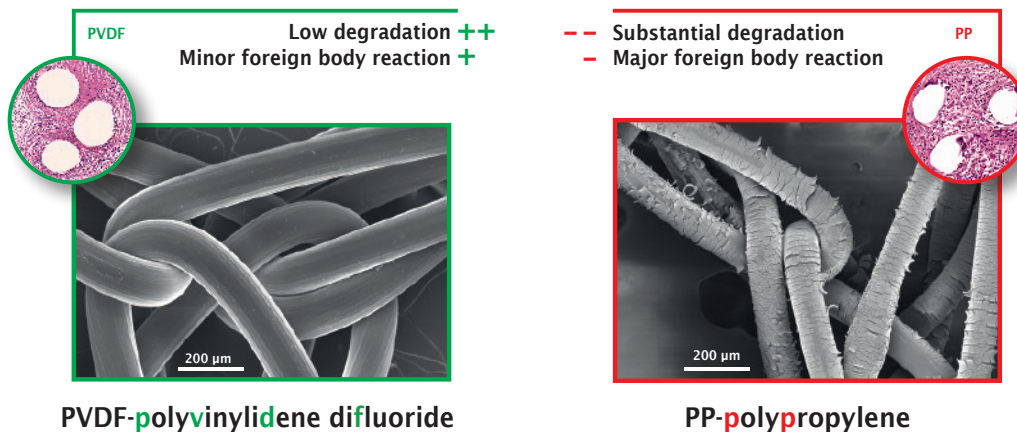
A comparison of different granuloma thicknesses



Therefore, the risk of undesirable foreign body reactions is minimised. PVDF has been used as a surgical suture material for many decades with great success, even in the most demanding areas of application such as ophthalmology and cardiology.

Long-term data with observation periods of up to seven years show:

The condition of the PVDF surface remains unchanged, filaments remain stable, nothing becomes brittle.



Surgical steps

1. Disinfection of the skin, disinfection of the vagina.



2. Placement of the catheter 18 ch.

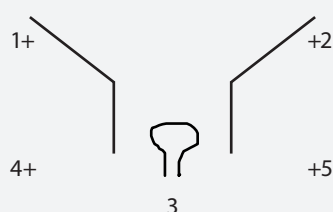


3. Infiltration anaesthesia 140 ml (100 ml Ropivacain 200 mg - topped with 40 ml saline solution) and analgosedation (retrosymphyseal, in the space of Retzius, pushing the urinary bladder away from the symphysis).



Anaesthesia for TVT-plasty

- Pre-medication:** 40-60 minutes before surgery, 1 tab. Dormicum
- Sedation:** Bolus - 0.1 mg Fentanyl shortly after positioning, Propofol (Disoprivan) - continuously 2-3(4) mg/kg body weight or Alfentanil 0.5 - 1 mg
- Local anaesthesia:** Ropivacain 2 mg (100 ml) + NaCl 0.9% (40 ml)
= Total volume of 140 ml
- Form of application:**



- 1 and 2: 5 ml intracutaneous
10 ml subcut.+intrafasc.
20 ml retrosymphyseal
- 3: 10 ml suburethral
- 4 and 5: 20 ml paraurethral

Source – Höxter: Bahlmann L., Bettin S.

4. No prolapse, visualisation of the urethra and palpation of the balloon catheter to allow for measurement of the length of the urethra.



5. Paraurethral infiltration anaesthesia 10 ml left, 10 ml right below the vaginal mucosa.



6. Incision of the anterior vaginal wall below the midurethra (approx. 1 cm = implant width).



7. Mobilisation of the vaginal mucosa with the scissors up to scissor closure, in the direction of the bottom edge of the symphysis.



8. Bilateral tunnelling conforming to the puncture canal on paraurethral right and left.



9. Suprasymphysary marking/incision of the exit location with the scalpel, 1 cm above the symphysis, 2 cm lateral on both sides of the midline.



10. Application of implant slings to DynaMesh®-ISR01 instrument.



11. Swinging instrument hold in front of the vagina, use of the needle curvature/parabola and guidance of the needle in constant contact with the posterior wall of the symphysis, please note - periosteal inflammation.



12. Guidance of the needle tip in the direction of the surgeon's "nose tip".



13. Following needle exit, loosening of the green implant sling from the DynaMesh®-ISR01 instrument.



14. Filling of the bladder, 2 x 100 ml (warm saline solution) and removal of the bladder catheter.



15. Cystoscopy - angled 70° visual control of whether the urinary bladder is perforated, the instrument or sutures have been placed in the urinary bladder. Visualisation of the ureteral ostia bilaterally and documentation of the condition of the bladder mucosa.



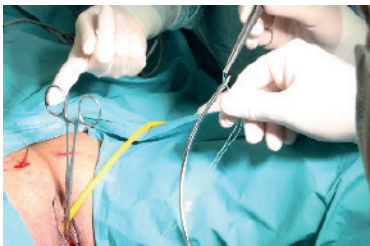
16. Following a successful cystoscopy, the DynaMesh®-ISR01 instrument is pulled back and removed. With the help of the implant sling, the implant is held and pulled up in a retrosymphiseal direction.



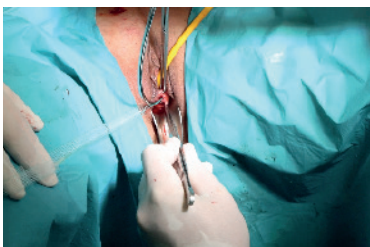
17. Bladder voiding once again; for assistance purposes the catheter is moved away from the urethra, placed toward the left.



18. Application of implant slings to DynaMesh®-ISR01 instrument.



19. Tape insertion of DynaMesh®-SIS soft on left side, introduce needle, hold implant slings under tension.



20. Swinging instrument hold in front of the vagina, use of the needle curvature/parabola and guidance of the needle in constant contact with the posterior wall of the symphysis, please note - periosteal inflammation.



21. Guidance of the needle tip in the direction of the surgeon's "nose tip".



22. Following needle exit, loosening of the green implant sling from the DynaMesh®-ISR01 instrument.



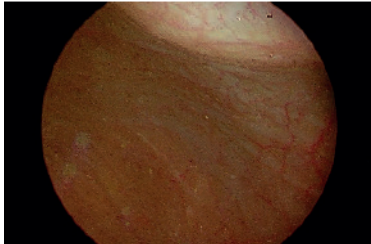
23. Filling of the bladder anew, 300 ml (warm saline solution), removal of the catheter.



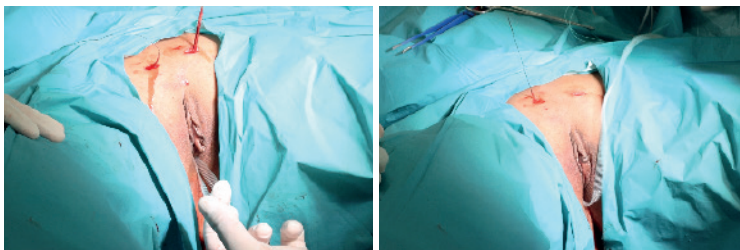
24. Repeated cystoscopy. Check that the bladder was not injured during tape insertion, i.e. that the tape was not pulled through the bladder.

Visualisation of the ureteral ostia bilaterally and documentation of the condition of the bladder mucosa.

Ruling out of pleated fold formation on the bladder mucosa. In the event of irritation of the urinary bladder muscularis, withdrawal of the application instrument and new placement.



25. Hoisting of the implant with uniform control, so that the implant lies flatly/evenly below the urethra and the tip of the tweezers fits between the tape and urethra. Important when doing so: "no twisting" - the tape must lie flatly, it may not twist.



26. Turning of the tip of the tweezers! This ensures a correct distance between the implant and urethra - "Höxter sling" / "tension-free".



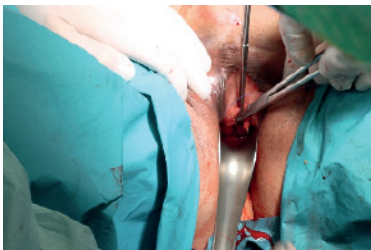
27. Conducting a cough test, asking the patient to cough three times. The tape (textile implant structure) makes contact with the surrounding tissue.



28. Pull the vaginal mucosa over the implant using two tweezers.



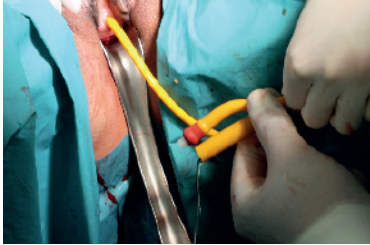
29. Closure of the vaginal mucosa with a simple interrupted suture (absorbable suture material (Vicryl) 3/0).



30. Cutting off the implant ends as deeply as possible at the exit locations, then intracutaneous suture with absorbable suture material 4/0.



31. Emptying of bladder and withdrawal of the catheter.



32. Encoding of tissue replacement PVDF 5-932.41 and handing out of implant passport to the patient.



Features and notes

- In the event of a bladder injury (usually at the bladder apex), the bladder is emptied and the instrument is removed vaginally. Repeated retrosymphyseal application of the instrument, guide it upwards more steeply and a little more laterally. Next, place an indwelling catheter for 24-72 hours.
- In the case of patients who have undergone previous irradiation and those who have a very short vagina, perform a transobturator tape placement (TOT), if needed.
- Performance of a cystoscopy after application of the implant, two times as described in the surgical steps. If the cystoscopy reveals a fold formation in the bladder muscles without injury to the serosa, the tape position must be corrected. Otherwise there is a risk of tape migration into the urinary bladder.
- We consider the critically discussed cough test to be a subjective safety in order to avoid an overcorrection and to optimise the position of the implant when pressing. An adjustment is only required in rare cases. It is important here to ensure that the implant is placed as loosely as possible and at the height of the midurethra.
- If a masked urinary incontinence should arise after performance of a prolapse operation, we can correct this by performing a tape insertion (implantation of DynaMesh®-SIS soft) under local anaesthesia and analgosedation, after three weeks.

- In the event of heavy intraoperative haemorrhaging, the intervention is quickly brought to a close. If needed, compression of the posterior wall of the symphysis with two fingers and tensioning of the heavily blocked transurethral catheter (10 ml) for a few minutes.
- If there is a postoperative haematoma, no execution of a retropubic revision. Revision of the implant only if there is chronic periostitis.
- In very rare cases of an overcorrection (postoperative post-void residual urine consistently over 100 ml) and ruling out of a periurethral haematoma, we sever the implant tape next to the urethra at 3 or 9 o'clock on the third day post-surgery ("hockey stick" effect).

Queries from colleagues and patients

How long has this treatment method existed?

- The first applications took place in 1996 and were published in an approval study.

What do you recommend for voiding dysfunction?

- In the case of persistent voiding dysfunction, we recommend severing the tape. With residual urine > 100 ml, severing of the tape starting on the third day post-surgery. The cut should not be suburethral, but rather at three or nine o'clock, to obtain a "hockey stick" effect.

How often does a re-TVT take place?

- In 25 years of application < 10 cases.

What do you think of "adjustable tapes"?

- This technique contradicts the tenet of the "tension-free" principle.

Why do you have low implant migration and penetration rates?

- It is important to consider that the tissue replacement is non-absorbable, the longest application took place 25 years ago, and local, lifelong oestrogen treatment must be conducted in order to preserve the elasticity of the vagina postoperatively/post-menopausally.

How do I inform my treating physicians later on about this intervention?

- The patient receives an implantation passport which contains relevant information on the implant and on the treatment.

Do you recommend oestrogen treatment?

- Without local oestrogen treatment, the mesh migration and penetration rate is significantly higher.

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