

The effectiveness of a pre-pubic four-arm NAZCA-TC mesh in treating cystocele and stress urinary incontinence simultaneously — results controlled with a pelvic floor ultrasound. A preliminary study

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ABSTRACT

Objectives: It is controversial whether pelvic organ prolapse and stress urinary incontinence (SUI) should be treated simultaneously with a single surgery or separately with two procedures. The pre-pubic four-arm NAZCA-TC® mesh was invented to treat cystocele and SUI with a single procedure. The objective of this study is to analyze short-term results after the implantation of NAZCA-TC mesh.

Material and methods: A total of 18 women underwent the evaluation of results of mesh implantation within a 24 to 36 months follow-up. Pre-operatively, patients were examined under standardized conditions. Postoperatively we analyzed the following: standardized interview and examination as well as pelvic floor ultrasound: 2D with a transvaginal probe and 4D with an abdominal probe.

Results: There was one case of intraoperative bladder damage noticed and repaired followed with NAZCA implantation. In 2 cases vaginal erosion was found that healed successfully after re-operation. In 3 cases hematomas were observed but resolved spontaneously. After the surgery there was a statistically significant improvement of prolapse in anterior ($p < 0.0003$) and in central ($p < 0.001$) compartment. Six women (33.3%) had no stress urinary incontinence symptoms during the control visit but we did not find a statistically significant improvement in SUI symptoms after the procedure. We recorded no case of hypomobile urethra after the surgery. The mesh covered > 50% of the urethral length in all of the patients.

Conclusions: Mid-term results showed that implantation of NAZCA TC mesh allows to achieve statistically significant improvement in reducing cystocele coexisting with enterocele in over 65% of patients. A complete cure from stress urinary incontinence was confirmed in 1/3 of patients. NAZCA-TC covered more than 50% of the urethral length, which can possibly have a negative influence on the effectiveness of the suburethral tape.

Key words: cystocele, stress urinary incontinence, prepubic four-arm transvaginal mesh, pelvic floor ultrasound, PFS-TV, transvaginal probe

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INTRODUCTION

Stress urinary incontinence (SUI) is the most common type of urinary incontinence in women [1–4]. SUI and pelvic organ prolapse (POP) are often the reasons for operative treatment, especially in ageing populations [5–11]. There

are no recommendations regarding an optimal surgical intervention in different clinical situations. Thus, controversies may arise in a situation where POP coexists with overt or occult SUI. In such case the question is whether POP and coexisting SUI should be addressed together at one proce-

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ture or not. While occult incontinence may coexist in up to 30% of women with POP, about 40–50% of women with POP observe a significant SUI [12, 13]. NAZCA-TC is a mesh with four arms: two pre-pubic and two transobturator. It was invented to treat anterior vaginal wall prolapse alone or together with SUI [12].

The polypropylene mesh and its arms are well visible during pelvic floor ultrasound. That is why many specialists advocate the use of sonography to control the effects after urogynecological procedures where such slings are used [14]. Introital pelvic floor sonography with a transvaginal probe (PFS-TV) was previously used to evaluate patients with SUI before and after anti-incontinence suburethral sling implantation [15, 16]. It was also found useful to evaluate POP and mesh used for treating it with a 2D or 4D pelvic floor ultrasound performed perineally with a transabdominal probe (PFU-TA) [14].

Urethral hypomobility was found to be one of the risk factors for failure of the implanted anti-incontinence suburethral tape. PFS-TV in turn was found to be very useful in detecting hypomobility of the urethra [15, 16].

In patients who had two tapes implanted, a collision phenomenon between 2 anti-incontinence suburethral tapes was observed during PFS-TV examination [17, 18]. That is why the literature suggests that the tape located near the middle part of the urethra be first excised and a new tape be implanted a few weeks later [17–19]. Because NAZCA-TC is implanted near the urethra, it would be valuable to check its location along the urethra and to evaluate its influence on the urethral mobility.

In the literature there is only one study that analyzes the influence of NAZCA-TC implantation on SUI [12]. There are no studies concerning NAZCA-TC evaluation using PFS-TV or PFU-TA.

OBJECTIVES

The objective of this study is to evaluate the results of NAZCA-TC mesh implantation in women with POP and coexisting SUI symptoms using PFS-TV and PFU-TA.

MATERIAL AND METHODS

NAZCA-TC® mesh (by Promedon, Argentina) was implanted in 21 patients. The mesh is made of type I polypropylene monofilament with a density of 60.5 [g/m²]. The mesh pore size is 0.5–1 [mm], the mesh thickness is 0.47 [mm] and the filament diameter is 0.14 [mm]. The central part of the sling has 16 circular orifices with 6 [mm] in diameter each, which enhances tissue integration and decreases the amount of synthetic material implanted allowing thus a greater flexibility. The sling has 2 arms — two pre-pubic and two transobturator. One pre-pubic and two transobturator needles with removable and ergonomic handles complete

the set [12]. All operated women had symptoms of SUI and a cystocele of stage 2 or higher as per Pelvic Organ Prolapse Quantification (POP-Q) system [9, 10, 20].

One and the same experienced surgeon (T.K.) performed the surgery on all the patients in the study. The data has been obtained retrospectively from a total of 18 patients who attended the control visit between 24 and 36 months following the procedure.

Pre-operatively, patients were examined under standardized conditions. Pelvic organ prolapse (POP) was classified in accordance with POP-Q system [20]. SUI was confirmed by a cough test [21].

The surgery and mesh implantations were performed according to the technique described by Palma et al. [12].

When it comes to the postoperative analysis, we included the following: standardized interview and examination that includes analysis of POP using POP-Q scale; urinary continence evaluated with a cough test and a PFS-TV — a standardized pelvic floor ultrasound using GE Voluson Expert: 2D introitally with a transvaginal probe (PFS-TV) and 4D translabially with an abdominal probe (PFU-TA).

The volume of urine in the bladder was evaluated during transabdominal ultrasound by performing three-plane measurements of the bladder calculated by the ultrasound system. We have evaluated urinary incontinence in patients with 250–350 [ml] of urine in the bladder. PFS-TV was performed under standardized conditions [15, 22, 23]. Cough test was performed in patients in lithotomy position. If the test was negative, it was repeated in standing.

During the post-operative visit urethral length, mobility and funneling with urine flow was evaluated with PFS-TV on a sagittal view as previously described [15, 22–26]. The urethral mobility was evaluated as a vector calculated from measurements obtained during PFS-TV according to the method described by Viereck. This parameter is also called a linear dorsocaudal movement (LDM) [15, 24]. The urethra was defined as hypomobile when the value of the vector was ≤ 5 [mm], normomobile when more than 5 [mm] but less than 15 [mm] and hypermobile when ≥ 15 [mm] [15, 23]. The urethral funneling with a urine flow, which was observed during Valsalva maneuver in PFS-TV, was regarded as a confirmation of SUI that was previously recorded with a positive cough test [25, 26]. We diagnosed no SUI when there were no clinical symptoms or when SUI was observed by the patient only periodically while sitting and standing cough test and PFS-TV examination were all negative. A first degree of SUI was diagnosed when the patient reported SUI symptoms to be periodical (from time to time, not every day) and the cough test as well as SUI during PFS-TV exam were positive. A 2+ degree of SUI was diagnosed when patients reported to have symptoms every day and the cough test was positive, which had to be confirmed during PFS-TV.

The location of urethral end of NAZCA-TC mesh was measured during PFS-TV on a sagittal view similarly to the measurements proposed by Kociszewski et al. for the sub-urethral tape [15, 23]. We measured the shortest distance between the mesh and the hypoechoic urethra. It was called mesh-urethra distance measured in [mm] (Figure 1). We calculated the mesh position relative to the urethral length in % according to the formula (1):

Relative mesh position = distance of the distal end of the mesh from the bladder neck*100%/sonographic urethral length (Figure 1).

PFU-4D was performed under standardized conditions. Hiatal dimensions at rest and during maximal Valsalva lasting minimum 5 seconds were measured in the plane of minimal hiatal dimensions, as described previously. Levator trauma was identified by tomographic ultrasound (TUI) as described previously [14, 27–28].

The statistical analysis was performed with STATISTICA 7.0 software of Stat Soft. The calculations of median, arith-

metic mean and standard deviation were done. Student's t-test was applied for testing the significance of differences for the dependent variables.

RESULTS

All 18 patients had the implantation of NAZCA mesh in a single procedure and it was their only treatment procedure. The mean age of women was 62 years (range, 40–78). The mean BMI was 29.2 [kg/cm²] (range, 22.2–38.0). There were no statistically significant differences between SUI cured and not-cured in age and BMI. Three women were premenopausal, the rest were 3 to 24 years after menopause (Table 1). One patient was taking insulin because of diabetes and 9 patients had hypertension. Four women were smoking > 10 cigarettes daily. One patient had a vacuum-assisted delivery, 3 patients had spontaneous deliveries and 1 patient had 3 spontaneous deliveries and a caesarean section. The rest delivered only vaginally from 1 to 7 times (mean = 3). Patients' first baby was delivered between the age of 19 and 35 (mean = 23.3). One woman had an abdominal hysterectomy in the history (leiomyomas) and one had a hysterectomy with bilateral salpingo-oophorectomy because of a benign ovarian tumor. None of the patients had a previous urogynecological surgery.

All of the patients had a cystocele of at least 2nd degree (POP-Q scale) confirmed during the preoperative examination. Additionally, an enterocele of 2nd degree was found in 5 patients and of 1st degree in 9 patients. In 7 cases examination revealed a rectocele of (patients with enterocele 1+). After the NAZCA implantation the prolapse improved significantly in both the anterior ($p < 0.0003$) and central ($p < 0.001$) compartment. In the posterior compartment the differences were not statistically significant. At the control visit a POP of 2nd degree was noticed in 6 patients in the anterior compartment, in 1 patient in the central compartment and in 1 patient in the posterior compartment (Table 2). Only 2 patients (11.1%) did not notice any significant improvement of POP symptoms.

Before the surgery all of the patients suffered from SUI 2nd degree that was confirmed during cough test. There was no statistically significant improvement in SUI symptoms after the NAZCA implantation. Although 8 patients (44.4%) observed symptoms to disappear or subside, 5 (27.8%) reported no change and other 5 (27.8%) reported the symp-

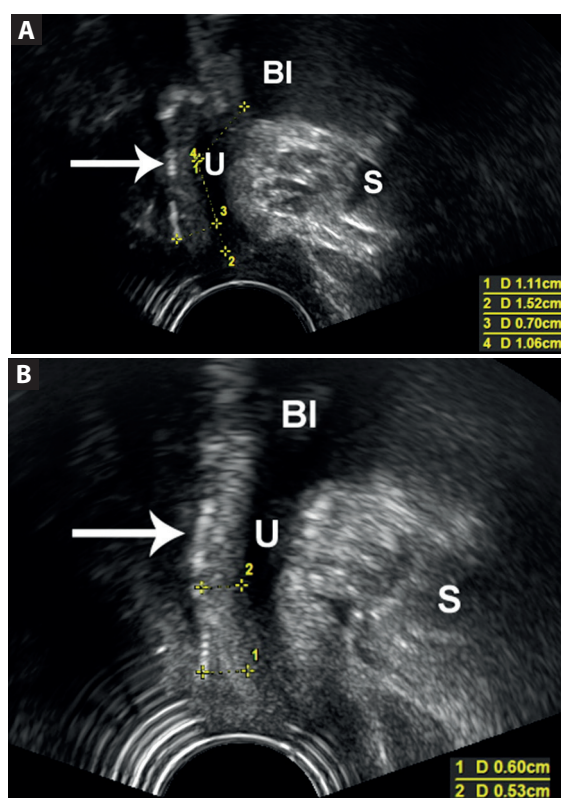


Figure 1. PFS-TV: evaluating mesh location. **A.** Evaluating relative mesh position. Legend: 1+2 — urethral length; 3 — projection of distal end of the mesh on urethral axis; 4 + 1 — distance between distal end of the mesh and bladder neck (internal urethral orifice); BI — bladder; U — urethra; S — symphysis pubis; relative mesh position = $1 + 2/4 + 1 \times 100\%$; **B.** Evaluating mesh-urethra distance. Legend: 1 and 2 — distances between mesh and hypoechoic urethra, mesh urethra distance is the smallest distance between tape and hypoechoic urethra; in this case measurement No. 2; BI — bladder; U — urethra; S — symphysis pubis

Table 1. Demographic data of the studied group

Mean age of women (min–max)	62.0 years (40–78)
Mean BMI (min–max)	29.2 [kg/cm ²] (22.2–38.0)
Number of premenopausal women	3
Number of postmenopausal women	15

Table 2. POP-Q evaluation before and after the NAZCA implantation

	Preoperative examination	Postoperative examination	p value
Cystocele of at least 2 nd degree	15	6	p < 0.0003
Enterocoele of at least 2 nd degree	5	1	p < 0.001
Rectocele of at least 2 nd degree	0	1	Not statistically significant

toms to worsen. Only 6 patients (33.3%) had no stress urinary incontinence symptoms at the control visit, of which 2 reported a periodical SUI despite a negative cough test and no signs of SUI during PFS-TV. The rest suffered from SUI 2nd degree.

Preoperatively, symptoms of dry overactive bladder were reported by 61.1% of patients. After the surgery 72.2% of them noticed a significant improvement. There was no case of urge de novo or wet overactive bladder.

Pelvic floor ultrasound revealed the mesh to be rolled up in 11 cases (61.1%) (Figure 2).

Mean urethral length in SUI cured and not-cured patients was nearly the same: 2.97 cm vs. 2.99 cm (NS). PFS-TV showed that the mesh was covering more than 50% of the

urethral length in all of the patients and 75% of the length in 72.2% of patients (Figure 2). The mean relative mesh position was 80.3% (range, 55.6–94.1%): in SUI cured group: 79.8%, in SUI not-cured group: 80.1% (NS). The mean mesh-urethra distance was 4.40 [mm] (range, 0.18–7.50), in SUI cured group: 4.4 mm, in SUI not-cured group: 4.5 mm (NS).

After the NAZCA implantation there was no patient with a hypomobile urethra. PFS-TV showed a hypermobile urethra in 12 patients (66.7%) and a normomobile urethra in 6 patients (33.3%). The mean LDM value was 19.3 [mm] (range, 6.1–31.4). The differences in mean LDM between SUI cured group and SUI not-cured group were not statistically significant.

PFU-4D revealed that the mean hiatal area was 23.5 cm² (15.6–39.0) at rest and 28.4 cm² (18.1–47.1) at maximal Valsalva. In 3 patients (16.7%) a unilateral puborectalis avulsion was identified. 72.2% of patients were at increased risk of postoperative POP recurrence due to hiatal area > 25 [cm²] and/or levator avulsion. In SUI cured group mean hiatal area at rest was 24.0 cm² and during maximal Valsalva — 29.2 cm², in SUI not cured group respectively 22.3 cm² and 26.7 cm² (NS).

Bladder damage has occurred in one patient that was found intraoperatively. It was repaired followed with NAZCA implantation. Vaginal erosion was noticed in 2 cases (11.1%) and after re-operation it was successfully healed. The erosions were identified among smokers only. In 5 women (27.8%) we noted a post-void residual > 100 mL, which lasted < 7 days. In 3 women (16.7%) hematomas were detected but resolved spontaneously. In 5 cases (27.8%) infection of urinary tract has occurred soon after the surgery.

A total of 3 patients did not attend the control visit but NAZCA implantation and hospitalization was complications free.

DISCUSSION

The pathophysiology of SUI is not fully understood. Recently, it has been claimed that urethral hypermobility and sphincter weakness called intrinsic sphincter deficiency can explain SUI in most of the cases [14, 29–31].

Suburethral tapes are highly successful in treating SUI but the mechanism of their action as well the reasons for eventual failure remain quite unknown. Urethral hypomobility is a generally accepted risk factor for failure. There are studies using PFS-TV showing that the relative tape position, the tape-urethra distance and the urethral mobility toge-

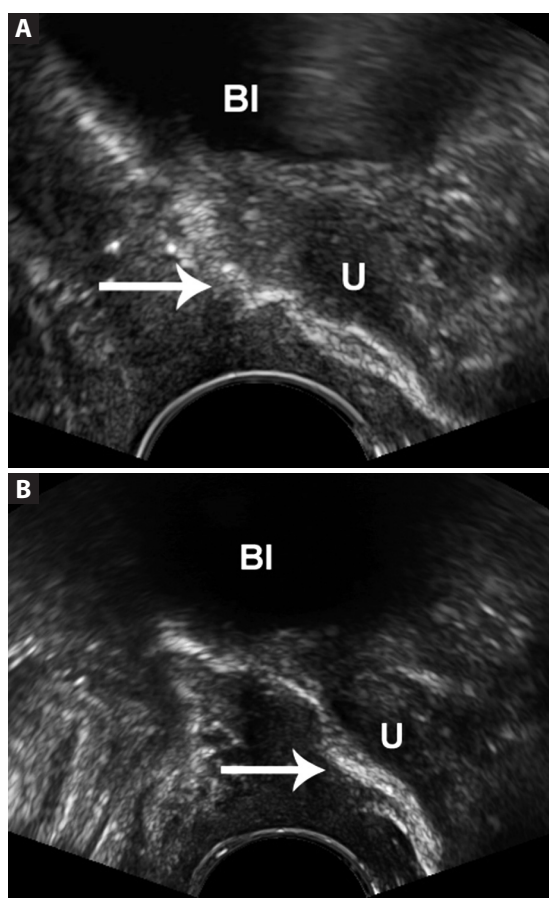


Figure 2. PFS-TV: NAZCA mesh, covering nearly the whole length of the urethra. **A.** Rolled-up; **B.** Without signs of rolling

ther have a definitive impact on the cure rate [15, 22, 23]. However, Dietz et al., using PFU-TA, was not able to confirm the results obtained during PFS-TV [32].

POP is a common female disease [33]. It often co-exists with overt SUI or occult SUI. It is still not clear if combining the treatment of POP and SUI to one procedure is an optimal choice. Yet, compared to anterior mesh procedure where 39–77% of women became free of SUI symptoms, combining anterior mesh with a suburethral tape implantation gave a 78–95% cure rate. However, the incidence of complications was significantly higher after a combined procedure [13, 34].

The study of Palma et al. evaluates a total of 104 women who had NAZCA TC implantation, of which 31 had POP co-existing with SUI pre-operatively. Only two of them (6.5%) report treatment failure after 12 months follow-up [12]. In the study of Delroy et al. 79 women underwent either a classic anterior repair or a method using NAZCA TC but urinary incontinence was not analyzed in that study [35]. In our population in turn, the objective cure rate from SUI was 33%. Subjective cure or satisfactory improvement was expressed by 44% of the patients. Yet, it is not clear why the difference between our results and those of Palma's is so big. It might be that the reason lies in the differences in the operating technique or in the very population of patients.

Two available studies concerning NAZCA TC report 5.0–5.7% cases of erosions, 4.0–4.5% cases of increased bleeding and 5–6% of patients with post-void residual lasting < 7 days. A urethral perforation happened in up to 2.5% of procedures, while bladder perforation in 0% of cases. Urinary tract infections (UTI's) were noticed by 20% of patients. A statistically significant improvement was observed in all compartments but additional procedure for posterior or central compartment in more than 50% of women had to be performed [12, 35].

Compared to the two studies mentioned above, the risk of complications in our population was similar. We did not record a statistically significant improvement in the posterior compartment since our patients had the anterior mesh implantation as the only procedure. It is worth highlighting that although 72.2% of patients were at a higher risk of postoperative POP recurrence (hiatal area > 25 cm² and/or levator avulsion), 24–36 months following the procedure we confirmed a statistically significant improvement of prolapse in both the anterior and central compartment.

We did not find a negative influence of the sling on the urethral mobility, as there was no case of hypomobility after NAZCA TC implantation. In some cases the mesh-urethra distance was less than 3 [mm] but we did not notice urge de novo in these patients. Kociszewski et al. observed a higher risk of urge de novo in cases of suburethral tape implantation when the tape-urethra distance was < 3 [mm] [22, 23].

The mesh was covering more than 50% of the urethral length in 100% of our patients and 75% of the length in 72.2% of patients. This may theoretically be the reason for the collision between mesh and suburethral tape, which may complicate the SUI cure after the tape implantation [17, 18]. Therefore, it would be interesting to analyze the effects of suburethral tape implantation in women with persistent SUI after NAZCA TC implantation.

There exist some limitations of our study. The analysis was retrospective and the ultrasound scan was performed after the surgery only. Also, we did not use standardized questionnaires for the evaluation. On the other hand, one and the same experienced surgeon performed all of the NAZCA implantations and the results were objectively evaluated using a clinical, PFS-TV and PFU-TA examination. The results of our study suggest the need to perform some prospective randomized studies confronting comparatively the transobturator mesh with and without a simultaneous suburethral sling implantation.

CONCLUSIONS

Mid-term results showed that implantation of NAZCA TC mesh allows to achieve statistically significant improvement in reducing cystocele coexisting with enterocele in over 65% of patients. A complete cure from stress urinary incontinence was confirmed in 1/3 of patients. NAZCA TC covered more than 50% of the urethral length, which can possibly have a negative influence on the effectiveness of the suburethral tape.

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