

ANATOMICAL AND FUNCTIONAL OUTCOMES OF SECONDARY VAGINAL PROLAPSE SURGERY USING THE PORCINE SUBINTESTINAL SUBMUCOSA (SIS) GRAFT.

Hypothesis / aims of study

Recurrence rates for vaginal prolapse surgery are as high as 30%. For this reason various graft materials have been proposed to improve the long-term surgical outcomes(1,2).

The aim of our study was to investigate the outcome and recurrence rates of secondary vaginal prolapse surgery using the biological prosthesis Porcine Subintestinal Submucosa (SIS).

Study design, materials and methods

Women with recurrent vaginal wall prolapse were recruited into this study. Women were assessed pre-and post operatively for symptoms of prolapse. Subjects had pre-and post-op assessment of prolapse severity using the Baden-Walker Halfway (BW) and ICS POPQ systems and completed the PISQ-31 sexual function questionnaire. The graft was placed anteriorly, posteriorly or in both compartments depending on the area of recurrence.

Ethical approval was obtained from the Local Research Ethics Committee (LREC) and all patients gave informed consent.

Results

The SIS graft was used in 21 women undergoing surgery for recurrent prolapse. The mean age was 63 years (range 42-89 SD=-/9). 11 women had an anterior vaginal repair with SIS (AVR+SIS), 7 women had posterior vaginal repair with SIS (PVR+ SIS) and 3 had both AVR+SIS and PVR+SIS. Concomitant procedures included Bilateral ilioococcygeus fixation in 4 patients, posterior IVS in 4 and transobturator tape in 3.

Pre-operatively 20 (95%) patients reported the symptom of vaginal bulge and 20(95%) reported vaginal discomfort. Of those women who had AVR+SIS, 84% had at least a Grade 2 cystocele on BW and more than Stage 2 anterior prolapse on POPQ points Aa and Ab pre-op. 90% of those women who had PVR+SIS, had at least Grade 2 rectocele on BW or Stage 2 on POPQ pre-op. At mean follow-up of 29 months (range 9-47months SD=-/10) for the whole cohort, there was a significant improvement in symptoms with 6 (28%) (p=0.001) patients complaining of a vaginal bulge and 8(38%) complaining of vaginal discomfort (p=0.001). At mean follow-up of 26 months, 91% of the women who had AVR +SIS had a Grade 1 cystocele and Stage 1 or less prolapse for point Aa and Ab. This represents a reduction from a pre-op mean of +0.57 for point Ab to a post-op mean of -1.57 (p=0.33). At a mean follow-up of 31 months for those women who had PVR+SIS, 100% had Grade 1 prolapse or Stage 1 or less on POPQ point Pa or Pb. The only graft related complication was the development of a haematoma in one patient. There were no graft erosions.

12 subjects completed the PISQ 31 sexual function questionnaire. The post-op total mean score was 84 (maximum 125 where a higher score indicates good function). The mean score in the physical domain was 33 (max 40).

Interpretation of results

These results suggest that SIS used for recurrent prolapse has good long-term subjective and objective success. Although sexual function data was not prospective, PISQ data would suggest that postoperative sexual function was good. There were no significant complications, most notably no mesh erosions.

Concluding message

Recurrent vaginal wall prolapse is a difficult management problem The porcine SIS graft may be useful to achieve long-term cure of secondary surgery. A larger study with long-term subjective and objective follow-up is required..

This study received no industrial funding.

References

1. Am J Obstet Gynecol. (2005);192(5):1649-54.
2. Int Urogynecol J Pelvic Floor Dysfunct. (2006)17(5);492-7.

FUNDING: none

CLINICAL TRIAL REGISTRATION: This clinical trial has not yet been registered in a public clinical trials registry.

HUMAN SUBJECTS: This study was approved by the Wandsworth and followed the Declaration of Helsinki Informed consent was obtained from the patients.