Prospective Evaluation of a Single Incision Sling for Stress Urinary Incontinence

Michael J. Kennelly,*,† Robert Moore,‡ John N. Nguyen,‡ James C. Lukban§ and Steven Siegel‖

From McKay Urology Research, Charlotte, North Carolina, Atlanta Urogynecology Associates, Alpharetta, Georgia, Southern California Permanente Medical Group Female Pelvic Medicine & Reconstructive Surgery Obstetrics & Gynecology, Downey, California, Eastern Virginia Medical School, Norfolk, Virginia, and Metro Urology, St. Paul, Minnesota

Abbreviations and Acronyms

CST = cough stress test

IIQ-7 = Incontinence Impact Questionnaire-Short Form

LFCF = last failure carried forward

PWT = pad weight test

QOL = quality of life

SUI = stress urinary incontinence

TOT = transobturator tape

TVT = tension-free vaginal tape

UDI-6 = Urogenital Distress Inventory-Short Form

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* Correspondence: Urology Department, McKay Urology Research, 1023 Edgehill Rd. S., Charlotte, North Carolina 28207 (telephone: 704-355-7466; FAX: 704-355-8687; e-mail: michael.kennelly@carolinashealthcare.org).

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‡ Financial interest and/or other relationship with AMS.

§ Financial interest and/or other relationship with AMS, Novasys and Pfizer.

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Purpose: We report 12-month outcomes of the MiniArc™ single incision sling for stress urinary incontinence in women.

Materials and Methods: We performed a multicenter, prospective, single arm institutional review board/ethics committee approved study evaluating the effectiveness of the MiniArc sling after implantation via qualitative (Urogenital Distress Inventory-Short Form and Incontinence Impact Questionnaire-Short Form) and quantitative (1-hour pad weight test and cough stress test) measurements. Secondary outcome measures included procedural variables (procedure time and estimated blood loss), length of stay, perioperative complications, Wong-Baker Faces Pain Scale and adverse events.

Results: A total of 188 women with a mean age of 51.1 ± 10.6 years (median 50.4, range 25.9 to 79.6) were enrolled in the study. At 1 year 157 patients were available for analysis. Mean procedure time, estimated blood loss and length of hospital stay were 11.0 ± 6.7 minutes (median 10, range 2 to 55), 41.7 ± 47.0 ml (median 25, range 0 to 250) and 9.5 ± 14.1 hours (median 3.2, range 0.5 to 77.2), respectively. At discharge from hospital the mean Wong-Baker pain score was 1.3 ± 2.0 (range 0.0 to 10.0). Of the patients 90.6% had a negative cough stress test and 84.5% had a 1-hour pad weight test less than 1 gm at 12 months. Median Urogenital Distress Inventory-Short Form and Incontinence Impact Questionnaire-Short Form scores showed a statistically significant decrease ($p < 0.001$). Adverse events included urinary tract infection (4.3%), constipation (3.7%), temporary urinary retention (3.2%), dyspareunia (2.1%) and vaginal extrusion (1.6%).

Conclusions: The MiniArc single incision sling is a safe and effective first line surgical procedure for the treatment of female stress urinary incontinence. It demonstrated excellent patient tolerability with minimal pain, early return to normal activity and low morbidity. In addition to sustained efficacy outcomes at 12 months patients treated with the MiniArc experienced a significant improvement in quality of life.

Key Words: surgical procedures, minimally invasive; suburethral slings; urinary incontinence, stress

Stress urinary incontinence is estimated to affect up to 35% of adult women worldwide, leading to deterioration in QOL.[1] Traditional surgical therapies including retropubic colposuspension and autologous sling procedures have proven successful in treating SUI. However, these meth-

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ods are invasive and often require general or regional anesthesia in a hospital setting. The introduction of the retropubic TVT in 1996 revolutionized the treatment of SUI, providing a minimally invasive, ambulatory procedure with high cure rates.[2] However, retropubic tension-free tape procedures have been associated with a measure of attendant morbidity including bladder perforation, pain, voiding dysfunction, de novo urge incontinence, as well as more serious complications such as major vessel and nerve injury, and even death.[3]

The transobturator approach to the tension-free tape sling was developed to help minimize the morbidity associated with blind retropubic needle placement because passes are through the groin and obturator space away from the viscera and neurovasculature.[4] This approach is also thought to place the sling in a more natural position that mimics the pubourethral ligament, and its attachment to the levators and pelvic sidewall muscles. The transobturator approach appears to have efficacy comparable to that of the retropubic approach as demonstrated in various randomized and nonrandomized trials.[5–10]

Recently single incision mini-slings have been developed to limit the number of incisions and reduce the risks of blind needle passes through the groin or abdomen, yet mimic the position and results of the TOT sling. The MiniArc single incision sling system provides such a minimally invasive approach for the treatment of female stress urinary incontinence. It uses self-fixating tips that provide immediate fixation into the obturator muscles, thereby eliminating the need for a full-length transobturator mesh.

We evaluated the quantitative and qualitative effectiveness of the MiniArc single incision sling in females for the treatment of SUI in general postmarket use. Secondary objectives were to evaluate the procedural variables of implantation and safety. We report a 12-month interim analysis with followup ongoing for 2 years.

MATERIALS AND METHODS

An international, multicenter, prospective, single arm clinical trial was conducted at 16 centers (United States 13, Canada 1, Belgium 1 and United Kingdom 1) in women 18 years old or older with confirmed SUI. The protocol was approved by the institutional review board/ethics committee at each site and all participants provided written informed consent before enrollment.

To be eligible for inclusion women had to be 18 years old or older, desire surgical treatment for SUI and demonstrate 1 of the objective SUI criteria of 1) evidence of SUI on urodynamics, 2) a 1-hour pad weight test greater than 2 gm or 3) a positive CST (fig. 1). Exclusion criteria were previous synthetic sling, pelvic organ prolapse greater than stage 3, any coexistent pelvic pathology, pregnancy, primary urge incontinence or detrusor overactivity, renal insufficiency and/or upper urinary tract obstruction, increased post-void residual volume greater than 100 ml, blood coagulation disorder or morbid obesity (body mass index greater than 40 kg/m^2).

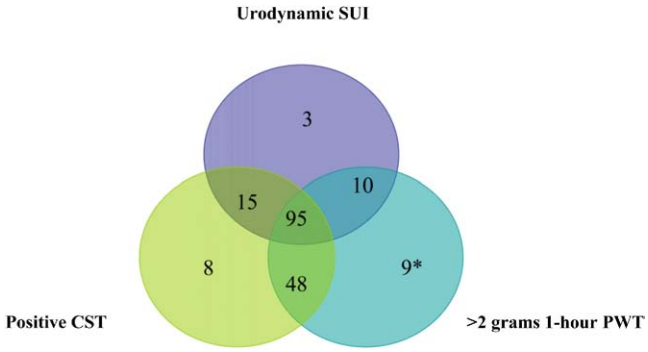

Figure 1. Baseline diagnostic SUI confirmation. Asterisk indicates 1 subject had 2 gm PWT.

Baseline evaluation included urogynecological history and physical examination, completion of the UDI-6 and IIQ-7, Wong-Baker Pain Scale, CST and 1-hour PWT. The CST protocol consisted of placing the patient in the lithotomy position and retrograde filling of the bladder with 250 ml normal saline. The patient was asked to cough 10 times and any leakage of fluid from the urethra was considered positive. The standardized 1-hour PWT was performed with 250 ml fluid in the bladder. Patients were asked to walk for ½ hour including climbing the equivalent of 1 flight of stairs up and down. For the remainder of the test patients had to stand up from sitting 10 times, stand and cough vigorously 10 times, run in place for 1 minute, bend to pick up small objects from the floor 5 times and wash hands in running water for 1 minute.

Patients were evaluated 7 days, 6 months and 12 months after surgery. CST, PWT, UDI-6 and IIQ-7 were completed at 6 and 12 months while safety data were assessed at each visit. The primary outcome measures analyzed were the number of patients with a negative CST and 1-hour PWT of 1 gm or less at 12 months. Subjective stress and urge incontinence at 12 months was determined by patient responses to the UDI-6 questions, "Do you experience urine leakage related to physical activity, coughing, or sneezing?" (question 3) and "Do you experience urine leakage related to a feeling of urgency?" (question 2), respectively. Bothersome symptoms were defined as responses of moderately or greatly. Other data collected included surgical location, anesthesia method, procedure time, estimated blood loss, length of stay, complications, and pain scores at discharge home and 7 days after surgery.

Statistical Analysis

For the purposes of this report objective efficacy from the CST and PWT was evaluated using the LFCF method, which carries forward objective failure at 6 months if the 12-month test results are missing. The LFCF analysis also considers cases with a revision for recurrent SUI within 12 months from the initial implant as failures regardless of the 6 and 12-month test results.

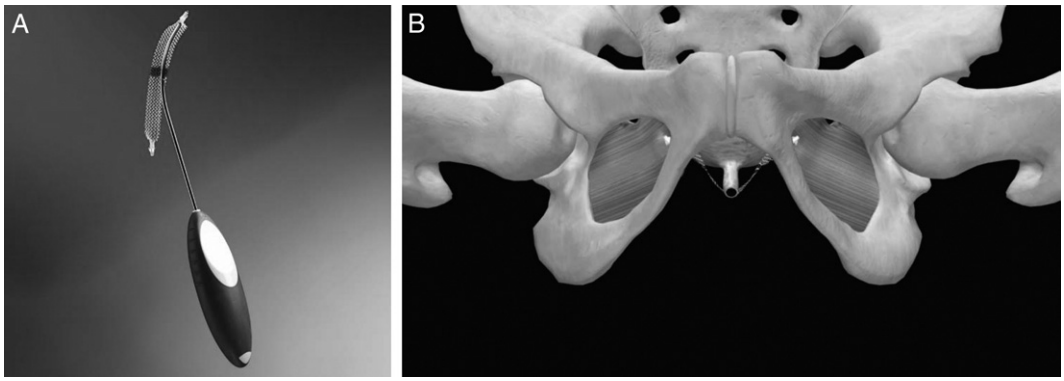

Figure 2. *A*, MiniArc needle and mesh. *B*, self-fixating tip anchors sling into obturator internus muscle, fixing it in hammock position.

Continuous variables were compared between baseline and 12 months with the paired t test (if the difference was normally distributed) or with the Wilcoxon signed rank test (if the difference was not normally distributed). Statistical significance was determined at the $p \leq 0.05$ level. All statistical analyses were performed using SAS® version 9.1.3.

Device Description

The MiniArc sling kit is comprised of a curved, 2.3 mm diameter needle that is used to deliver an 8.5 cm monofilament macroporous type I polypropylene mesh with small, integrated polypropylene self-fixating tips through a single 1.5 cm midurethral vaginal incision (fig. 2). The mesh with its integrated self-fixating tips assumes a hammock position on final placement.

Surgical Procedure

The sling was introduced through a single anterior vaginal incision of 1.5 cm at the mid-urethra with subsequent periurethral dissection using Metzenbaum scissors. The sling/needle assembly was advanced behind the ischiopubic ramus in a transobturator trajectory toward the obturator space bilaterally. The needle was removed after fixation of the integrated sling tip into the obturator internus muscle following penetration of the obturator internus fascia. This same step was repeated on the contralateral side. On sling placement further tension could be delivered by a re-docking feature providing access to the implanted tip placed on the initial side. The tensioning technique used was per surgeon discretion. The incision was irrigated and closed using delayed absorbable suture. Cystoscopy was performed at the discretion of the surgeon as was the administration of perioperative antibiotics.

Table 1. *Baseline study population characteristics*

		Median (range)
Mean parity (SD)	2.0 (1.0)	2.0 (0.0–8.0)
Mean kg/m^2 body mass index (SD)	27.9 (5.0)	27.5 (17.9–40.1)
No. menopausal (%)	97 (51.6)	
No. ethnicity (%):		
White	157 (83.5)	
Black	7 (3.7)	
Hispanic/Latina	24 (12.8)	
Mean UDI-6 score (SD)	49.8 (19.1)	44.4 (0.0–100.0)
Mean IIQ-7 score (SD)	43.8 (25.2)	40.5 (4.8–100.0)
Mean 1-hr pad wt (SD)	26.2 (38.2)	11.9 (0.0–246.2)

RESULTS

Baseline characteristics are shown in table 1. Of the 188 patients implanted 157 (83.5%) were evaluated at 12 months (fig. 1). Attrition was the result of loss to followup (7), withdrawal of consent (8) or missed visit (16). Of the 8 patients who withdrew consent in 4 this was due to sling failure.

Procedural data are shown in table 2. There were 3 reported intraoperative complications of vaginal wall perforation, conversion of monitored anesthesia care to general anesthesia secondary to airway difficulty and bronchospasm due to general anesthesia. The vaginal wall perforation was due to poor exposure of the sling placement site that was related to the choice of implant location (office). The perforation was managed by removing the initial tape and successfully placing a new sling during a different session at the hospital.

The CST and PWT efficacy rates at 12 months were 90.6% and 84.5%, respectively. The details of the LFCF analyses can be found in table 3. Median pad weight decreased from 11.9 gm (IQR 3.6, 30.0) at baseline to 0.0 (IQR 0.0, 0.5) at 12 months ($p < 0.001$). Four patients underwent a second sling procedure within the first year of followup, with 1

Table 2. *Procedural anesthesia data*

	Office	Hospital	Ambulatory Surgery Center	Totals
No. procedures	38	127	23	188
% General	0.0	44.1	5.3	49.5
% Intravenous	5.3	19.7	6.9	31.9
% Local	14.9	2.7	0.0	17.6
% Epidural	0.0	1.1	0.0	1.1
Totals (%)	20.2	67.6	12.2	100.0

Table 3. *LFCF efficacy analysis*

	CST	PWT
Subjects with 12-mo visit	157	157
Unable to complete or refused test at 12 mos	−2	−4
Completed 12-mo tests	155	153
Failures:		
Revision surgery for SUI	+4	+4
Failures carried forward from 6-mo visit	+1	+4
Pos test at 12 mos	+10	+17
Total failures	15	25
Successes:		
Neg test at 12 mos	145	136
Efficacy rate at 12 mos	145/(145 + 15) = 90.6%	136/(136 + 25) = 84.5%

receiving a retropubic sling and 3 receiving transobturator slings. Table 4 presents post hoc efficacy analysis by procedure location.

As shown in table 5 significant improvements occurred from baseline to 12 months in UDI-6 ($p < 0.001$) and IIQ-7 ($p < 0.001$) scores. The proportion of patients with improvement in the UDI-6 and IIQ-7 scores was 94.3% and 96.8%, respectively. Of those patients with bothersome urge urinary incontinence symptoms at baseline on UDI-6 question 2, 87.3% reported symptoms resolved at 12 months. De novo urge incontinence was reported in 7.7% of patients at 12 months based on UDI-6 question 2 as a change of a score at baseline of 0 or 1 to a score of 2 or more at 12 months. Based on the UDI-6 question 3, 89.9% of patients reported resolution of SUI symptoms at 12 months. Table 6 presents postoperative complications. Of the 6 patients with temporary urinary retention who required postoperative Foley catheterization 5 were under general anesthesia and underwent concomitant surgery. At the 7-day evaluation 96.8% of patients (181 of 187) reported normal voiding, 76.5% (143 of 187) considered themselves able to return to normal activities and median pain level was 0.0 (range 0.0 to 8.0).

DISCUSSION

The MiniArc sling was first introduced internationally in August 2007. The device was designed to simplify previous midurethral techniques, minimize complication rates related to needle passage and, most importantly, improve outcomes including QOL. Our prospective multicenter study demonstrated that the MiniArc procedure is quick and carries minimal patient morbidity without the significant blind passage of needles. Although not a comparative trial, MiniArc appears to have similar procedural data to the Monarc™ transobturator sling. In a prospective Monarc sling trial Moore et al reported a 13-minute procedure time, average estimated blood loss of 35 ml, a mean time to void without a catheter of 13 hours and 11% of patients needing a Foley catheter postoperatively.[11]

The patient tolerability of the MiniArc procedure in our study was highlighted by the short facility stay, minimal postoperative discomfort and quick return to normal activities. As a testament to the minimal invasiveness of the procedure and patient acceptability, our study demonstrated that MiniArc may be safely and effectively performed in an office setting (20% of the study population), often with the patient under only local anesthesia.

Several complications have been documented from the blind passage of needles in the retropubic space (major vascular, bowel, and bladder injuries) and obturator regions (groin/leg neuropathy, thigh abscess).[12,13] Although less invasive than retropubic slings, transobturator slings are not without risk. The development of clinically significant groin pain/leg neuropathy following inside-out transobturator slings was 24.4% initially and 3.7% in the long term.[14] The mesh is thought to undergo various

Table 4. *Results by procedure location*

	% Neg CST LFCF (No./total No.)	% PWT 1 gm or Less LFCF (No./total No.)
Office	91.2 (31/34)	97.1 (33/34)
Ambulatory surgery center	100 (18/18)	88.9 (16/18)
Hospital	88.9 (96/108)	79.8 (87/109)

Table 5. *Changes from baseline in UDI-6 and IIQ-7 scores*

	Baseline	12 Mos
UDI-6:		
Median (IQR)	44.4 (33.3, 61.1)	11.1 (0.0, 22.2)
Median change (IQR)		−33.3 (−50.0, −22.2)
IIQ-7:		
Median (IQR)	40.5 (23.8, 61.9)	0.0 (0.0, 4.8)
Median change (IQR)		−33.3 (−52.4, −19.1)

All values $p < 0.001$.

Table 6. *Postoperative complications*

	No. (%)
Urinary tract infection	8 (4.3)
Constipation	7 (3.7)
Pain/discomfort-other	6 (3.2)
Temporary urinary retention*	6 (3.2)
Urinary incontinence-de novo urge	5 (2.7)
Infection-vaginal	4 (2.1)
Dyspareunia	4 (2.1)
Urinary urgency	4 (2.1)

* Of the 6 patients 5 had general anesthesia and concomitant surgical repair.

form changes of ingrowth and fibrosis causing contracture and shrinkage of the material that may contribute to the leg neuropathy. No trauma to the urethra, bladder, bowel or blood vessels occurred during this study and no patients experienced a thigh abscess or leg neuropathy. By avoiding the transobturator space and the medial groin muscles MiniArc minimizes these complications as demonstrated by the current study. Although our study resulted in no bladder perforations, cystoscopy was only performed in 55.3% of cases. Surgeons may consider cystoscopy when first learning this technique or when the dissection is not straightforward.

There is a paucity of published data available and certainly to our knowledge no published comparative trials of the MiniArc. Our study success rates are consistent with what has been reported to date in other 12-month MiniArc and traditional transobturator sling series. In a retrospective MiniArc trial Moore et al reported an overall 12-month cure rate of 91.4% determined by physician and patient assessment in 58 of 61 patients.[15] UDI-6 total scores decreased from an average of 41.8 ± 24.9 preoperatively to 11.2 ± 13.8 postoperatively ($p < 0.001$). In a prospective multicenter trial on TOT DeRidder et al reported an 87.6% negative CST and a 1-hour pad weight decrease from 65.8 gm preoperatively to 9.5 gm 2 years postoperatively.[16] Improvements in global UDI-6 and IIQ-7 QOL scores were also statistically significant ($p < 0.001$). In a multicenter, randomized trial comparing retropubic TVT with TOT Barber et al reported similar negative CST results at 1 year (90% TOT and 91% TVT).[17]

Recent published data on the MiniArc by Gauruder-Burmester and Popken[18] and Debodinance and Delporte[19] have shown lower efficacy rates of 77.8% at 12 months and 75.7% at 2 months, respectively, as opposed to our 90.6% CST and 84.5% PWT success at 1 year. The factors that may have impacted lower efficacy rates in the articles by Gauruder-Burmester and Popken[18] and Debodinance and Delporte[19] may be due to patient selection (eg enrolling patients with failed prior sling procedures, low urethral pressure or intrinsic sphincter deficiency and mixed urinary incontinence). The patient population in our MiniArc prospective study was fairly homogeneous in that those with a prior failed synthetic sling were excluded from study, all had urethral hypermobility and only 5.9% (11 of 188) had mixed incontinence.

MiniArc effectiveness may be attributed in part to the design of the self-fixating tip and needle introducer. The small tissue tunnel delivery of the sling allows minimal tissue disruption with immediate and excellent tip fixation into the obturator muscles, minimizing early sling slippage and failure. Bench testing indicates that the average pull-out force to remove the MiniArc from the obturator muscle is 5.5 lbs of force (4 times the normal pelvic floor pressures of 1.3 lbs).[3,20]

However, our study has several limitations. It was not randomized for comparison to another conventional treatment for SUI to apply a more rigorous assessment. In addition, concomitant procedures were allowed in the study as per surgeon discretion. As a result the additional repairs may have impacted the effectiveness by perhaps altering urethral mobility and increasing the number of adverse events. Lastly there was no standardized tensioning technique for the MiniArc sling. Intraoperative cough testing to enhance continence efficacy was not uniformly used for tensioning because this hypothesis is controversial and not all investigators were familiar with this practice.[21–24] In our series less than half of patients underwent the procedure under general anesthesia. The intraoperative cough test was performed in 12.8% of cases. Although the study was not designed for this comparison, post hoc analysis did not demonstrate any efficacy differences between cases with general vs local anesthesia, or with or without intraoperative CST.

The study also has several strengths. It is a large, international, multicenter, prospective study design using up-to-date validated outcome measures. The use of subjective and objective outcome measures complies with National Institutes of Health recommendations for outcomes of urinary incontinence trials.[25] In addition, the study is designed for followup of an international patient population representative of the condition of female SUI.

CONCLUSIONS

Based on objective and subjective measures this 12-month prospective study demonstrates effective and safe treatment for SUI in women. The data showed excellent patient tolerability with minimal pain, early return to normal activity, low morbidity and a procedure profile that may allow for in-office placement. This multicenter prospective study shows encouraging results for the MiniArc sling as a first line treatment for female patients with SUI. Additional followup along with appropriately powered randomized comparative sling trials is warranted.

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