

## TWO YEAR FOLLOW UP OF SEXUAL FUNCTION SYMPTOMS AND QUALITY OF LIFE SYMPTOMS AFTER AN INNOVATIVE PROCEDURE - AVAULTA SYNTHETIC MESH FOR PELVIC ORGAN PROLAPSE

### Hypothesis / aims of study

Avaulta™ BioSynthetic support system (Bard) repair is one of the latest and most innovative methods in pelvic floor surgery relying on an advanced synthetic implant with biological coverage to support defective vaginal walls. The technique has shown to be reproducible and adequately corrects compartment defects (1). In this study we qualified and quantified patient perception of outcomes and success, independent of medical opinion or surgical success

Observational studies on monofilament polypropylene mesh implants have shown that the anatomical recurrence rate is lower after the use of mesh material as compared to classical prolapse repair without mesh.

### Study design, materials and methods

Our prospective study at the University Hospital of North Staffordshire in United Kingdom involved the prospective recruitment of 40 patients in 2007 who underwent anterior and/or posterior Avaulta Plus™ BioSynthetic support system (Bard) repairs.

Women with Stage II or more prolapse equivalent to POPQ staging were invited to participate in this study. Women with primary prolapse surgery were excluded from the study. Women requiring anterior or/and posterior compartment repair or with prolapse of the vaginal vault in the opinion of the assessing surgeon were included in the study. Conventional Urodynamic study was performed on subjects with urinary incontinence prior to surgery. If a tension-free vaginal tape (TVT) was required this was undertaken at the start of surgery. Validated ICIQ-VS (International Consultation on incontinence modular questionnaire – Vaginal symptoms (ICIQ- VS) (2) was used to analyse and quantify the various types of symptoms. The questionnaire was filled in the clinic pre operatively. The questionnaire done again during 6 weeks post operative follow up. And it was repeated again two years post operatively by postal questionnaire. Severity of different symptoms was assessed using an Visual analog scale (VAS) of zero to ten.

### Results

Main outcome measures were subjective success, sexual function, Quality Of Life (QoL) outcomes and patients' satisfaction at 6 weeks and 2 years. Secondary outcome measures were complications.

Comparison between baseline and 2 years data was analysed using a paired *t* test. The women also completed a visual analogue scale (VAS) of their bother of vaginal and sexual symptoms. This is considered a clinical surgical audit, and formal ethical approval was not required.

**Table 1**

Patient demographics and details of previous pelvic operations	
Variables	Result
Mean age (SD)	67.2 (±9.1)
Mean BMI (SD)	26.4 (±6.3)
Mean parity (SD)	2.2 (±1.4)
<b>Previous surgery</b>	<b>n (%)</b>
Hysterectomy	30(75%)
Vaginal repair	5(12.5%)
Abdominal Sacrocolpopexy	3(7.5%)
Sacrospinous fixation	2 (5.0%)

**Table 2**

Details of surgery performed for pelvic organ prolapse	
Surgery	n (%)
Anterior Avaulta	16 (40.0%)
Posterior Avaulta	21 (52.5%)
Anterior and posterior Avaulta	3 (7.5%)
<b>Concomitant surgical procedures</b>	
TVT	4 (10%)

### Interpretation of results

**Table 3**

Summary of satisfaction with surgery and QOL outcomes				
Outcome measures	Preoperative	6 weeks	2 years	P value
	<i>n</i> = 42	<i>n</i> = 40	<i>n</i> = 40	
Mean VAS	8.3 (±2.0)	3.5(±2.1)	3.2 (±2.1)	
Mean QOL (SD)	1.99 (±0.80)	1.28(±0.54)	1.34 (±0.52)	<0.0001

Using ICIQ-VS we assessed different variables such as dragging pain in vagina(60% improvement),vaginal soreness( 70% improvement) , vaginal laxity(80% improvement),sensation of vaginal lump(90% improvement),exteriorisation of lump (90% improvement), necessity of digitation to defecate (60% improvement), Vaginal dryness (40% improvement),tightness in vagina (10% improvement), interference of vagina with sex life (60% improvement), effect on relationship with the partner due to vaginal symptoms (60% improvement), sex life spoilt by the vaginal symptoms (decreased by 50% ) and overall quality of life (90% improvement) noted. Pre operatively the average VAS score was 8.3 (SD ± 2.0) and at 6 weeks it was 3.5(±2.1) and at 2 years the VAS is 3.2 (±2.1).There was an obvious improvement. The QOL domain improved from 1.99 (±0.80) preoperatively to 1.34(± 0.52) at 2 years (*P* < 0.0001).

**Table 4**

Postoperative complications	
Complication	<i>n</i> (%)
Mesh exposure	2 (5%)
Stress incontinence	2 (5%)

**Table 5**

Further surgery	
TVT	1( 2.5)%
Anterior avaulta	3(7.5%)
Posterior avaulta	2(5%)

### **Concluding message**

Many older adults are sexually active and it should not be under estimated. Our study demonstrated good improvement with sexual function symptoms therefore an improvement of patient lifestyle quality. The results of surgery described in this study compare favourably with the results of abdominal sacral colpopexy and vaginal sacrospinous fixation(3). Studies reporting on the use of mesh placed vaginally reported success rates of 94–100 %. This study reports encouraging outcomes with the surgery described. Further clinical studies, including comparative studies, are required to establish the role of this surgery.

### **References**

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2. Development and psychometric evaluation of the ICIQ Vaginal Symptoms Questionnaire : the ICIQ-VS. Authors, Price N.;Jackson S.R.;Avery K.;Brookes S.T.;Abrams P.;BJOG May 2006
3. Maher CF.Abdominal sacral colpopexy or vaginal sacrospinous colpopexy for vaginal vault prolapse: a prospective randomized study. Am J Obstet Gynecol. 2004;190:20–6.

<b>Specify source of funding or grant</b>	<b>not applicable</b>
<b>Is this a clinical trial?</b>	<b>No</b>
<b>What were the subjects in the study?</b>	<b>NONE</b>