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6 MONTHS AND 1 YEAR CLINICAL OUTCOMES OF THE MINIARC™ SINGLE-INCISION SLING: A MULTI-CENTER PROSPECTIVE STUDY

Hypothesis / aims of study
To evaluate the effectiveness and safety of the MiniArc sling, a minimally invasive urethral sling for the treatment of Stress Urinary Incontinence (SUI) in women at 6 months and at 1 year.

Study design, materials and methods
In a multi-center, prospective, cohort study designed, 151 subjects with documented SUI were implanted with the MiniArc sling only. At baseline, 6 months, and 1 year all patients completed the UDI-6 and IIQ-7. Along with a Standardized 1-hour pad weight test and cough stress test (+CST). A standardized procedure for placement of the MiniArc sling which utilized a single mid-urethral vaginal incision (1.5cm) and placement of the sling (polypropylene, monofilament) along a transobturator trajectory into the obturator internus muscles. Intra and peri-operative parameters collected included estimated blood loss (EBL), length of stay (LOS) and pain scores at discharge. Adverse events were also collected. Follow-up data at 6 months (132 subjects) and 1 year (73 subjects) is reported. At 6 months and 1 year, UDI-6 and IIQ-7 mean scores were compared to baseline using the Paired t-test and Wilcoxon Signed Rank tests; the McNemars test was used for the CST and the 1-hour pad weight tests.

Results
The average age was 51 years (32, 79 range) and mean body mass index was 27.6 kg/m^2 (17.9, 40.1 range). The median LOS was 2.8 hours. The median EBL was 25 mL. At discharge, subjects reported a mean pain score of 0.78 ± 1.23 (0, 5 range) per Wong-Baker Faces Pain Scale (range from 0-10). At the 7 days evaluation, 99% of subjects reported normal voiding with the mean pain level at 0.6 ± 1.2 (0, 7 range).

Table1. Baseline, 6 month and 1 year outcomes

	baseline	**6 month**	**1 year**	p value
UDI-6	49.2±18.0	13.7±15.0	10.6±13.0	p<.001
IIQ-7	41.6±23.5	5.4±13.9	4.0±11.5	p<.001
Question #2 UDI-6 – improvement of urgency		81% (89/110)	83% (50/60)	
# of subjects with de novo urge		4	1	
CST	CST (+) 87% (131/151)	CST (-) 91% (105/115)	CST (-) 95% (59/62)	P<.0001
Mean Pad wt	25.5±35.6	5.7±28.9	0.4±1.0	p<.001
Pad wt <1gm		98% (98/125)	91% (62/68)	P<.001

Comment [AS1]: we can also report it as 4/22=18% and 1/12=8% to be consistent with the format in the table

The adverse events greater than 1% reported are: UTIs (3), dyspareunia (3), and extrusion (2). There was 1 intra-operative complication (vaginal wall perforation).

Interpretation of results
At 6 months, results showed short facility stay and minimal EBL and low pain levels. The objective results and QOLs showed marked and significant improvements in subjects. The MiniArc procedure to date shows promising results to be confirmed with the full data set at 1 year.

Concluding message
The MiniArc sling system is effective at treating SUI at 6 months with minimal morbidity and few adverse events. In addition, this study demonstrated short facility stay, minimal EBL and low pain levels. Significant improvements in both subjective and objective measures of continence are seen. Subjects in the MiniArc™ study will continue to be followed for twenty-four months. .

Specify source of funding or grant	**This study was sponsored by American Medical Systems**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**Yes**
Specify Name of Public Registry, Registration Number	**ClinicalTrials.gov Identifier: NCT00541151**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Health Authority: United States: WIRB Institutional Review Board and Local IRB review boards (full details of local IRB's can be provided upon request if needed); UK: South Glasgow and Clyde Research Ethics Committee; Europe: Commissie voor Medische**

	Ethiek Klinisch Onderzoek
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**