Pubovaginal bone anchor fixation with polyethylene versus fascia lata slings in the treatment of female stress incontinence: sling material and processing are predominant factors in success

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SCHULTE-BAUKLOH H, THALAU F, STURZEBECHER B, KNISPEL HH. Pubovaginal bone anchor fixation with polyethylene versus fascia lata slings in the treatment of female stress incontinence: sling material and processing are predominant factors in success . The Canadian Journal of Urology. 2005;12(2):2581-2587.

Objective: *The opponents of the In-Tac™ bone anchor system note the risk of a high rate of wound infection and osteitis pubis. We evaluated whether there is a difference in the outcome of the use of two different sling materials – polyethylene and fascia lata – with regard to wound infection, and analyzed the incidence of osteitis pubis further in a larger series.*

Material and methods: *A total of 61 women (mean age = 65.4 years) were treated for stress urinary incontinence (SUI) type II and III using the In-Tac™ bone anchor system. In 15 of 61 patients, we used a synthetic sling of polyethylene, and in 46, a fascia lata sling. The subjective success rate was determined with validated questionnaires (Urinary Distress Inventory-6, Symptom Severity Index and Symptom Impact Index). The objective assessment included a pad test according to the ICS- standard and a urogynecologic evaluation. Mean follow-up was 10.2 months.*

Results: *Wound inflammation of only very mild degree occurred in 15% in the fascia lata group, whereas 33% in the polyethylene group developed serious sling infection; in three patients explantation of the sling was necessary. Accordingly, satisfaction with the procedure was low in the polyethylene group. In both groups, there were no hints of osteitis pubis. The sling material used did not affect continence rate.*

Conclusion: *Using the bone anchor system, the infection rate depends primarily on the sling material used and its processing: polyethylene is well tolerated in other reconstructive procedures (such as TVT, where a netlike mesh is used), so the processing of synthetic sling material plays an extremely important role in infection rate: platelike, dense synthetic material tends to cause wound infection.*

Key Words: bone anchor, fascia lata, In-Tac™, polyethylene, stress incontinence

Introduction

The goals of numerous modifications of the vaginal approach to treating female stress urinary incontinence (SUI) type II and III have been to minimize morbidity, optimize outcome, and provide greater technical ease.[1,2] The In-Tac™ bone anchor system is minimally invasive. Opponents of the procedure claim that it has a high infection rate[3] and causes complications related to the bone anchors (anchor displacement and osteitis pubis).[4,5] To investigate the influence of sling material on infection rate, we used two types of sling material - synthetic and allogenic - and evaluated the outcome with regard to osteitis pubis further in a larger series.

Accepted for publication February 2005

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Patients and methods

From December 1998 to April 2001 our department treated 69 women (average age, 65.4 years; range, 35-81 years; median, 68 years) for SUI with the In-Tac™ bone anchor system (Influence Medical Technologies™). Of the 69, 61 could be analyzed retrospectively. The diagnosis of SUI was based on history, including urination diary; a general physical and urogynecologic examination; a pad test according to the International Continence Society (ICS) standard; midstream urine (MSU) samples; ultrasonography of the bladder to determine postvoiding residual volume (PRV); cystoscopy; and a urodynamic evaluation according to ICS standards to exclude detrusor instability. We used MMS® devices (Type Libra+, Medical Measurement Systems, Holland) with a 5 Fr intravesical microtip catheter (Rehau® UROBAR-ELS5, Germany) and a 10 Fr rectal balloon two-way catheter (Porgès® France). Bladder filling rate (normal saline solution at 32°C) was 40 mL/min. Patients with unstable detrusor muscles were excluded from the study.

Operative procedure

Prophylactically, patients were given low doses of heparin for 5 days. Perioperatively they received prophylactic antibiotics of the cephalosporin group at the beginning of the operation and for 5 days afterward. The bone-anchor system has generally been described in detail[6-13] before and will be described here only partly Figure 1: The operation is done under general or regional anesthesia. Patients are placed in the lithotomy position. A 16 Fr Foley catheter is inserted and blocked with 10 mL of aqua destillata. After filling of the bladder with 400 mL of normal saline, a 12 Fr suprapubic cystostomy is placed. A weight speculum of 500 g is inserted into the vagina to allow good visibility of the operating field. A suburethral transverse colpotomy, about 3 cm long, is made, and the paraurethral and suburethral tissue is mobilized carefully for later placement of the sling. Further retropubic preparation with penetration of the endopelvic fascia on both sides - partly with an instrument, partly with a finger – enables insertion of the bone anchor from the back of the pubic bone.

Bone anchor system

The In-Tac™ System (Influence Medical Technologies™) uses a spring-loaded metal inserter for multiple use with prethreaded bone anchors consisting of nickel - titanium alloy (Nitinol™). The bone anchor, 9 mm long, is conical and has a sharp tip

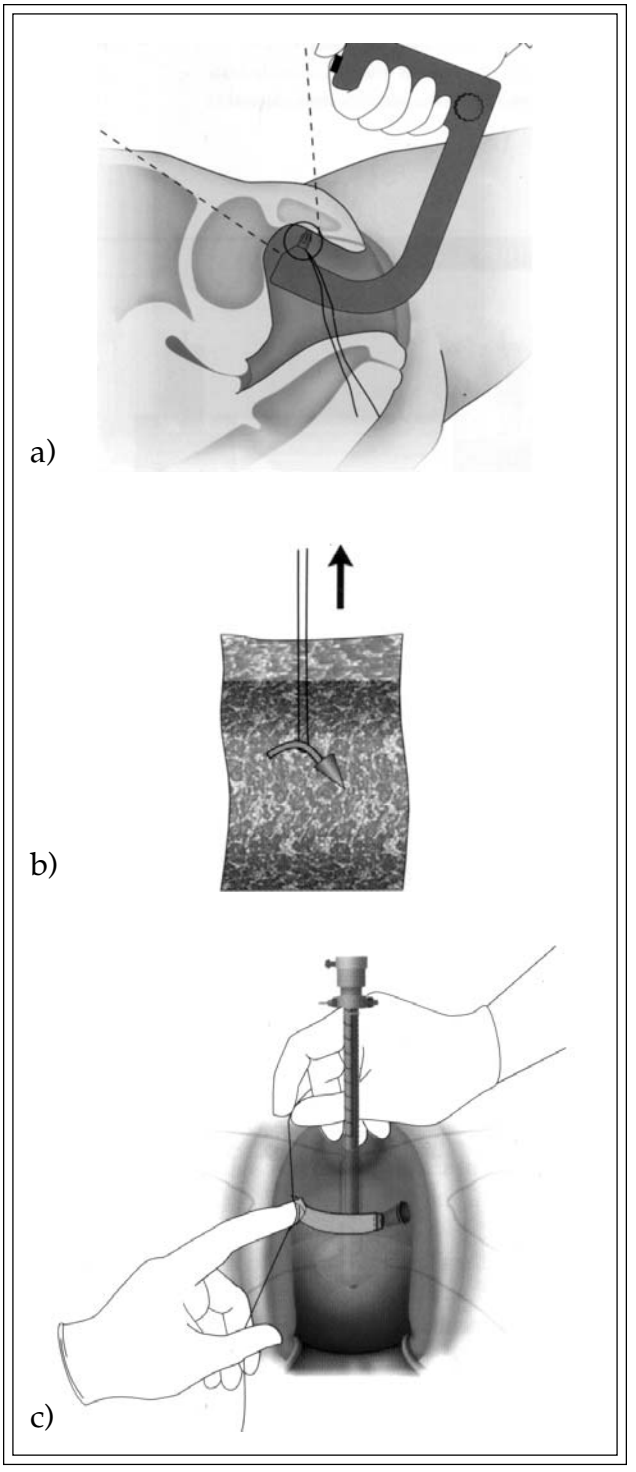

Figure 1 a-c. The In-Tac™ bone anchor system: spring-loaded metal inserter is positioned against posterior surface of pubic bone (a). Bone anchor, armed with polypropylene sutures No.1, is shot straight through bone cortex into medulla (b). Sling is fixed suburethrally on threads, resulting in tensionfree suspension of urethra (c).

that enables penetration into the posterior side of the pubic bone. With the fingers palpating the bladder neck and the transurethral catheter - the urethra is kept medial by the finger and must keep a safe distance - the metal inserter is positioned through the transverse colpotomy a finger's breadth away from the urethra against the posterior surface of the pubic bone, that is, in the middle of the corpus ossis pubis. It should be in direct contact with the cortex of the bone, that is, there should be no vaginal or paravesical tissue between them. When the inserter is fired, the bone anchor is shot straight through the bone cortex into the medulla. This procedure is performed on each side, so two anchors are necessary. The bone anchors are preloaded with No.1 polypropylene sutures. Fixation of the anchors in the bone must be proved by exertion of moderate tension on the sutures.

Sling insertion

We used a synthetic sling of dense polyethylene (Triangle® of Influence Medical Technologies™) that was provided by the manufacturer together with the In-Tac™ System (Influence Medical Technologies™) in the first 15 patients (24.6%); because our impression during the following months was that these tapes might pose a considerable risk of infection, we used only autologous fascia lata in the following 46 patients (75.4%). The slings were 7 cm long and 2 cm wide. Before insertion, the slings are soaked in a gentamycin - containing saline solution. The safely fixed polypropylene sutures on each side of the urethra are threaded through the sling, and the sutures are knotted behind the pubic bone so that the suspending sling is placed under the urethra without tension. To make sure that the suspension is not too tight, a forceps is used as a distance holder between sling and urethra. The sling should be placed smoothly and with no wrinkles under the urethra. The transverse colpotomy is closed with No. 3/0 single vicryl sutures. The vagina is tamponaded with iodine - soaked gauze, which is left for 1 day. The transurethral catheter can be removed immediately. After surgery, patients are mobilized as soon as possible. The cystostomy is removed within 5 days after the operation, as soon as PRV is below 50 mL.

Follow-up visits

All patients were evaluated in our clinic. The success rate of the procedure was determined subjectively and objectively. Subjective satisfaction with the outcome was evaluated with standardized questionnaires. We used four validated instruments with a total of 28 questions: the "Urogenital Distress Inventory" (UDI-6),[14] the "Symptom Severity Index" (SSI) and "Symptom Impact Index" (SII),[15] and the "Satisfaction Questionnaire".[16] Objective success was assessed with a pad test according to the ICS standard. If a patient complained of vaginal discharge, pain in the pelvic or pubic area, or discomfort during sexual intercourse, a urogynecologic examination was performed and, if necessary, x-ray pictures were taken. For statistical analysis, we used the χ^2 test, Student's - t test, and the Fischer test, respectively, and we regarded $p<0,05$ as statistically significant (n.s. = not significant).

Results

For follow-up examination, 61 patients were included; six patients had moved, one refused a visit in our clinic, and one had died. Stress incontinence existed for 6 months to 32 years (average, 8.2 years, median, 6.0 years). According to the classification of Ingelman-Sundberg,[17] the degree of urine loss was grade II in 70% and grade III in 30% of the patients; none of the patients was classified as grade I (mild incontinence). Of the 61 patients, 58 had had vaginal deliveries before (average, 1.8 deliveries). Fifty-six (91.8%) had nonsurgical pretreatment (pelvic floor exercises and stimulation, pessar), and 12 (19.7%) had surgery for stress incontinence before: the Burch procedure in five, the Raz procedure in one, the Stamey procedure in three and other surgical interventions in three cases. In 41 patients, hysterectomy had been performed beforehand: 24 vaginally and 17 abdominally. Regarding obesity, 36% of the patients had a body mass index (BMI) of up to 25 (normal), 39% had a BMI of 25 to 30, and 25% over 30. Mean follow-up was 10.2 months (range, 3 - 27 months). In 55 patients (90.2%), the operation was done at least 6 months before.

Wound infection and osteitis pubis

Mild wound inflammations occurred in 15% of the 46 patients in whom fascia lata was used, but as they were all very mild - most consisting of just some subjective discomfort - they could be controlled with conservative local treatment (such as sitz bath). However, wound infection occurred in 33% of the polyethylene group (n = 15); most of these infections were severe, and some even had purulent secretion. The sling had to be removed in three cases; in the others, the infection could be treated successfully with "blindly" prescribed antibiotics. Accordingly, six (40%) of the patients in the polyethylene group would not undergo this procedure for treatment of incontinence again, whereas 37 (80.4%) in the fascia lata group would Table 1, question 11.[16] In both

TABLE 1. **Postoperative questionnaire (selection) was used to evaluate the subjective satisfaction with the outcome. We used a combination of four modified validated instruments with 28 questions altogether: the "Urogenital Distress Inventory" (UDI-6),[14] the "Symptom Severity Index" (SSI) and "Symptom Impact Index" (SII)[15] and the "Satisfaction Questionnaire".[16]**

UDI-6. Do you experience and, if so, how much are you bothered by

		Not at all	A little bit	Moderately	Greatly
Question 4[14]	Small amounts of urine leakage (drops)	0	1	2	3

SSI and SII. These questions ask about your usual symptoms over the past half year

Question 1.[15] How often do you wet or leak urine?

Never	1-4 times a months	2-4 times a week	Once a day	More than once a day
( )	( )	( )	( )	( )

Question 2.[15] How would you describe the amount of urine you usually leak?

Damp/ a few drops	Wet/ a small amount	Quite wet/ cupful	Very wet floods
( )	( )	( )	( )

Question 5.[15] In the past week how often have you leaked urine?

Not at all	*A few* days	*About half* the week	*Most* days	*Every* day
( )	( )	( )	( )	( )

Satisfaction questionnaire

Question 3.[16] How satisfied are you with the results of your incontinence operation? Please circle the number that best reflects your satisfaction rate.

0	1	2	3	4	5	6	7	8	9	10
Completely dissatisfied					Neutral					Very satisfied

Question 11.[16] Knowing what you know now, would you still have chosen to undergo surgery for this condition?

( ) Yes ( ) No Maybe ( )

groups, there were no symptoms or signs of osteitis pubis.

Assessment of satisfaction

Forty-nine (80.3%) of all patients were satisfied or very satisfied (score > 5) with the result of the operation question 3.[16] The difference in satisfaction between the two groups (polyethylene versus fascia lata) is significant; in detail, nine (60%) patients in the polyethylene group versus 40 (86.9%) in the fascia lata group scored > 5 ($p<0.05$).

Objective continence rate using the pad test

Seventy-six percent of the patients are continent or improved, with *no* significant difference regarding the sling material used (polyethylene versus fascia lata) Table 2.

Assessment of subjective continence rate using validated questionnaires (selection)

Subjective continence or only slight incontinence was reached in 74%-87% of the patients, questions 4;[14] questions 1,2 and 5.[15] As in the objective assessment,

TABLE 2. **Postoperative continence rate in 61 patients using the Pad-test according to ICS standard**

Urine loss (ml/h)	Continence classification	Patients (n)	%
< 2	completely continent	40	66
2 – 10	improved, mild incontinence	6	10
10 - 50	moderate incontinence	7	11
> 50	complete incontinent	8	13
Sum		**61**	**100**

there was no significant difference regarding the sling material used.

Assessment of BMI versus outcome

There were no significant differences regarding continence or satisfaction with respect to BMI or duration of incontinence.

Discussion

The In-Tac™ bone anchor system is a minimally invasive procedure for the treatment of genuine stress incontinence (GSI). That system has been replaced with the Infast™ anchor system, in which the fixation of the sling is achieved by screws, but the principle is the same. The idea of fixation of the suburethral sling or the paraurethral suspension on the pubic bone is established in various forms.[6-13] It is obvious that results are reported mainly with regard to continence; but even in connection with the same or similar operative procedures, therapeutic success does not have a standard definition and is assessed subjectively,[18] with evaluation of urine loss in the pad test[6] or different bone anchor systems are evaluated without any definite criteria.[3] The continence rate in our series was only 76% (as objectively assessed with a pad test) and 74%-87% (as subjectively assessed with a questionnaire), and is average compared with the results of others using this technique Table 3. Our recruitment rate of 88.4% is very high, especially compared with other postal[21] or telephone[22] questioning, so our outcome must be regarded as representative, and no exclusion of individual bad outcomes can be implied. However, it must be stated that before the operation none of our patients could be classified as grade I, according to the classification of Ingelmann-Sundberg,[17] and vice versa all the patients' incontinence was of an advanced degree - grade II in 70% and grade III in 30% of the patients. Black and Griffiths[23] categorized only 81.6% of their patients as grade II or III. The argument of the advocates of the bone anchor systems is based primarily on the strength and intransigence of the fixation.[13] The procedure is simple, brief, and easy to learn and can be performed with[11] or without[6] vaginal incision. The opponents criticize especially the high rate of osteitis pubis, infection, or erosion with the use of synthetic slings,[3,11,24,25] although such complications were recently also reported in this journal with the use of autologous rectus fascial slings.[26] Schostak et al[25] reported wound infections after the implantation of polypropylene slings in 17 of 36 patients (47%), and 16 patients had to be operated on again. He did not report any osteomyelitis. Our data support the safety

TABLE 3. **Continence rate (cured or significantly improved) after bone anchor procedures for stress urinary incontinence**

	Patients (n)	Mean followup (months)	Continence rate (%)
Appell 1997[10]	189	24	82-98
Nativ 1997[6]	50	12	96
Seemann 1997[19]	42	12	24
Hom 1998[20]	32	8	91
Schultheiss 1998[5]	37	11	68
El-Toukhy 1999[18]	30	12	80
Kaplan 2000[12]	72	12	86-97
Giberti 2000[11]	67	17	91
Hartanto 2003[13]	64	12	70-83

of the bone anchors themselves: no osteomyelitis, osteitis pubis, or anchor dislocation occurred, so no anchor explantation was necessary. This experience was not shared by others performing this technique: FitzGerald et al[4] reported an explantation due to infection of the anchor insertion; Schultheiss et al[5] found infection of the anchors in two of 37 patients. Bernier and Zimmern[27] stated that pain in the retropubic area might often be caused by irritation of the sensitive genitale branch of the genitofemorale nerve, and not by osteitis pubis; because of retropubic complaints, a bone anchor was removed, but microbiologically there were no signs of bone infection. This possible complication of nerve irritation has to be taken into consideration in all retropubic procedures, as emphasized by Miyazaki and Shook.[28]

We must confirm the results of Schostak et al[3,25] that the polyethylene slings tend to lead to major periurethral infections. In our series, explantation of the slings was necessary in 20% of the polyethylene group but in none of the fascia lata group. Why the explantation rate in the reported series of Schostak[25] was so high (44%) is not known; we used the same operative technique and prophylactic antibiotics. But other authors also reported higher infection rates than ours with the use of synthetic materials, such as with Goretex, polytetrafluoroethylene or Marlex.[29-31] Giberti et al[11] reported an explantation rate of 16% due to vaginal erosion when gelatin-coated Dacron slings were used. The frequent finding of wound infection in our series urged us to stop using polyethylene slings, and we used only fascia lata in the later operations. Because of lower infection rates, others also prefer fascia lata and have favorable experience regarding continence, as stated in detail also in this journal.[12,13,32] However, Hom et al[20] reported good results and *no* infection or erosion with synthetic material, a polypropylene mesh, and the Vesica™ bone anchor system; the continence rate was 91.4%. Kuo[33] reported that only one in a series of 50 patients in whom polypropylene mesh was used developed a sling infection. With respect to the TVT sling procedure, Ulmsten et al reported no infections of the tapes.[2] The question therefore arises: what is the reason for different rates of wound infections in different surgical procedures in which the same sling material is used? It seems obvious that not only different synthetic material but also the processing of the material is of major importance with respect to infection. The netlike mesh of the TVT allows the wound secretion to drain and the tissue to grow in; with the use of our platelike, dense polyethylene tape, the drainage of blood and wound secretion is insufficient; fibroblasts cannot grow in, and this obviously facilitates wound infection.

This study was designed to evaluate objectively the incidence of osteitis pubis with the once broadly used bone anchor systems and the relation of infection rate to sling material. However, the overall success rate of this procedure in achieving continence was only moderate, and since there exist by far less invasive and minimally invasive procedures for the treatment of SUI today (for example several types of tension-free vaginal tapes or transobturator tapes), with excellent results reported, the authors do not recommend the use of these bone anchor systems any more and they themselves gave up this system in favor of the more modern procedures mentioned.

Conclusion

Osteitis pubis is not a typical complication of the bone anchor system. We emphasize that the outcome with regard to infection rate depends primarily on the sling material used and its processing: in contrast with netlike mesh (such as TVT), platelike, dense synthetic material tends to cause wound infection. That is not a typical complication when Fascia lata is used. The continence rate in this series was only average. All together, the authors do not recommend the use of bone anchor systems any more, since there are less invasive procedures for the treatment of SUI, like tension-free or transobturator tapes, on the market.□

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