119

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PORCINE SKIN COLLAGEN IMPLANTS (PELVICOLTM) TO PREVENT ANTERIOR VAGINAL WALL PROLAPSE RECURRENCE: A RANDOMIZED STUDY

Hypothesis / aims of study our aim:
To evaluate the efficacy of porcine skin collagen (Pelvicol[TM]) implant in preventing recurrence of anterior vaginal wall prolapse in patients undergoing primary surgery for pelvic organ prolapse.

Study design, materials and methods:
All women with anterior vaginal wall prolapse > stage II planning to undergo primary pelvic reconstructive surgery were randomly selected to receive anterior vaginal repair with or without Pelvicol[TM] implant reinforcement. Pre-operative evaluation included history, urine culture, and pelvic examination. At physical examination, pelvic floor defects were determined using the POP -Q system. Measurements were made at different vaginal sites (anterior and posterior vagina and cervix) with the patient recumbent and straining down. Treatment assignment was given according to a computer-generated random list. The sample size was determined by a power analysis that was based on 18% difference in recurrence rate that was observed between patients receiving or not a synthetic mesh for anterior repair [1]. Assuming a 2-sided hypothesis test with a 5% type I error and 80% power, we estimated that a sample size of 90 patients in each study arm was necessary to detect a 15% reduction in recurrent cystoceles when implants were used. We assumed a dropout rate of approximately 15% and sought to enrol 207 subjects into the clinical trial. Follow-up visits were scheduled after 6 and 12 months, and every year thereafter and included a detailed urogynaecological history and pelvic examination. The primary outcome measure was rate of anterior vaginal prolapse recurrence. The secondary outcome measure was the rate of complications observed for each procedure. All patients were informed about the trial aim and procedures and gave their informed consent. The Statistical Package of Social Sciences was used for data analysis. Continuous data were analysed with Student's t test and categoric relationship by the χ^2 test with Yates' correction or Fisher exact test, as appropriate. Probability values of < 0.05 were considered statistically significant.

Results
Between March 2003 and June 2004, 206 women agreed to participate and were enrolled in the trial. After random assignment 100 patients underwent anterior vaginal repair with Pelvicol[TM] implant reinforcement and 106 without. There were no differences between the two groups with respect to demographic and clinical characteristics. Overall the associated procedures performed at the time of operation included: vaginal hysterectomy with McCall culdoplasty in 186 (90%) patients and posterior repair in 133 subjects (65%). No intra-operative complications occurred in both groups and the mean blood loss was 151 $\pm$ 112 ml and 167 $\pm$ 96 ml respectively. No differences were found in the time to resumption of spontaneous voiding and in the average hospital stay between groups. Two-hundred and one women were available for analysis of surgical outcome (98 with Pelvicol[TM] implant and 103 without). The mean length of follow-up was 14 months for both groups. Most of the women were satisfied with their condition with only 22 subjects (11%) reporting symptoms of pelvic organ prolapse. Unsatisfactory anatomic outcomes at point Ba were observed in 7 patients in the Pelvicol group (7%) and in 20 women (19%) in the other ($P = 0.019$). Overall there were 11 women with posterior recurrence (5%) and 6 (3%) with unsatisfactory results at the upper vaginal segment. Only one patient that received the porcine implant had rejection of the graft, that was removed one month after surgery.

Interpretation of results
Our data show that Pelvicol[TM] implant can be easily used as reinforcement of anterior colporraphy in women undergoing primary surgery for anterior vaginal wall prolapse $\geq$ stage II. At one year follow-up anatomic outcomes at point Ba were significantly better in women

who received Pelvicol than in those who did not. No difference in the rate of complications has been observed between groups.

<u>Concluding message</u>
The use of porcine skin collagen implant is safe and effective in restoring anterior vaginal anatomy.

<u>References</u>
1. Prospective randomized trial of polyglactin 910 mesh to prevent recurrence of cystoceles and rectoceles. Am J Obstet Gynecol 2001;184:1357-64