

The MiniArc® Sling System in the Treatment of Female Stress Urinary Incontinence

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ABSTRACT

Aims: To assess the technical feasibility of a new mini-invasive sling procedure (MiniArc®) and present short-term results in the treatment of female urinary incontinence.

Materials and Methods: A total of 97 women with mixed or stress urinary incontinence (SUI) were treated by placement of the new single-incision sling. Pelvic organ prolapse was graded using the POP-Q system (pelvic organ prolapse quantification system). Preoperative workup included urodynamic evaluation, cough stress test and introital ultrasound. Postoperatively, introital ultrasound was performed to determine residual urine and check tape position. Quality of life was measured using King's Health Questionnaire. A voiding diary and pad count served to verify the patients' subjective complaints.

Results: The MiniArc® single-incision sling procedure was the initial intervention in 37 (38.2%) patients and the second intervention in 60 (61.7%) patients with recurrent incontinence. The cough stress test was negative in 79 (83.1%) women 6 weeks after the sling procedure and in 74 (77.8%) at 12 months. De novo urge occurred in 32 (36.8%) women. Quality of life was significantly improved at 12-month follow-up in 65 (69.1%) patients ($p < 0.001$). The number of pads decreased significantly from 2.2 to 0.6 ($p < 0.001$) after the procedure. One patient developed an hematoma and bladder perforation occurred in another.

Conclusions: Our short-term clinical results suggest that the MiniArc® is a safe and effective minimally invasive sling procedure for treating female SUI. Randomized comparative controlled trials and long-term results are still required to define the role of the new sling system in comparison to established mid-urethral tape techniques for treating incontinence.

Key words: stress incontinence, urinary; suburethral sling; minimally invasive procedures; quality of life

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INTRODUCTION

As the population is aging, the medical community is increasingly challenged with the problem of urinary incontinence. More women (prevalence of 31% to 63%) are affected than men (1). Urinary incontinence can severely restrict patients in their daily activities and social life. The costs in terms of healthcare expenditure are a burden on the National Health System.

Medical advances in the prevention, diagnosis, and treatment of urinary incontinence mean an improved quality of life for a large number of women.

Open colposuspension and conventional tape procedures are considered the most effective interventions for treating female stress urinary incontinence (SUI) to date. Good long-term results have been reported for both interventions (2). The TVT (tension-free vaginal tape) procedure is the most widely

used technique for tape placement worldwide. The operation was first described by Ulmsten et al. in 1996 and aims at restoring continence by placement of a monofilament polypropylene mesh under the mid-urethra (3). Various complications have been reported in association with the TVT procedure including bladder perforation, voiding dysfunction, retropubic hematoma, and injuries to structures of the true pelvis. A second generation of tapes has been applied using the transobturator approach, which was developed by Delorme (4) and De Leval (5). This approach avoids the retropubic space, thereby reducing the risk of inadvertent bladder and intestinal injury. Moreover, no adhesions are induced in the retropubic space, which could be important for the feasibility of future interventions. Transobturator tapes have since been established as the second tape procedure in addition to the TVT (6,7).

The new MiniArc® single-incision sling procedure is comparatively less invasive and is used to reduce complications such as bladder perforation, injury to structures in the true pelvis, and postoperative pain in the region of the adductor muscles. The MiniArc® mini-sling is an approved medical device manufactured by American Medical Systems. Data on the outcome of the mini-sling procedure is still sparse. Tasinen et al. (8) have reported very poor results one year after surgery using a mini-invasive collagen sling to treat neurogenic urinary incontinence. Neuman has reported a failure rate of 7% in a study of 100 women who underwent TVT-SECUR insertion (9) in 13 hospitals. Transobturator tapes have since become established and are not inferior to the TVT (10).

The aim of our study was to assess the technical feasibility of a new mini-invasive sling procedure (MiniArc®) and present short-term results in the treatment of female urinary incontinence.

MATERIAL AND METHODS

We studied 97 women with mixed or stress urinary incontinence based on reported subjective complaints (voiding diary, pad count) and objective workup by means of urodynamic evaluation as well as physical and imaging examination, that included: a) tonometry - premature urge at less than 200 mL blad-

der filling, b) bladder capacity - reduced to less than 350 mL, c) compliance - reduced at a bladder pressure increase of over 2.6 cm H₂O per 100 mL bladder filling (11), d) profile at rest - low-pressure urethra defined as urethral pressure < 10 cm H₂O, e) profile during straining, f) cough stress test, g) pelvic examination, POP-Q (pelvic organ prolapse quantification system) (10), and h) introital ultrasound (12,13). The patients were operated on between January 2007 and July 2008. The women with pure stress urinary incontinence had undergone prior conservative treatment with biofeedback, electrostimulation, and duloxetine hydrochloride between January 2007 and July 2008 (Tables-1 and 2).

Of the 97 patients, 79 (81.4%) had pure SUI, 18 (18.6%) mixed urinary incontinence. All patients with mixed incontinence had sensory urgency (premature first urge without detrusor contraction). Urodynamically proven urethral insufficiency and a positive cough stress test were present in all cases. Tonometry findings were unremarkable in all patients without sensory urge.

Four (4.2%) women had a cystocele (AaBa > +1) based on the POP-Q system, but, based on their symptoms, only required sling insertion.

Since it was our intention not to select patients as regards constitution, prior surgery, concomitant disease, and urodynamic findings, a retrospective design appeared to be the most suitable approach.

The MiniArc® sling investigated in our study was 8 cm in length and has self-fixating tips for anchorage in the obturator internus muscle and membrane (Figures-1 and 2).

Table 1 – Characteristics of the study population.

Characteristics	Study Population (N)
Nulliparae	24 (%)
Multiparae	61 (%)
Caucasian	91 (%)
Asian	6 (%)
Age	65 (± 12)
BMI	29 (± 6)
Introital ultrasound funneling	42 (%)

BMI = body mass index.

Table 2 – Prior operations in the patients with recurrent urinary incontinence.

Colposuspension	Injection	Tape Insertion	Prolapse Surgery
36%	18%	6%	43%

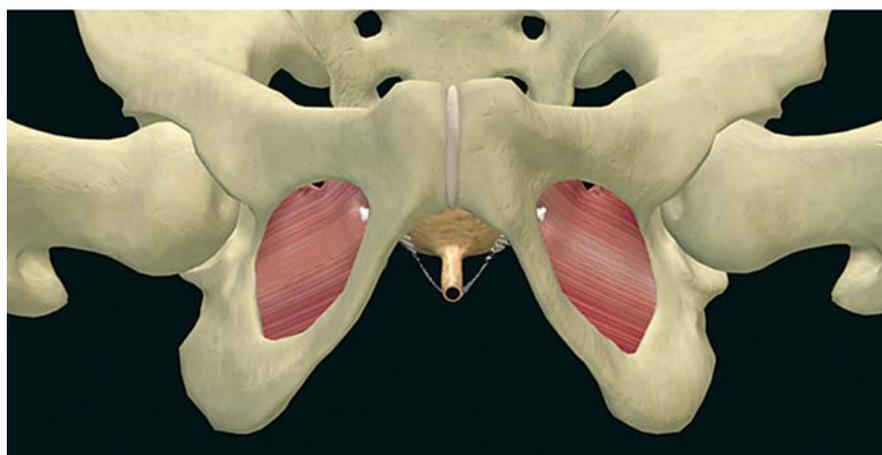


Figure 1 – Tape insertion technique.



Figure 2 – The needle kit.

All patients were comprehensively informed about the new procedure by the same person. The transobturator tape was offered as an alternative approach, and it was emphasized that long-term experience with the MiniArc® is still lacking. Drawings were presented to the patients to illustrate the two approaches. Patients were not influenced and could freely select the method they preferred.

All patients were operated on at the German Pelvic Floor Center in Berlin. Two experienced operators performed all sling procedures included in the analysis. Each of them had previously performed the new procedure in 10 patients not included in the study to become familiar with the technique. The women included in the study underwent isolated minimally invasive sling insertion without additional prolapse repair in order to exclude other factors that might impact the outcome. Patients with mixed urinary incontinence were initially treated for the urge component using electrostimulation and/or anticholinergic medication (Table-3).

All surgical interventions were performed in the lithotomy position under general anesthesia

Table 3 – Preoperative treatment of the patients with mixed urinary incontinence.

Anticholinergics	Additional Electrostimulation
Oxybutinin 2%	1%
Darifenacin 8%	5%
Propiverin 5%	5%
Tolterodine 2%	0%
Trospium chloride 1%	1%

(laryngeal mask). A Foley catheter was placed and patients received single-shot intraoperative antibiotic prophylaxis (cephalosporin). The vagina was incised approximately 1.5 - 2 cm below the external urethral

orifice. Next, the paraurethral tissue was dissected with scissors, creating a tunnel up to the inferior ramus of the pubic bone. The sling was then advanced into the obturator internus muscle and obturator membrane below the inferior pubic ramus with a needle. Tension-free positioning of the sling was ensured by inserting a forceps handle between the tape and the urethra. The insertion angle was 45 degrees in the direction of the adductor longus muscle tendon (Figure-3). The vaginal incision was closed with vicryl sutures.

Upon completion of the procedure, the catheter was removed and the patient had to void spontaneously within the next four hours. The hospital stay was two days. Postoperative evaluation comprised of the patients' subjective assessment (voiding diary, pad count) and quality of life questionnaire. The clinical evaluation included a pelvic examination, a

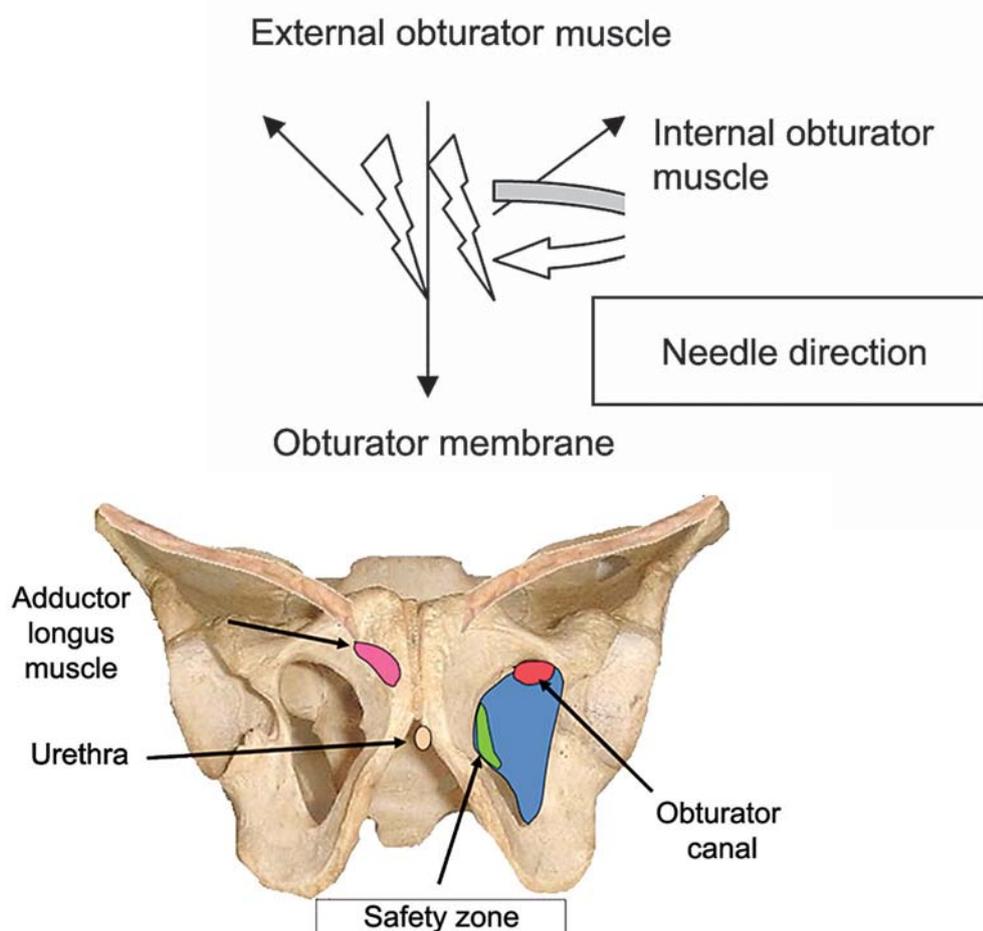


Figure 3 – Tape insertion technique.

Table 4 – Outcome after primary versus repeat intervention.

Intervention	Primary Intervention	Repeat Intervention
No. of incontinence episodes > 3/day	None	18%
No. of pads used > 1/day	6%	14%

cough stress test, and introital ultrasound to measure the postvoid residual urine volume and determine the sling position.

Follow-up examinations were performed directly postoperatively as well as 6 weeks and 12 months after tape insertion.

Therapeutic failure was defined as persistent SUI that impaired the patient's quality of life and was confirmed by the clinical findings.

A pad count and a voiding diary served to objectively ascertain restored continence.

RESULTS

Thirty-seven (38.2%) patients underwent the MiniArc® procedure as a primary intervention, 60 (61.7%) for recurrent urinary incontinence. Outcome differed between these two groups (Table-4).

A low-pressure urethra was diagnosed in 23 patients (24.2%) and was found to significantly ($p < 0.001$) correlate with outcome. Thirteen of the 23

patients (56.5%) in this subgroup were therapeutic failures with persistent SUI.

The intra- and postoperative complications in the study population are summarized in (Table-5).

Postoperative voiding dysfunction was defined as a residual urine volume greater than 100 mL and was treated by alpha-blocker administration and catheterization.

Patients who developed bladder infection received cephalosporin for one week.

De novo urge symptoms were treated by anticholinergic medication in 20 (20.6%) patients and by physical therapy in 12 (12.4%).

The preoperative urge component present in 18 (18.6%) patients persisted after conservative treatment and the sling procedure in five (27.8%) cases.

The cough test was negative in 79 (83.1%) women at 6-week follow-up and in 74 (77.8%) women at 12-month follow-up. The test was positive in 16 (16.8%) women at 6 weeks and in 20 (21.3%) women at 12 months.

At 12-month follow-up, 77.8% ($n = 66$) of the women reported to be continent while 21.3% ($n = 20$) reported persistent urine loss during physical activity. These results were also reflected in self-reported quality of life questionnaires.

Significant improvement in quality of life was observed for 66 (68.0%) patients at 6-week follow-up ($p < 0.001$) while 22 (22.7%) had an unchanged quality of life, and 9 (9.4%) reported deterioration compared with their situation before the intervention. At 12-month follow-up, there was persistent improvement for 65 (69, 10%) patients ($p < 0.001$), unchanged quality of life for 17 (17.5%), and deterioration for 15 (15.5%) women. The number of pads used decreased significantly from 2.2 before to 0.6 ($p < 0.001$) after the sling procedure.

The patients who reported deterioration after the intervention used more pads than preoperatively, had greater involuntary urine loss (based on the

Table 5 – All adverse events by patient ($n = 95$).

Adverse Event Type	Patients / N (%)
Retention	2 (2.1) ¹
Pelvic pain	0
Bleeding	1 (1.0) ²
Bladder perforation	1 (1.0) ³
De novo urge	32 (36.8) ⁴
Other	0

1 - Retention resolved after 2 days in both patients, 2 - Hematoma was amenable to conservative treatment, 3 - The patient was not operated on in the conventional lithotomy position and had a history of three anti-incontinence operations. The position of the needle for tape insertion was corrected and an indwelling catheter was placed, which was left in the bladder for 10 days, 4 - For details see the Results section and Table-3.

voiding diary entries), and developed de novo urge (voiding frequency > 10/day).

Ultrasound was performed to evaluate the postoperative tape position. The tape was in the area of the mid-urethra in 82 (84.5%) women, under the distal urethra in 9 (9.3%) women, and close to the bladder neck in 6 patients (6.2%). There was no correlation between tape position and de novo urge. There was also no correlation between the tape position at ultrasound and subjectively reported deterioration of incontinence after surgery. The mean length of surgery was 6 ± 3.5 minutes and the mean blood loss was 10 ± 25 mL.

DISCUSSION

The results we achieved with the MiniArc® sling system in treating female urinary incontinence are representative of the short-term outcome of this new minimally invasive sling procedure. The long-term success rates (5-10 years) reported in the literature are 78 % (14) to 90% (14) for colposuspension and 81% for the TVT (15). The outcome reported for transobturator tapes is comparable to that of the TVT procedure (16). A new method should be similar or superior to established therapies and/or be safer and technically easier to handle.

We encountered only one intraoperative hemorrhage, which did not require blood transfusion, and one bladder perforation, which was most likely due to scar formation as this patient had already undergone multiple prior operations. On the whole, the new sling was easy to insert and the duration of the procedure was very short compared to existing techniques. When the procedure is properly performed, the risk of injury to the bladder, intestine, or urethra is negligible. Since the needle is very thin and can be inserted at different angles, proper advancement requires strict adherence to anatomic structures, which is why physicians require a training course before performing the procedure in patients. As with transobturator tapes, the retropubic space is avoided, which is an advantage if patients need future surgery. Since all interventions were performed in the setting of a workshop, we opted for standardized anesthesia with a laryngeal mask. The MiniArc® sling proce-

dures can also be performed with local anesthesia and analgesia. Further advantages over the transobturator tape are that there is no risk of obturator nerve damage or adductor muscle pain. Postprocedural symptoms of overactive bladder are most likely attributable to the anchorage of the tape. In contrast to TVTs, the self-fixating tip of the MiniArc® sling does not allow much correction after placement. This is why the MiniArc® sling should be placed at a distance of 0.5 cm from the mid-urethra (i.e. the distance between the tape and the urethra) without further intraoperative tensioning after placement.

The high rate of de novo urge is probably due to the mode of anchorage of the new tape, which has self-fixating tips. As a result, tension-free tissue integration is a challenge and depends on numerous factors such as tissue properties, insertion technique, tape position and retraction. Despite the standardized technique used in our study, it was not possible to eliminate de novo urge.

In the patients included in our study, de novo urge was treated with a combination of anticholinergic medication and physical therapy. Our findings do not allow any final conclusions to be drawn as to whether the rather high rate of de novo urge might be lowered by changing the insertion technique. The cure rates of 83.1.0% after six weeks and 77.8% after 12 months are good but not comparable to the rates achieved with established tape procedures. The poorer outcome may be attributable to the large proportion of patients with recurrent incontinence in our population and the inclusion of 13 (13.6%) patients with low-pressure urethra. Recurrent incontinence is likely attributable to scar formation or even rigid tissue integration of the tape, suggesting that the tape does not provide adequate dynamic support of the urethra. Another possible contributing factor is neurogenic damage. Established tape procedures are also known to have poorer results in patients with a low-pressure urethra (17-20). Outcome was poorer in women with prior incontinence surgery compared with the women who underwent the MiniArc® procedure as a primary intervention. We did not include a control group because we wanted each patient to have a choice to opt for any of the conventional treatments after comprehensive information about the new sling procedure. This is also why we chose a retrospective design.

The MiniArc® sling can be placed with minimal tissue injury and is easy to use. However, the instrument design leaves the surgeon with little control over tape positioning and injury cannot be excluded. Our preliminary experience suggests that the new tape appears to be associated with fewer complications in terms of organ damage and bleeding compared with established tape procedures for treating urinary incontinence.

The indications for MiniArc® insertion will be defined by its minimal invasiveness and the lower complication rates.

Further studies are needed to determine whether the new tape is beneficial in women with recurrent urinary incontinence or a low-pressure urethra. Future studies must also elucidate the causes of the high rate of de novo urge. Prospective randomized comparative controlled trials and long-term follow-up are needed to define the relative place of the new sling system in comparison with other mid-urethral tape techniques used for anti-incontinence surgery.

The patients who reported deterioration after the intervention used more pads than preoperatively, had greater involuntary urine loss (based on the voiding diary entries), and developed de novo urge (voiding frequency > 10/day).

Thirty-seven (38.2%) patients underwent the MiniArc® procedure as a primary intervention, 60 (61.7%) for recurrent urinary incontinence. Nevertheless, there were differences in outcome between these two groups.

CONFLICT OF INTEREST

None declared.

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EDITORIAL COMMENT

The evolution of anti-incontinence surgery has evolved from the retro-pubic colposuspension to the retro-pubic TVT, then to the trans-obturator TVT and now, possibly, to the mini sub urethral slings. The background rationale for these changes is the desire to maintain and further improve the therapeutic results, while reducing the operative related complications. Given that the current operations for the treatment of female urinary stress incontinence are far from being perfect in terms of cure and related complications, and that the industry is moving faster than the clinical trials, one is required to make personal decisions regarding the exact procedure for their patients with no sufficient data to rely on. Thus, one should be reluctant to endorse any newly launched surgical

technique, unless appropriate data is provided to support the efficacy and safety. Moreover, it might be misleading to believe that they the mini-sling is a very simple procedure to perform – it is not. Extremely important is proper training with about 20 training operations – and as for any other new surgical procedure, meticulous theoretical understanding of the pathophysiology, therapy and complication management and reduction is essential. Skill maintenance is crucial as well, and this might be achieved by doing 20 operations yearly.

For the time being there are no accepted well structured indications for different operations for sub-groups of the female urinary incontinent patients. Some surgeons believe that the retro-pubic

TVT are better for the ISD patients, the trans-obturator for obese patients and the mini-slings for the old and feeble. This is not supported by reported data,

neither are the long term efficacy and safety of these operations. Multi-centered prospective studies are essential for providing the world wide urogynecologic community with this reported data.

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EDITORIAL COMMENT

The introduction of the intravaginal sling (IVS) in 1996 has revolutionized the surgical treatment for female stress urinary incontinence (SUI) (1). Subsequent the minimal invasive suburethral slings replaced the colposuspension as surgical gold standard for SUI (2). In recent years, various slings with minor and major modifications have been introduced. The first major modification was the transobturator slings with reduced rates of bladder perforation (3,4). Lately the mini-slings followed. However, do we need this further modification to the existing and what is possible to improve?

With the mini-slings, external incisions can be eliminated, only a single vaginal incision is necessary. The mesh became shorter and no mesh lateral to the obturator is needed. Thus, the tissue trauma can be reduced and maybe also postoperative pain. The procedure time can possibly be shorten and less anesthesia are necessary. It is postulated, that the minis-lings are more minimal invasive than the retropubic and transobturatoric slings.

However, for a new surgical treatment of a non-life-threatening disease like SIU, the most important issue is to show better results, lower complication rates and a higher postoperative quality of life and patients' satisfaction as the established treatment options.

The first mini-sling, the TVT-secure, showed a steep learning curve but with some implant challenges and a high variability in efficacy (5,6).

In the article of Gauruder-Burmester and Popken results after the implantation of the newest mini-sling, the MiniArc, with a follow-up until 12 months postoperatively were published. The new sling seems to be very safe, but the cure rate is not better than the established gold standard. In addition, the authors report a high rate of de-novo-urgency. However, its cause remains unclear.

In total, the results look promising, but we need more data especially long-time data for a final assessment. Thus, prospective comparative randomized controlled trials with a long follow-up and evaluation of the quality-of-life and of the postoperative pain are necessary to determine its true efficacy.

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