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ANATOMICAL AND FUNCTIONAL OUTCOMES OF A SUBINTESTINAL SUBMUCOSA (SURGISIS) GRAFT TO AUGMENT ANTERIOR REPAIR. A PROSPECTIVE OBSERVATIONAL STUDY.

Hypothesis / aims of study

Failure of surgery for anterior compartment prolapse is a reality facing every pelvic floor surgeon and for this reason a number of modifications to the traditional colporrhaphy technique have been introduced over the past decade. Many of these include the use of synthetic mesh based devices. These biomaterials have brought a significant improvement in outcomes but many surgeons have remained reluctant to embrace these new techniques due to very real concerns relating to the issues of infection, erosion, pain and dyspareunia associated with these synthetic mesh products. The biological grafts have the advantage of a reduction in these risks. Data regarding the outcomes of anterior compartment surgery using the porcine subintestinal submucosal graft (SIS) is currently limited. The only two case control studies in the literature on this product have conflicting outcomes with one reporting significant improvements (1) and another smaller study (2) showing no difference. The biological grafts have not been shown to improve outcomes in the posterior compartment (3). The aims of this study were therefore to prospectively assess the anatomical and functional outcomes of anterior compartment prolapse surgery reinforced with the SurgiSIS subintestinal submucosa graft.

Study design, materials and methods

This was a prospective cohort study undertaken in a single centre. Pre-operatively, subjective symptoms were recorded including prolapse, stress incontinence, urgency, sexual dysfunction, defaecatory difficulty and digitation. Women were examined and prolapse was staged according the ICS POP-Q system. This was repeated at 6weeks, 6 months, 12 months and 24 months. The PFDI and PISQ-12 questionnaires were completed pre-operatively and at 6 months, 12 months and 24 months. The surgical technique for the anterior compartment involved placing 4 sutures on the pelvic sidewall, following the arcus tendineus fascia pelvis (white line) on both sides. Two of these are within 1 centimetre of the ischial spine, marked as A and B. A third is placed half way between the ishial spine and the symphysis pubis (marked as C), and the last one lateral to the urethra on the para-urethral ligaments (marked as D). Only Maxon 0 (monofilament polytrimethylene carbonate) suture material is used. Sutures A and B are used for the re-anchoring of the severed bladder base sideways onto the white line- correcting the para vaginal defects and the centrally prolapsed anterior vaginal wall. With three sutures (Maxon 0) the base of the bladder base is re-attached to the cervix or vault, closing the high transverse defect usually present. SurgiSIS is placed over the bladder base, anchored by the same sutures A, B C and D. Utilizing B and the three sutures on the cervix, the SurgiSIS is pulled laterally and inferiorly to form a scaffold running from ischial spine to ischial spine.

Results

Sixty –two women underwent anterior compartment surgery with SurgiSIS augmentation. Pre-operatively, 46 (74%) women had greater than stage 2 prolapse on ICS POP-Q scoring of the anterior compartment with a mean value of point Ba of 0.27 (-2 to +6, SD 1.33). The patients in this cohort generally had good pre-operative apical support with only 5 (9%) having a point C greater than stage 1. The women in our cohort had had a number of previous operations including vaginal hysterectomy 2 (3.2%), TAH 9 (14.5%), anterior repair 7(11.3%), posterior repair 6 (9.7%) and colposuspension 3 (4.8%). Of the 62 women in our cohort, 41 (66%) had concurrent posterior repair, two had a TVT-O procedure and four (6.5%) had a vaginal hysterectomy. There were no intra-operative bladder or bowel injuries in our cohort. Mean intra-operative blood loss was 148ml (range 20-600, SD +/-113).

Only two (3.4%)women had greater than stage 1 anterior compartment prolapse at six weeks. At six and 12 month follow up only 3 (6.3%) women had stage one or greater and at one year all women were a maximum of grade 1 in the anterior compartment with none progressing to a stage 2. At six week follow up, only one woman (1.7%) had symptoms of prolapse (table 2). Five women (10.6%) at six month follow up complained of prolapse with one woman (3.7%) having prolapse symptoms at one year. These symptoms were most likely related to a posterior compartment prolapse recurrence. Six (13%) of those women followed up at six months had a posterior point Ap of more than stage 1 with this figure increasing to 19% at 6 months. Despite this, we demonstrated significant improvements in quality of life as measured on the PFDI.

Pre-operatively, 32 (52%) women reported being sexually active with 17 (53%) reporting sexual dysfunction associated with the prolapse. We demonstrated excellent post –operative sexual function with only 2(4.2%) reporting dysfunction at six months and one year follow up. This was reinforced by significant improvements on the PISQ-12. Overall mean scores improved from 15.6 to 11.3 at 6 months (p=0.000). These were sustained at one year.

Table 1

Parameter	**Pre-op (n=62)**	**6 weeks (N=58)**	**6 months (N=47)**	**12 months (n=27)**	**24 months (N=3)**
Prolapse symptoms	54 (87%)	1 (1.7%)	5 (10.6%)	1 (3.7%)	0 (0%)
Stress Incontinence	30 (48%)	18 (31%)	16(34%)	0	0
Urgency	13 (21%)	4 (6.8%)	8 (38%)	0	0
Sexually active	32 (52%)	0	21	13	3

Sexual Dysfunction	17	N/A	2	2	0
Aa >-1	45 (73%)	1 (1.7%)	3 (6.3%)	0	0
Ba>-1	46 (74%)	2 (3.4%)	3 (6.3%)	0	0
Ap>-1	22 (35%)	6 (10%)	6 (13%)	5(19%)	0
Bp>-1	9 (15%)	2 (3%)	4 (9%)	3 (11%)	0
C>-1	5 (8%)	1(1.7%)	3 (6.3%)	0 (0%)	(0%)
Mean PISQ-12	16	N/A	11**	7	9
Mean PFDI	21		14*	6	9*

*p<0.05, **p<0.001

Interpretation of results

The Surgisis graft is associated with good anatomical and functional outcomes when used to augment anterior compartment prolapse surgery. In particular, the sexually active women in our study demonstrated excellent function with only 4% reporting any sexual dysfunction. These data should be interpreted with caution, however, since they eminate from a single centre with one surgeon. We also did not have a control group.

Concluding message

These data suggest that SurgiSIS is associated with excellent anatomical outcomes when used to augment anterior compartment prolapse surgery. An adequately powered randomised controlled trial is urgently needed to evaluate this technique in anterior compartment prolapse surgery.

References

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Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**No**
Is this a Randomised Controlled Trial (RCT)?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Stichting Zorgsaam Board**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**