MiniArc™ Single-Incision Sling System: A new minimally invasive single-incision sling for treatment of female SUI

R.D. Moore[1], T. Erickson[2], B. Feagins[3], JR Miklos[1], S. Serels[4], D. Van Drie[5]

[1]Atlanta Center for Laparoscopic Urogynecology, Atlanta, GA
[2]Rosemark Womancare Specialists, Idaho Falls, ID
[3]Dallas Center for Pelvic Medicine, Dallas, TX
[4]Urology Associates of Norwalk, Norwalk, CT
[5]Female Pelvic Medicine in Urogynecology Institute of Michigan, Grand Rapids, MI

Abstract

Objective: To evaluate the safety and effectiveness of a new minimally invasive single-incision sling with no retropubic or groin needle passage for the treatment of female stress urinary incontinence (SUI).

Methods: A multi-center retrospective evaluation of 60 female subjects from five centers in the United States that underwent placement of the MiniArc™ Single-Incision Sling System (AMS Minnetonka, MN, USA) for treatment of SUI. Data for this clinical summary include all subjects who had MiniArc procedures beginning March 1, 2007 and were seen for follow-up visits through August 10, 2007. The MiniArc sling kit is comprised of an 8.5 cm monofilament

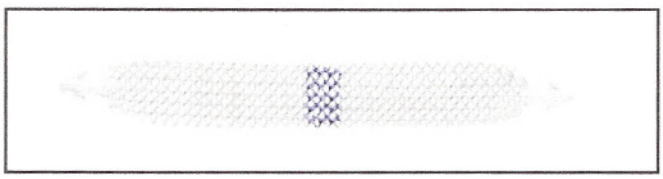

Figure 1. Depiction of MiniArc™ Sling.

macroporous Type I polypropylene mesh (same mesh as utilized for Monarc® and SPARC®) with small, integrated self-fixating tips that are made of polypropylene, and a curved needle that inserts into the self-fixating tip for advancement and placement of the sling. See Figure 1 for a depiction of the MiniArc sling.

Patient Selection: Female subjects 21 years and older who underwent treatment for genuine SUI due to urethral hypermobility and/or intrinsic sphincter deficiency with the MiniArc sling were included in the study. The first 5-20 consecutive subjects to receive a MiniArc at each site were evaluated. There were no specific exclusion criteria, as each individual surgeon included their consecutive subjects that they deemed candidates for the procedure. Retrospective chart review was performed and data was collected on the pre-operative evaluation, including cough stress test and urodynamics as performed and recorded by the investigator. Subjects with concomitant procedures (e.g. pelvic organ prolapse) were included in this data collection.

Procedure: Subjects were taken to the operating room and placed in dorsal lithotomy position. Anesthesia was chosen by the physician and included either general anesthesia, epidural or MAC with injection of local anesthetic. The suburethral tissues were infiltrated with a local anesthetic solution and a 1.5 cm suburethral incision was made. This incision is identical to the incision made for Monarc transobturator sling or other similar tension-free vaginal tape slings. The vaginal epithelium was dissected off the underlying suburethral tissues out to the pelvic sidewall, adjacent to the posterior surface of the ischiopubic ramus. This dissection follows the same path of the Monarc sling but is made only slightly larger than the mesh to avoid full dissection. The tunnel that is created should be only large enough to ensure the mesh lies flat under the urethra and to avoid "button holing" the vagina. The obturator internus fascia and muscle then can be injected with the local anesthetic solution, if necessary. To aid in the placement of the sling, a mark may be made on the subject's skin just inferior to where the adductor longus tendon meets the pubic ramus. This is the same location the Monarc technique uses to introduce its needle. The MiniArc blunt needle tip is then inserted into the sling's self-fixating tip to advance the sling into place. The sling/needle assembly is then placed into the dissected tunnel and directed towards the obturator space into the obturator internus muscle. See Figure 2. While advancing, the needle tip should be kept in close proximity to the posterior surface of the ischopubic ramus. This is similar to the "hammock" type position of the Monarc transobturator sling. Once the pelvic sidewall is penetrated, i.e. the obturator fascia and muscle, the needle is advanced until the midpoint of the sling is at the mid-urethra, or just beyond the mid-urethra. The needle is then easily removed by simply sliding it back out of the fixating tip. Due to the tip's slip-fit design, the sling does not move while disengaging the needle from the sling.

The needle is then placed into the other self-fixating tip, and the sling is introduced into the contralateral side. The needle is slowly advanced into the obturator internus muscle until a tension-free adjustment is completed under the mid-urethra. The design of the self-fixating tip and curved needle provide the surgeon with excellent control in advancing the needle to obtain precise tension-free adjustment