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MINIARC SINGLE-INCISION SLING FOR STRESS URINARY INCONTINENCE

Hypothesis / aims of study
The MiniArc single-incision, midurethral sling is a minimally−invasive treatment for stress urinary incontinence (SUI) due to urethral hypermobility (UHM). The aim is to evaluate outcomes with respect to efficacy for treatment of SUI and to assess potential impact on sexual function.

Study design, materials and methods
A registry of MiniArc slings performed from February 2008 to February 2010 was reviewed. Patients were routinely evaluated preoperatively for baseline data, and postoperatively at 3-5 days, 2 weeks, 3, 6 & 12 months. Follow up (F/U) visits consisted of interval symptom history evaluation, physical exam, direct visual stress test (DVST), catheterized postvoid residual assessment (PVR), catheterized urinalysis (UA) with subsequent urine culture (UCx) as necessary, and validated questionnaires: Urinary Distress Inventory (UDI-6), Incontinence Impact Questionnaire (IIQ-7), Global Quality of Life Question (QOL), Female Sexual Function Inventory (FSFI), Sexual Distress Scale (SDS) and Prolapse-Incontinence-Sexual Questionnaire (PISQ-12).

Results
A total of 320 slings were performed and evaluated. Mean age 53 years (26-88). Concurrent prolapse repair was performed in 64. All MiniArcs were done as an outpatient procedure unless a concurrent procedure was performed. Median surgical time was 10 minutes and median EBL <10cc. There were 6 UCx proven UTIs at 2wks. Subjective reports of postoperative pain within the first 2 weeks were minimal. Median PVR was <10cc (drops – 1100cc). Sling revisions due to obstruction were required in 7 patients (2%). Mean F/U was 10 months (2weeks-24months). At last F/U, 15 patients (7%) had rare, mild SUI, but only two of these patients with mild leak demonstrated on DVST. At baseline, 160 patients complained of overactive bladder (OAB) with urge incontinence (UI) and 78 required anti-cholinergic medication. Postoperatively, 37 patients experienced persistent OAB/UI symptoms, and 32 continued to require anticholinergics. Mild de-novo OAB was noted in 5 patients (1.5%). Significant improvements were noted on pre and post UDI-6 [total as well as sub-totals for urgency (questions 1 & 2) and SUI (questions 3 & 4)], IIQ-7, and QOL questionnaires ($p<0.05$). There were no mesh-related extrusion/erosion or infections. No pain was elicited on postoperative transvaginal palpation along the trajectory of the sling during physical exam. No reports of dyspareunia related to the sling. One patient reported occasional irritation over the healing ridge of the vaginal incision during intercourse with certain sexual positions which resolved with time. No significant differences were noted on FSFI (totals or domain-specific subtotals) or SDS ($p<0.05$). Significant improvement in total PISQ-12 was noted owing to improvements in incontinence and prolapse domains ($p<0.05$).Two patients noted transient postoperative sexual arousal and orgasmic difficulty. One patient's problem was due to pelvic congestion from enlarged fibroids noted on post-PDE5-I MRA/MRI. Her sexual pain completely resolved and orgasms ultimately improved after hysterectomy. The other patient improved after proper education about sexual anatomy (location of the clitoris) and physiology. Postoperative biothesiometry for genital sensitivity testing was normal in both patients.

Interpretation of results
All patients in this registry were cured (93%) or significantly improved (7%) with regard to SUI. Complications were low with no reports of significant postoperative pain, no mesh extrusion/erosion or infection, denovo OAB 1.5%, postoperative obstruction requiring re-operation for sling revision only 2%, and no reports of dyspareunia.

Concluding message
The MiniArc single-incision, midurethral sling is an excellent minimally-invasive treatment (both subjectively and objectively) for SUI due to urethral hypermobility with excellent patient satisfaction. It is not associated with dyspareunia or other impediments to sexual function. On the contrary, improvements in sexual function were noted following MiniArc relating to cessation of coital incontinence and/or sexually inhibiting fear thereof. Results thus far appear to be durable. Registry continues to assess more long-term (2 yr) outcomes.

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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	**Health East IRB**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**