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EXPERINCE WITH THE MINIARC™ SINGLE INCISION SLING SYSTEM FOR THE TREATMENT OF STRESS URINARY INCONTINENCE

Hypothesis / aims of study
Controversy exists over the success and durability of the single incision sling (MiniArc™) for the management of stress urinary incontinence (SUI) in women. As such it is the aim of this study to report outcomes of patients treated with the MiniArc™ single incision sling system at our single institution with regards to symptoms related to SUI, urgency, overall quality of life, and sexual function.

Study design, materials and methods
A prospective analysis of patients with SUI who underwent surgical intervention with the MiniArc™ Single Incision Sling System was performed. Longitudinal data was collected at follow-up with regards to success defined as completely dry, number of pads per day required pre and post-op, number of pain pills used, and complications of surgery. In addition patients were sent an envelope and were asked to fill out and return a quality of life questionnaire, a female sexual function index (FSFI), an IIQ-7 and UDI-6 form. Patients at one year out from surgery had their forms compared to those at their one month follow-up. The quality of life questionnaire was used to determine who would be considered a treatment failure at one year. Statistical analysis was performed.

Results
From September 2007 to March 2010, a total of 342 patients underwent placement of a MiniArc™ Single Incision Sling System with no concomitant procedures. 312 patients have follow-up data of which 190 have at least one year follow-up data. Patient age ranged from 26-88 years old with a mean of 52.7. 143 patients (42%) had moderate to severe urgency and or urge incontinence preoperatively. Mean Body Mass Index (BMI) was 28.3 with a range of 18.7-48.3. Preoperative pad use averaged 3.4 per day per patient. Mean IIQ-7 and UDI-6 scores were 2.6 and 2.5 per question respectively. At one month 298 patients were totally dry with 9 patients >50% improved. Initially there were only 5 treatment failures. At one year follow-up, 175 responders (92%) were completely dry, 11 responders (6%) were >50% improved, and 4 (2%) reported bothersome SUI. Average pads per day at one year was 0.2 ($p<0.005$). Average IIQ-7 scores were 0.3 ($p<0.005$) and average UDI-6 scores were 0.3 ($p<0.005$) at one year. The number of pain pills used postoperatively was found to be 1.5. Average quality of life scores went from 4.2 preoperatively to 8.8 at one year postoperatively. Based on FSFI results, 51% of our patients never had discomfort with intercourse, 7% had occasional discomfort, and 2% always had discomfort. 40% of our patients were currently sexually inactive. Operative complications included: 3 bladder perforations treated with a Foley catheter for 24 hours, 5 episodes of retention of which 4 resolved without surgical intervention. There were no vaginal or urethral erosions.

Interpretation of results
Our results show that even after one year most patients continue to have improved quality of life scores, durable continence rates, and minimal adverse events.

Concluding message
Based on our experience, treatment outcomes with the MiniArc™ Single Incision Sling System are durable at one year. Quality of life is significantly improved with minimal impact on sexual function.

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Is this a clinical trial?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**IRB University of Tennessee-Knoxville**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**