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## THE USE OF AVAUTA PLUS® FOR ANTERIOR REPAIR. A MULTICENTER RANDOMISED PROSPECTIVE CONTROLLED STUDY.

### Hypothesis / aims of study

It is well-known that the recurrence rate following anterior vaginal wall prolapse is 20-40%. In order to avoid this complication implantation of mesh in the anterior vaginal compartment has gained more interest and most studies report a decreased recurrence rate. However, these studies have also observed an increased complication rate, especially erosions and dyspareunia. Recently, it was demonstrated that implantation of Prolift® was associated with an increased frequency of stress urinary incontinence (1).

Although there are a large number of studies evaluating the effects of mesh surgery for anterior vaginal wall prolapse, surprisingly few studies are performed as a randomized controlled study. We therefore established a Nordic study group in order to evaluate the effect of Avaulta Plus® for surgical treatment of anterior vaginal wall prolapse. The Nordic multicenter randomized study has been design to evaluate the incidence of erosions, pain perception, urinary tract symptoms and sexual function following mesh implantation. All patients were allocated to either conventional anterior repair or implantation of Avaulta Plus® mesh. The patients are followed for three years with clinical examinations and standardized questionnaires. All measurements have been in accordance with Pelvic Organ Prolapse Quantification (POP –Q). The study was approved by the local Ethics Committee. The study was not supported financial by any funds or company. The present study presents the first three months follow-up data.

### Study design, materials and methods

Avaulta Plus® Anterior Biosynthetic System is a monofilament, polypropylene mesh coated in the central part with a porous, a cellular crosslinked collagen barrier. The polypropylene mesh is made of small fibers, which provide a thin cross section of the mesh without loss of strength. The thin cross section may also decrease the size of encapsulation. The central part, but not the outer limit of the polypropylene mesh is covered with a layer of porcine collagen. Patients randomized to Avaulta Plus® underwent a standardized trocar-guided vaginal procedure. The anterior colporrhaphia was performed using a midline incision, and the bladder was dissected for the vaginal mucosa by blunt or sharp dissection. The pubocervical fascia was plicated using intermittent 2-0 absorbable sutures. Excess vaginal mucosa was excised. The vaginal mucosa was closed using a running resorbable unlocked suture.

150 patients are planned to be enrolled in the present randomized clinically controlled study. Exclusion criteria was age < 55 years, previous vaginal surgery and prolapse of the uterus more than stage  $\leq 2$ . In total 75 patients were available for the present three months follow-up analysis. Of these 40 were randomized to a conventional anterior repair and 35 to Avaulta Plus®.

### Results

The anterior colporrhaphy and the Avaulta Plus® groups were comparable regarding age (63yr +/- 8 vs 64 +/- 7 yr), mictions per day (8.7+/-2.6 vs 8.6+/-3.8), residual urine (43ml+/- 57 vs 31 +/-33), leakage times per day (0.6 +/-1.3 vs 1.5 +/-3.9), Ba (1.8cm+/-1.2 vs 2.4+/-1.3) but not Aa (0.9cm+/-1.4 vs 1.7+/-1.3, p=0.05). The surgical procedure was significantly prolonged in the Avaulta Plus® group (30+/- 13 min vs 46+/-12). In average 71% vs 74% of the patients were discharged within 24 hours. The postoperative pain perception was equal in the two groups until day three. Both the pain perception and the use of analgetics were significantly lower in the anterior repair group from day three and remained decreased during the rest of the week (observation period) except at day six, where the two groups had the same consumption of pain killers.

Three months follow-up disclosed no difference between the groups regarding urinary frequency per day, incontinence episode frequency or residual urine, but Aa and Ba were significantly improved in the Avaulta Plus® group (-1.7 +/- 1.1cm vs -2.8+/-0.36 and -1.3 +/- 1.2 vs -2.8+/-0.36, respectively). Five patients (15%) had an erosion following Avaulta Plus®. There was no difference between the two groups regarding infection, de novo stress incontinence or voiding difficulties.

### Interpretation of results

Although our results are preliminary we observed a more anatomically correct position of the anterior compartment following the Avaulta Plus® procedure. However, since we do not have the subjective cure-rate this may not have any importance for the patient's wellbeing. Furthermore we observed a high erosion rate. This may be due to learning difficulties. Any conclusions regarding the importance of the positon of Ba and erosion rate have to wait for the three year follow up. Surprisingly, we did not observe an increased number of patients with stress urinary incontinence as observed in Prolift studies (1). This may be due to a different size of the two meshes.

### Concluding message

The present study demonstrates that the objective cure rate is increased following the Avaulta Plus® procedure, but was associated with a high erosion rate. Whether the improved anatomy is favourable for the patients has to await the three years follow-up. We did not observe a higher incidence of de novo stress incontinence as observed by others following mesh implantation.

## References

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<b>Is this a clinical trial?</b>	Yes
<b>Is this study registered in a public clinical trials registry?</b>	Yes
<b>Specify Name of Public Registry, Registration Number</b>	17.431
<b>Is this a Randomised Controlled Trial (RCT)?</b>	Yes
<b>What were the subjects in the study?</b>	HUMAN
<b>Was this study approved by an ethics committee?</b>	Yes
<b>Specify Name of Ethics Committee</b>	Den regionale videnskabsetiske komitte for region Sjælland (The regional etichs committee for regions Sealand, Denmark)
<b>Was the Declaration of Helsinki followed?</b>	Yes
<b>Was informed consent obtained from the patients?</b>	Yes