

QUALITY OF FIXATION OF MINISLING AJUST

Hypothesis / aims of study

This study aimed to describe site of fixation and quality of fixation of the mini-sling Ajust™ and describe possible complications that might occur during this procedure.

The mini-slings were introduced as a modification of current treatment of female stress urinary incontinence in 2006. The concept of mini-slings was to eliminate foreign material, easing the procedure to be carried out under local anesthesia with achieving the same efficacy as previous generations of tension free vaginal tapes. However the first mini-sling TVT-Secur™ did not reach expectations of surgeons as the proper insertion was rare [1].

As different types of tapes and mini-slings have different fixation point it is essential to test whether correct fixation of the tape can be easily achieved and if the way of insertion poses risks of complications. The path of the tape might be influenced by the position of the legs [2] - therefore we have examined different position of the legs. There is no scientific evidence about insertion of the Ajust™ or about the efficacy of this method.

Study design, materials and methods

This study was aimed to describe anatomical localization of the fixation tips of the Ajust™ mini-sling.

We have used a group of eleven formalin embalmed bodies (FE) with legs positioned in 30°flexion and 30°abduction and second group of five fresh frozen bodies (FF) with legs positioned as during the normal procedure. This would allow us to compare the results if they differ.

The insertion was performed by an urogynecologist well trained to carry out Ajust™ same as other previous methods. After insertion, abdominal dissection was carried out to describe the path and location of the fixation tips. Distances from important structures were measured.

The distance to the obturator nerve was considered as a primary safety parameter. For evaluation of the location we have considered the obturator membrane as the desired fixation point. Obturator muscles we considered as possible but less favorable insertion point. As a failure we have considered insertion without proper fixation – in example prevesically. The placement into obturator internus muscle was considered as a less favorable insertion due to the fact that is not so firm as the obturator membrane. Insertion of the tip deeply to obturator externus muscle was also considered as a failure due to creating greater hole with the inserter in the obturator membrane and therefore the anchor might fail to hold properly.

For comparison of the groups we have used Student's t test and Mann-Whitney test, p value less than .05 was considered as statistically significant.

Results

The mean distance from the anchoring point to the obturator nerve was in the group of formalin embalmed bodies 4.23mm with the SD 0.88mm. The same distance in the group of fresh frozen bodies was 3.15mm with the SD 0.51mm. There was statistically significant difference (p value less than .05) between the group of formalin embalmed and fresh frozen bodies based on Student's t test. No statistical significant difference was found in comparison of the sides in each group.

In the group of formalin embalmed bodies the anchor was placed within the complex of obturator muscles and membrane in nineteen cases out of twenty-two. In two cases the inserter was not correctly attached and was found in lesser pelvis prevesically. In the group of fresh frozen bodies the inserter was placed within the obturator muscles or membrane in nine cases out of ten and once we have found the anchoring point prevesically in lesser pelvis.

Interpretation of results

The acceptable placement into obturator membrane or obturator muscle is more than 85% of the cases. It seems to us, that despite of failing place the anchor just into the obturator membrane that the obturator muscle could be sufficient anchoring point. Answer to this will bring reports of clinical efficacy.

Concluding message

The anchoring point of the mini-sling Ajust™ was in all cases more than two centimeters away. Correct placement into the obturator membrane happened in more than 60% of the cases and in more than 85% of the cases the anchor was placed in obturator muscles or the membrane. There was statistical significant difference between group of formalin embalmed bodies and fresh frozen bodies – however to confirm this findings, we would need to increase number of bodies in each group.

References

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2. Hinoul P, Vanormelingen L, Roovers JP, de Jonge E, Smajda S (2007) Anatomical variability in the trajectory of the inside-out transobturator vaginal tape technique (TVT-O). Int Urogynecol J Pelvic Floor Dysfunct 18:1201-1206

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<i>What were the subjects in the study?</i>	NONE