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# ONE AND THREE YEARS FOLLOW UP AFTER MINIARC SINGLE-INCISION SLING ® OPERATION FOR URINARY STRESS INCONTINENCE.

### Hypothesis / aims of study

The cure rate after MiniArc Single-incision Sling ® operation for urinary stress incontinence has not been studied in detail previously. The aim of the study was to determine the cure rate of this operation and compare this with the results of the Swedish national registry for incontinence operations.

# Study design, materials and methods

A prospective consecutive cohort study of all patients operated with MiniArc Single-incision Sling ® from American Medical Systems (AMS).

Typically, a small 1.5cm incision is made in the anterior vaginal wall followed by periurethral dissection after application of local infiltrative anesthesia. The needle is inserted toward the obturator foramen and retracted to deploy the Sling Tip. The second Sling Tip is inserted into the contralateral side toward the obturator foramen. The needle is advanced until appropriate tension is achieved.

Since 2009 all patients operated for urinary incontinence in were registered in the national registry. All women received standard questionnaires after eight weeks and one year. The questionnaire are; A. Do you have incontinence? Never, almost never, 1-3 time a months, 1-3 time a week, daily. B. Do you have leakage during physical activity? Never, almost never, 1-3 time a months, 1-3 times a week, daily. C. Do you have over active bladder? Never, almost never, 1-3 time a months, 1-3 times a week, daily. D. How many Pads do you use? None, 1-3 per week, 4-6 per week, 1-4 per day, more than 4 per day. F. Postoperatively do you fell, Much better, better, the same, worse or much worse. G. Are you satisfied of the postoperative results. Very satisfied, satisfied, the same, worse, much worse. All patients operating in the whole country will answer the same questionnaire why it is possible to compare the results.

#### Results

Since 2009 we operated 145 women with SUI or mixed incontinence with MiniArc Single-incision Sling and only 3 patients did not respond to the postoperative questionnaire follow-up. The postoperative follow up after 1 year showed 74% (n=108/145) had no incontinence episode and furthermore 8% had episodes less than 1-3 time per months, a total. 88% (n=127/145) answered that they did not have leakage during physical activity. 19% (n=28) of all women included did use pads at least once a day. In total 86% (n=125/145) were satisfied with the operation results and only 3% were not satisfied. The patients felt better in 96% and only 2% reported no change and 3% felt that they were worse.

In comparison, 2238 women from the Swedish national incontinence registry have answered the same questionnaire operated 2011-2012. The incontinence operations performed were: 56% -TVT-retropubic, 19% - TVT-O (inside-out), 22% -TOT (outside-in) and 3% mini-slings. The results show that 67% had no incontinence episodes and 19% had leakage 1-3 times per month. 83% were satisfied and 7% became worse.

45 women operated with MiniArc Single-incision Sling ® between 2008 - 2009 were interviewed using the same questions as above 3 years postoperatively. 96% were either satisfied or very satisfied after the operation furthermore 89% had no leakage and 80% had no urge.

Operation related complications were minimal. There was one case of bladder perforation that was recognized and sutured before the sling introduced. One patient was diagnosed with urethral erosion eight months postoperatively due to increased du novo urge. The intraurethral part of the mesh was removed and she was later operated with TVT-retropubic procedure.

## Interpretation of results

The results from the MiniArc Single-incision Sling ® shows slightly better results compared to the results from the Swedish national registry for incontinence operations.

## Concluding message

In our opinion, the MiniArc Single-incision Sling ® has as at least as good results as the other TVT procedures and can be used for the treatment for SUI. The MiniArc is more simple and easier to perform than the traditional TVT procedure and can be performed on an office procedure.

### References

 Kennelly MJ, Moore R, Nguyen JN, Lukban JC, Siegel S Prospective evaluation of a single incision sling for stress urinary incontinence. J Urol. 2010 Aug;184(2):604-9. doi: 10.1016/j.juro.2010.04.003. Epub 2010 Jun 19.

# **Disclosures**

**Funding:** The study has been financed with grants form FoU found in Skaraborgs Hospital Skövde. Sweden The AMS has arranged educations for the MiniArc surgery as well as operations for the Elevate Mesh but no other financial support **Clinical Trial:** Yes **Public Registry:** No **RCT:** No **Subjects:** HUMAN **Ethics Committee:** Gothenburg Regional ethics committee, Sweden **Helsinki:** Yes **Informed Consent:** Yes