

PORCINE DERIVED MATERIAL (SIS) IN PROLAPSE REPAIR: SAFETY, EFFICACY AND FUNCTIONAL DATA

Hypothesis / aims of study

Genital prolapse is a very common condition whose treatment involves surgery in the vast majority of cases. Despite different surgical techniques and approaches have been tempted, a certain rate of recurrence is to be expected, even for very skilled surgeons. The genital prolapse can be considered a kind of hernia and borrowing from general surgery the concept of using prosthetic material to reinforce hernia repair, in the last few years different materials have been used to minimise recurrence. The good anatomical outcome of synthetic materials used so far was accompanied by morbidity to an extent considered unacceptable for many surgeons which abandoned them. Biological materials have been manufactured by different companies in the attempt to maintain a good anatomical result but with a decreased morbidity rate. The aim of our study is to test a porcine derived biological material (SIS), to reinforce prolapse repair in terms of safety, efficacy, bladder, and bowel function.

Study design, materials and methods

In this prospective observational study we included women with symptomatic anterior or posterior vaginal prolapse referred to our urogynaecological clinic. They were all assessed pre and post-operatively for urinary, bowel, prolapse and sexual symptoms using specific questionnaires. At vaginal examination prolapse was classified using the ICS POP-Q system. Women underwent anterior or posterior repair which always involved a fascial plication and a subsequent placement of a modeled porcine derived patch of intestinal submucosa (SIS). In each woman an antibiotic prophylaxis (cephalosporine and metronidazole x 3/die) was started just before surgery. Each woman was then re-evaluated for morbidity (erosion, granuloma, infection etc), for anatomical restoration and for urinary and bowel disorders at 1, 6, 12 months and then yearly since the operation using the same protocol adopted pre-operatively. Data were collected and stored onto a database and a separate analysis was performed as to whether prosthetic material was placed on the anterior or on the posterior vaginal compartment.

Results

Fifty-two women, with a mean age of 64 years (range 38-81 years) were considered. The mean time at follow-up was 18 months (range 6-36). The overall efficacy rate, in terms of anatomical restoration was of 94 %. No major complications, nor mesh infection were observed.

Fifteen women had surgery for an anterior vaginal compartment prolapse. Mean age was 64 years (range 54-61 years). All of them had at least a stage IIa according to the POP-Q system. Table 1 shows the pre and post-operative distribution of prolapse and urinary symptoms.

Table 1. Pre and postoperative prolapse and urinary symptoms in women who had an anterior repair with SIS mesh.

	Prolapse Symptoms n.	Urinary Symptoms		
		Urgency	Urge incontinence	Stress incontinence
Preoperatively	100%	40%	33%	13%

Postoperatively	7%	28%	21%	7%
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No mesh erosion through the anterior vaginal wall was observed. One patient developed a granuloma which was surgically removed.

The other 37 women, with a mean age of 64 years (range 38-77 years) had a posterior repair using SIS mesh for at least a stage IIp according to the POP-Q system.

Table 3 shows the pre and post-operative characteristics of these women for prolapse, and bowel symptoms.

Table 3. Pre and postoperative prolapse and bowel symptoms in women who had a posterior repair with SIS mesh.

	Prolapse Symptoms n.	Constipation Mean Wexner's score	Anal Incontinence
Preoperatively (%)	97%	13,5	13,8%
Postoperatively (%)	7%	8	13,8%

We had 3 cases of de-novo anal incontinence. In 1 case we observed a mesh erosion through the vaginal wall which healed with a conservative management. No granuloma formation were detected in the posterior repair group.

Interpretation of results

The anatomical efficacy of this biological material (SIS) is comparable with what reported for syntetic material. On the contrary morbidity appears to be lower, being granuloma formation and mesh erosion rates both less than 2%. Concerning visceral (urinary and bowel) function this biological material seems not detrimental.

Concluding message

Subintestinal submucosa (SIS) seems to be a safe and efficacious material to reinforce prolapse repair.