

## **MINIARC SINGLE INCISION SLING:1 YEAR FOLLOW-UP ON A NEW MINIMALLY INVASIVE TREATMENT FOR FEMALE SUI**

### Hypothesis / aims of study

The mid-urethral tension-free vaginal tape sling has emerged as the gold standard to treat female stress urinary incontinence (SUI). The transobturator approach was then developed to reduce risks of retropubic needle passage. Most recently, the mini-sling has been developed in attempts to place the sling without any needle passages through the abdomen or groin. The current study was conducted to report on the technique, safety and early efficacy of a single-incision mini-sling to treat female SUI.

### Study design, materials and methods

Women suffering from SUI were offered a single-incision approach to place a sub-urethral polypropylene mesh tape in a position similar to that of a transobturator sling without passage of needles through the groins. The sling is comprised of a Type I polypropylene mesh, with self-fixating tips on each end that anchors the sling into the obturator muscle and fascia. Retrospective data was collected on the first 61 patients that underwent the new MiniArc (American Medical Systems, Minnetonka, MN) single-incision sling at our specialty center in the United States. All patients had urodynamic proven SUI. Patient selection and concomitant procedures were determined by the senior authors at the center. The senior authors (RDM, JRM) were the primary surgeons in all cases. Procedures were completed under general, regional, or MAC anesthesia as determined by the surgeon.

### Results

Sixty-one patients underwent the Mini-arc single incision sling. 92% of patients had concomitant procedures for prolapse during the same setting. Average age was 58 years (range 26-84) and average LPP was 71.3. Average operative time for the sling procedure alone was short and average blood loss was 29cc. There were no intra-operative complications. There was one post-operative adverse event secondary to urinary retention which was resolved by loosening of the sling under local anesthesia in an office setting. Significant urge symptoms were present in 55% of patients pre-operatively and only 14% post-operative (75% resolution of urge symptoms). Overall cure rate at 12 months determined by physician and patient assessment in 58/61 patients was 91.4%. No patients suffered pain or dyspareunia secondary to the sling and no erosions or extrusions were reported.

### Interpretation of results

The MiniArc mini-sling is an excellent minimally invasive alternative to mid-urethral tension free slings that appears to have a similar cure rate with less risk than either retropubic or transobturator approaches. The sling is placed in a hammock type position and is anchored through the same muscle and fascia as the TOT sling, however does not pass through the groins minimizing risks of groin pain. The sling has a self-fixating tip that anchors the sling to the sidewall with excellent immediate fixation, which we feel helps assist in the high cure rate that was achieved in the current study.

### Concluding message

In this initial study, the MiniArc single-incision sling appears to be a safe approach to treat female SUI and the early clinical results are encouraging with 12 month cure at 91.4%. A multicenter US prospective trial is ongoing.

<b><i>Specify source of funding or grant</i></b>	<b>None</b>
<b><i>Is this a clinical trial?</i></b>	<b>Yes</b>
<b><i>Is this study registered in a public clinical trials registry?</i></b>	<b>No</b>
<b><i>What were the subjects in the study?</i></b>	<b>HUMAN</b>
<b><i>Was this study approved by an ethics committee?</i></b>	<b>Yes</b>
<b><i>Specify Name of Ethics Committee</i></b>	<b>Sterling IRB</b>
<b><i>Was the Declaration of Helsinki followed?</i></b>	<b>Yes</b>
<b><i>Was informed consent obtained from the patients?</i></b>	<b>Yes</b>