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ORIGINAL ARTICLE

Miniarc® single-incision sling for treatment of stress urinary incontinence: 2-year clinical outcomes

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Abstract
Introduction and hypothesis We report 2-year data on the effectiveness and safety of the MiniArc single-incision sling in women with stress urinary incontinence.
Methods This multi-center, prospective, single-arm, industry-sponsored study measured the effectiveness of the MiniArc sling via quantitative (cough stress test and 1-h pad weight test) and qualitative (Urogenital Distress Inventory-Short Form and Incontinence Impact Questionnaire-Short Form) measurements. The objective efficacy rate was defined as the number of patients with a negative cough stress test or 1-h pad weight test≤1 g at 2 years. The subjective efficacy rate was determined by patient responses to the UDI-6 question # 3, "Do you experience, and if so, how much are you bothered by urine leakage related to physical activity, coughing, or sneezing?" Secondary objectives were to evaluate procedural variables of implantation and long-term safety.
Results One hundred and eighty women with a mean age of 51.1 years were implanted in the study. Mean procedure time, blood loss, and length of stay were 11.0 min, 41.7 mL and 9.5 h respectively. At 2 years, 142 patients were available for analysis. The objective efficacy rates for the cough stress test (CST) and pad weight test (PWT) were 84.5 % and 80.1 % respectively and the subjective efficacy rate was 92.9 %. Median Urogenital Distress Inventory-Short Form and Incontinence Impact Questionnaire-Short Form scores showed statistically significant improvement ($p<.001$). The most common adverse events included UTI (4.8 %), constipation (3.7 %), and temporary urinary retention (3.2 %).
Conclusion MiniArc is a safe and effective surgical procedure for the treatment of SUI in women with follow-up through 2 years.

Keywords Single-incision sling · MiniArc · Stress incontinence

Abbreviations

AE	Adverse events
BMI	Body Mass Index
CST	Cough stress test
EBL	Estimated blood loss
EC	Ethics Committee
IIQ-7	Incontinence Impact Questionnaire-Short form
IRB	Institutional Review Board
LFCF	Last failure carried forward
LOS	Length of stay
MOS	Months
PWT	One-hour Pad Weight Test

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QoL	Quality of life
SUI	Stress urinary incontinence
UDI-6	Urogenital Distress Inventory-Short form
USI	Urodynamic stress incontinence
WBFPS	Wong-Baker Faces Pain Scale

Introduction

Stress urinary incontinence (SUI) is estimated to affect up to 35 % of adult women worldwide, leading to deterioration in quality of life of those affected [1]. Nearly 20 million adult women in the United States experience SUI, yet only half discuss it with a physician, and only 20 % of those who do speak up actually pursue treatment. Patients may believe that SUI is a normal consequence of aging or that few treatment options are available [2]. Over the past 10 years there has been an evolution in the treatment of this disorder trending toward less and less invasive techniques. The retropubic (TVT) and transobturator (TOT) minimally invasive slings are effective and relatively safe with cure rates of between 80 and 90 %; however, there are inherent risks associated with the external needle passes through the abdomen or the groin [3–5]. Randomized clinical trial data and a Cochrane review comparing TVT and TOT slings have demonstrated no significant differences between groups in terms of efficacy, postoperative urgency incontinence, satisfaction with the results of the procedure, or quality of life [6]. There was less voiding dysfunction, blood loss, bladder perforation and shorter operating time with the TOT route [7].

In 2007, the MiniArc® single-incision mini-sling was developed and released to the market to limit the number of incisions and reduce the risks of blind needle passes through the groin or abdomen, while mimicking the position and results of the TOT sling. Over recent years their use has been increasing worldwide as numerous observational cohort studies have shown minimal complications, quick recovery and 1-year efficacy within the range 85–90 % [8–10]. However, these studies have all been relatively short in nature with 1 year follow-up, and there is a need for studies with longer term follow-up to support their use.

The current study is a continuation of the previously reported 1-year results of a prospective multicenter trial of the MiniArc single incision sling [8]. We report on the durability of the procedure over longer term follow-up, specifically its efficacy, quality of life improvements, and long-term safety at 2 years' follow-up.

Materials and methods

This was an international, prospective single-arm industry-sponsored study performed at 16 centers (USA 13, Belgium 1, Canada 1, and UK 1) in women with confirmed SUI. The inclusion criteria for this study were age>18 years, desire for surgical correction of SUI, and objective demonstration of SUI by at least one of the following; urodynamic documentation of SUI; a 1-h pad weigh test>2 g; a positive cough stress test (CST).

Women with a previous synthetic sling, pelvic organ prolapse greater than stage 3, any coexistent pelvic pathology, pregnancy, primary urgency incontinence or detrusor overactivity, renal insufficiency and/or upper urinary tract obstruction, elevated post-void residual volume>100 mL, blood coagulation disorder, or morbid obesity (BMI>40 kg/m^2) were excluded.

The study was approved by the ethics committee (EC) or institutional review board (IRB) of each institution and each participant provided written informed consent prior to enrollment.

All patients underwent a preoperative clinical assessment including a detailed history and urogynecologic examination, documentation of SUI, standardized CST with 250 mL in the bladder and 1-h standardized pad weight test (PWT). Patients also completed the Urogenital Distress Inventory-Short Form (UDI-6) [11], Incontinence Impact Questionnaire-Short Form (IIQ-7) [11], and the Wong Baker Faces Pain Scale (WBFPS) [12].

The MiniArc single-incision sling system (AMS, Minnetonka, MN, USA) provides such an approach for the treatment of female SUI, employing self-fixating tips that provide immediate fixation into the obturator internus muscles, eliminating the need for a full-length transobturator mesh. The mesh is an 8.5-cm-long macroporous polypropylene tape that is anchored in place via self-fixating tips into the obturator internus muscle bilaterally via a small (1.5 cm) vaginal incision at the mid-urethra. The mesh, with its integrated self-fixating tips assumes a "hammock" position upon final placement. The surgical procedure was performed as previously described with patients under general, intravenous sedation (IV) or only local anesthesia [10]. No standardized tensioning technique was employed. The tensioning technique was per surgeon discretion. However, all surgeons in the study placed the sling flat against the urethra with no spacing.

Patients were evaluated at 7 days, 6 months, 12 months, and 24 months after surgery. Cough stress test, PWT, UDI-6, and IIQ-7 were completed at 6, 12, and 24 months while safety data were assessed at each visit.

The objective efficacy rates of MiniArc were measured by the number of patients with either a negative CST or PWT≤1 g at 24 months. The 24-month subjective efficacy rate was determined by the number of negative patients' response to the UDI-6 question "Do you experience, and if so, how much are you bothered by urine leakage related to physical activity, coughing, or sneezing?" (Question 3). Other data collected included surgical location, anesthesia

method, duration of procedure, length of stay (LOS), estimated blood loss (EBL), adverse events and pain scores at discharge and at 7 days post-surgery. Baseline subjective urgency incontinence and the incidence of subjective de novo urgency incontinence was determined by patient's response to the UDI-6 question, "Do you experience, and if so, how much are you bothered by, urine leakage related to a feeling of urgency" (Question 2) and by patient self-reported de novo urgency incontinence as an adverse event. Baseline presence of urgency incontinence symptoms was defined as responses of "moderately" or "greatly" on the UDI-6, Question. The number of patients who responded "not at all" or "slightly" at baseline and "moderately" or "greatly" at 24 months. De novo urgency incontinence was also captured as an adverse event if the patient self-reported urgency incontinence during any of the follow-up visits.

Statistical analysis

Objective efficacy from the CST and PWT were evaluated using last failure carried forward (LFCF). The LFCF analysis carries forward a patients' latest objective failure (e.g. 6 or 12 months) if their 24 months' test results are missing, and also considers patients who had a subsequent reoperation for SUI as failures.

Continuous variables were compared between baseline and 24 months with paired t-test (if the difference was normally distributed) or Wilcoxon signed rank test (if the difference was not normally distributed). Fisher's exact test was used to compare the efficacy rates between groups. Statistical significance was determined at the $P \leq 0.05$ level. All statistical analyses were performed using SAS, version 9.1.3 (SAS Institute, Cary, NC, USA).

Results

From (September) 2007 to (June) 2008, 188 patients with confirmed SUI were enrolled into the trial. The baseline demographic and clinical characteristics are detailed in Table 1. The median number of patients implanted per site was 11 (range: 1–20). One hundred and fifty-one patients (80.3 %) had a MiniArc only procedure and 37 patients (19.7 %) had a concomitant procedure performed. Of the 188 patients implanted, 142 (75.5 %) were evaluated at 24 months. Attrition was caused by patients being lost to follow-up (23), withdrawing consent (16), and (7) by failure of the sling. The 7 patients with sling failures had secondary sling surgery (5 transoburator and 2 retropubic slings; Fig. 1).

The mean operative time was 11.0 min, mean EBL was 41.70 mL, mean LOS was 9.5 h, and mean immediate postoperative pain score 1.3, as per the WBFPS (Table 2). The majority of procedures were done in the hospital (67.6 %) and under general anesthesia (49.5 %). However, 20.2 % (38 patients) had the MiniArc sling performed in the office under local anesthesia/IV sedation.

Table 1 Baseline characteristic of study population (N=188)

Characteristics	Total (N=188)
Age (years)	
Mean±SD	51.1±10.6
Median (minimum to maximum)	50.3 (25.9–79.6)
Ethnicity	
Caucasian (%)	157 (83.5 %)
Black/African American (%)	7 (3.7 %)
Hispanic/Latina (%)	24 (12.8 %)
BMI (kg/m^2)	
Mean ± SD	27.9±5.0
Median (minimum to maximum)	27.5 (17.9–40.1)
Menopausal status	
Post-menopausal (%)	97 (51.6 %)
Parity	
Mean ± SD	2±1
Had a hysterectomy?	
Yes (%)	58 (30.9 %)
Type of stress incontinence	
Urethral hyper-mobility (%)	169 (89.9 %)
Intrinsic sphincter deficiency (%)	8 (4.3 %)
Both (%)	11 (5.9 %)
Experienced urge symptoms?	
Yes (%)	127 (67.6 %)
1- Hour PWT	
Mean ± SD	26.2±38.2
Median (minimum to maximum)	11.9 (0.0–246.2)
UDI-6 score	
Mean ± SD	49.76±19.13
Median (min - max)	44.44 (0.00–99.99)
IIQ-7 score	
Mean ± SD	43.79±25.19
Median (minimum to maximum)	40.47 (4.76–99.99)

There were three reported intraoperative complications. One subject was transferred from intravenous sedation to general anesthesia secondary to airway difficulty; one subject experienced bronchospasm due to general anesthesia, and one subject had a vaginal wall perforation owing to poor operative exposure in the office. This procedure was terminated and the subject was implanted with MiniArc 7 days later in the hospital.

The CST and PWT objective efficacy rates at 24 months were 84.5 % and 80.1 % respectively and the subjective efficacy rate was 92.9 %. The details of the LFCF analysis can be found in Table 3. The median pad weight decreased from 11.9 (IQR: 3.6, 30.0) at baseline to 0.0 (IQR: 0.0, 0.6) at 24 months (p<0.001). With regard to MiniArc as a standalone procedure

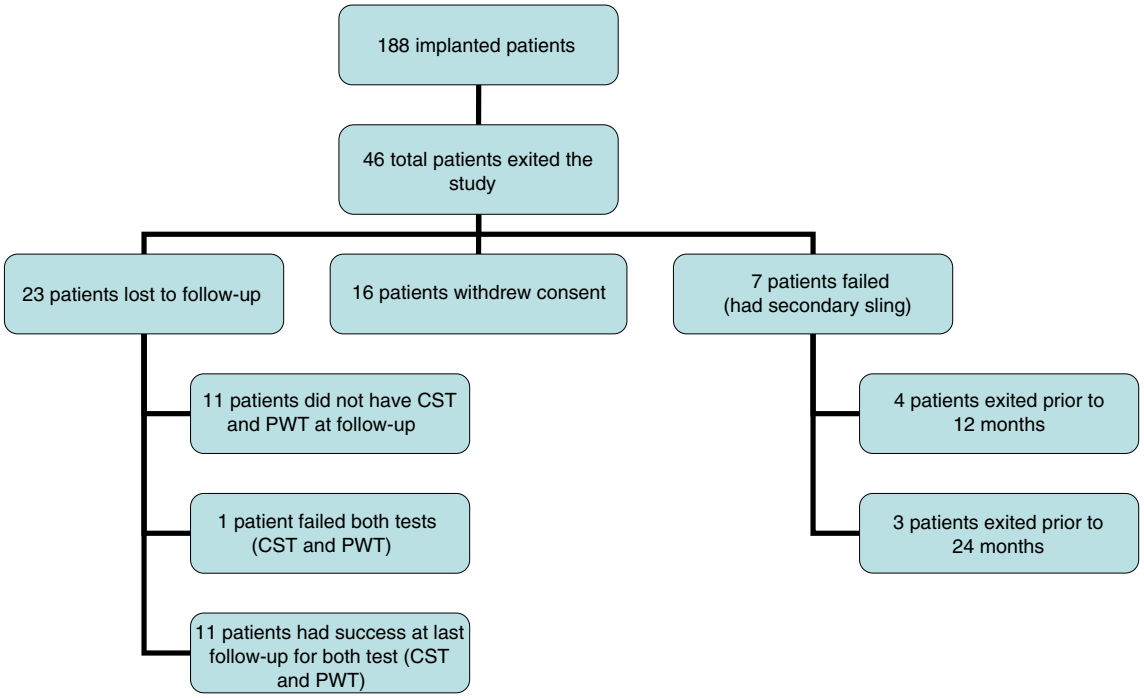

Fig. 1 Study subject distribution tree. *CST* cough stress test, *PWT* pad weight test

or concomitant procedure, post hoc efficacy analysis showed no statistical difference for both the CST and the PWT via Fisher's exact test (p=0.373 for CST; p=0.425 for PWT).

Table 2 Procedural parameters study population (N=188)

Parameters	Total (N=188)
Postoperative pain (WBFPS)	
Mean ± SD	1.3±2.0
Median (minimum to maximum)	0.0 (0.0–10.0)
Was a concomitant procedure performed?	
Yes (%)	37 (19.7 %)
No (%)	151 (80.3 %)
Length of stay (h)	
Mean ± SD	9.5±14.1
Median (minimum to maximum)	3.1 (0.5–77.2)
Estimated blood loss during study treatment (mL)	
Mean ± SD	41.7±47.0
Median (minimum to maximum)	25.0 (0.0–250.0)
Duration of study treatment (min)	
Mean ± SD	11.0±6.7
Median (minimum to maximum)	10.0 (2.0–55.0)
Total time duration of study treatment including anesthesia (min), mean ± SD	
General anesthesia	38.6±40.1
Local (only)	31.1±20.5
IV sedation	14.0±7.9
Other (no general, no IV, not local only)	34.5±20.5

As shown in Table 4 significant improvements occurred from baseline to 24 months in UDI-6 (p<0.001) and IIQ-7 (p<0.001) scores. The proportions of patients with improvement in the UDI-6 and IIQ-7 scores were 90.1 % and 95.7 % respectively. Of those with bothersome urgency urinary incontinence symptoms at baseline on UDI-6 question #2, 80.3 % of patients reported symptom resolution at 24 months. De novo urgency incontinence was reported in 10.0 % of patients at 24 months based on the UDI-6, question 2. There was no significant change in the de novo urgency rates of patients who reported de novo urgency at 12 months (6/78, 7.7 %) and at 24 months (7/70, 10 %).

Table 3 Efficacy objective results based on last failure carried forward (LFCF)

LFCF		Success	
	Total	*N* (%)	Exact 95 % CI
CST			
12 months	160	145 (90.6 %)	85.0–94.7 %
24 months	142[a]	120 (84.5 %)	77.5–90.0 %
1-h PWT			
12 months	161	136 (84.5 %)	77.9–89.7 %
24 months	146[b]	117 (80.1 %)	72.7–86.3 %

[a] The denominator of 142 reflects 134 subjects who attended the visit and completed the CST+8 failures that were carried forward

[b] The denominator of 146 reflects 134 subjects who attended the visit and completed the PWT+12 failures that were carried forward

Table 4 Changes from baseline in (UDI-6) and (IIQ-7) validated questionnaires

Questionnaire	Baseline scores median (IQR)	24 months scores median (IQR)	Median change (IQR)
UDI-6	44.4 (33, 61.1)	5.6 (0.0, 22.2)	−33.3 (−50.0, −22.2)
IIQ-7	40.5 (23.8, 61.9)	0.0 (0.0, 4.8)	−33.3 (−47.6, −19.1)
UDI-6 Questionnaire			Percentage of patients answered "Yes" at baseline
UDI-6, question #2 (Do you experience, and if so, how much are you bothered by, urine leakage related to a feeling of urgency?)			83 %
UDI-6, question #3 (Do you experience, and if so, how much are you bothered by urine leakage related to physical activity, coughing, or sneezing?)			99 %

Postoperative complications through 1 year have previously been reported [8]. There were no additional complications that occurred from 12 to 24 months and the only device-related adverse events>2 % were self-reported urgency incontinence—de novo (4.3 %), temporary urinary retention (3.2 %), UTI (2.7 %), dyspareunia (2.1 %), and urgency (2.1 %). Table 5 lists all reported adverse events throughout the 2-year follow-up period.

Discussion

To our knowledge, this report is the first prospective, multicenter trial evaluating the 2-year effectiveness and safety associated with the MiniArc single incision sling. At 2 years, the MiniArc's objective efficacy rates for the CST and PWT were 84.5 % and 80.1 % respectively and the subjective efficacy rate was 92.9 % as measured by UDI-6 question 3. Improvements in global UDI-6 and IIQ-7 quality of life scores were also statistically significant ($p<0.001$).

Although there have been limited published reports on the MiniArc, the majority of the studies (all ≤1 year) have been consistent with successful cure rates seen in the current report. Moore et al. reported a 12-month overall cure rate of 91.4 % (58 out of 61 patients) determined by physician and patient assessment defined by improved UDI-6 scores and resolution of SUI symptoms [13]. In contrast, Deole et al. [14] reported the results of 74 patients who underwent the MiniArc procedure in a single-center case series. The objective cure rate (negative cough stress test) was 66 % in 59

Table 5 Postoperative complications

Adverse event	No. of events	Relationship						Total (N=188)		Resolved events	
		Possible		Probable		Definite					
	n	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%
Urinary tract infection (UTI)	10	8	4.3	1	0.5			9	4.8	8	80.0
Urinary incontinence—de novo urge	8	8	4.3					8	4.3	1	12.5
Constipation	7	1	0.5	6	3.2			7	3.7	7	100.0
Urinary retention	6	2	1.1	3	1.6	1	0.5	6	3.2	6	100.0
Pain/discomfort—other	6	2	1.1	2	1.1	1	0.5	5	2.7	5	83.3
Infection—Vaginal	4	2	1.1	1	0.5	1	0.5	4	2.1	4	100.0
Dyspareunia	4	2	1.1	1	0.5	1	0.5	4	2.1	1	25.0
Urinary urgency —De Novo	4	4	2.1					4	2.1	1	25.0
Extrusion	3			2	1.1	1	0.5	3	1.6	1	33.3
Pain/discomfort—urogenital	3			1	0.5	2	1.1	3	1.6	2	66.7
Other	3	2	1.1	1	0.5			3	1.6	2	66.7
Reaction to medication	2			2	1.1			2	1.1	2	100.0
Pain/discomfort—leg	2	1	0.5			1	0.5	2	1.1	2	100.0
Dysuria	3	2	1.1					2	1.1	1	33.3
Urinary frequency	2	2	1.1					2	1.1		
Urinary urgency	2	1	0.5	1	0.5			2	1.1	1	50.0

patients who completed the 1-year evaluation. However, in this study a forceps handle was used as a spacer between the sling and urethra during tensioning, which may have resulted in lower efficacy rates.

Several studies have also directly compared MiniArc with either retropubic or transobturator midurethral slings. In a randomized controlled trial, Basu and Duckett performed the MiniArc in 38 women and TVT in 33 women with stress incontinence. The postoperative outcomes were based on subjective evaluation (e.g. PGI-I and King's Health questionnaires). This study found the MiniArc to be associated with a significantly higher rate of persistent SUI (6 weeks, OR 9.49, 95 % CI 2.8–32.6; 6 months OR 8.14, 95 %, CI 2.7–24.7) and of urodynamic stress incontinence (OR 7.58, 95 % CI 2.7–24.7) at 6 months [15]. Detailed patient factors including prior surgical failures, intrinsic sphincter deficiency patients, or tensioning methodology were not mentioned.

In contrast, De Ridder et al. [9] compared the MiniArc with the Monarc and reported a much higher objective cure, defined as a negative CST, in 85 % of patients following MiniArc and 89 % following Monarc slings (no statistical difference in cure rates) with significant improvement in UDI-6 and IIQ-7 scores. The longest follow-up of a comparative trial was reported by Enzelsberger et al. [16]. Ninety stress-incontinent women were randomly treated with either the MiniArc or the Monarc sling. After 2 years, the continence success rates for the two groups were 82 % (MiniArc) and 86 % (Monarc). The results showed no significant difference in success rates. Lastly, in a randomized controlled trial reported by Oliveira et al., the MiniArc yielded 12-month cure rates (87 %) similar to that of TVT-O (83 %) and superior to that of TVT Secur (67 %) in women treated for SUI [8].

The majority of these studies to date have reported cure rates similar to traditional transobturator and retropubic slings. However, in the studies that have shown lower cure rates various factors may have been involved. The variability in subject factors (inclusion of intrinsic sphincter deficiency patients, prior failed surgical patients, obesity, etc.) and tensioning methodologies make true comparison between studies difficult. Appropriate tensioning is an important factor in achieving optimal success as per the study investigator consensus. The MiniArc sling should be placed flat and snug at the mid-urethra with no spacing. In addition to variable subject factors and tensioning techniques, various definitions and measures of success (subjective vs objective, cough stress test, pad weight, urodynamic, pads, etc.) between studies could affect the efficacy rates reported.

Our study has several limitations that warrant discussion. First, we acknowledge that our study population is a non-homogeneous group, which may confound the interpretation of results. Although all patients demonstrated SUI, they only needed to demonstrate SUI via only one of the objective measurements (CST, PWT, and urodynamics). In addition, certain concomitant procedures were allowed as per surgeon discretion in the study. Both of these factors may confound the interpretation of results and should be noted. Because our trial excluded patients with concomitant stage 3 or 4 prolapse, the clinical outcomes for the treatment of SUI and significant prolapse conditions should not be extrapolated from these results. Second, no baseline symptom measures or threshold bother scales were utilized for inclusion criteria. Although this study used validated questionnaires (UDI-6 and IIQ-7) for subjective cure measurements, it is possible that patients might still have urine leakage, but are not bothered by it. Third, the 25 % attrition rate at 2 years could have certainly had an impact on the clinical outcome. To account for this effect, our statistical plan utilized the LFCF methodology. Other potential limitations to the study that should be noted are its single-arm, non-randomized design, varied surgeon experience with the MiniArc, possible patient selection bias per investigator, and unbalanced enrollment per site. Finally, regarding the de novo urgency incontinence rate, we feel that the results should be interpreted with caution as two methods were utilized. The de novo urgency incontinence rate of 10 % was determined solely by the subjective scoring of question 2 of the UDI-6 and the rate of 4.3 % was determined by self-reported urgency incontinence during follow-up.

The strength of this study is that it is the largest, international multi-center prospective study with greater than 1-year follow-up with standardized objective and subjective outcome measurements in patients with uncomplicated SUI. Most studies use the completer method, which evaluates the results of patients who completed a follow-up visit. Our study utilized the LFCF method, which is more conservative in comparison to completer analysis. The LFCF carries forward failures. The study primary endpoint was to evaluate functional improvement after the implantation of the MiniArc via objective (CST and PWT) and subjective measurement (UDI-6). The ideal objective test for SUI measurement is debatable; hence, our study utilized two methods. We acknowledge the limitations of the PWT in that patients who have urgency incontinence during the test will register false-positive for SUI. Potentially, this may have accounted for the variability in our CST and PWT 2-year efficacy rates. Because of the limitations of objective testing, one must not forget about a subjective assessment. In addition to impressive objective efficacy, our study demonstrated 92.9 % subjective efficacy at 2 years.

Apart from this study, there is a paucity of data on the effectiveness of other single-incision slings. We believe that the MiniArc's effectiveness can 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 internus 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 (four-times the normal pressure of 1.3 lbs transmitted by a cough to the pelvic floor) [4, 17].

Although there are no published 2-year results on the MiniArc with which to compare the results of this study, other mid-urethral slings have demonstrated similar efficacy rates via objective and/or subjective outcomes at the 2-year follow-up [18–20]. Long-term (beyond 2 years) clinical evidence on effectiveness and durability is valuable in confirming short-term (less than 1 year) results, especially in counseling individual patient expectations.

Conclusion

Based on quantitative objective and qualitative subjective measures this 2-year prospective, international, multicenter trial demonstrates that the MiniArc is effective and safe for treating SUI in women. The procedure is associated with minimal perioperative and postoperative pain, low morbidity, and resulted in significant improvement in patients' quality of life. At 2 years, there was no statistical significant change from the 1-year to the 2-year objective and subjective outcomes. Subjective outcomes remained very successful with a cure rate at 92.9 %. There are further long-term studies under consideration to continue the long-term evaluation of the MiniArc.

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