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PROSPECTIVE RANDOMIZED TRIAL OF TWO NEW MATERIALS FOR THE CORRECTION OF ANTERIOR COMPARTMENT PROLAPSE: PELVICOL AND PROLENE SOFT

Hypothesis / aims of study

New soft synthetic implant materials and biomaterials are being developed with the aim of maintaining high cystocele repair rates while reducing the incidence of complications associated with the use of the mesh, in particular erosions. This prospective randomized clinical study was designed to compare two new soft prosthetic materials (Pelvicol® vs. Prolene soft®) for the correction of medium/high grade anterior compartment vaginal defect.

Study design, materials and methods

From June 2003 to June 2004, 82 patients with symptomatic cystocele ≥ grade 2 according to the Baden and Walker Half-Way System (HWS) were enrolled. The pre-and post-operative work-up for all patients included: history (age, parity, menopausal status, HRT usage, previous prolapse surgery), urogynecological symptoms survey, clinical urogynecological examination with supine stress test and evaluation of the vaginal profile using the HWS, Q-tip test for urethral hypermobility, retrograde and voiding cystography, cystoscopy and conventional urodynamic studies. The patients were randomized into two groups (computer generated randomization list): in the first group the cystocele was corrected with a Prolene soft® synthetic mesh; in the second group a biological mesh was used made of acellular porcine dermis (Pelvicol®). All the patients underwent Tension-free Cystocele Repair (TCR) [1] and Levator Myorraphy (LM). The results were analyzed using two statistical tests: T-Test and the Least Difference Fisher Test. We considered $p<0.001$as statistically significant.

Results

Mean age of the sample was 62 years (range 41-81); 72 were post-menopausal (87%); mean parity was 2 (range 0-5). 51 patients (63%) also underwent concomitant vaginal hysterectomy. The groups were matched for age, parity and menopausal status. 72 patients (87%) were eligible for the follow-up study. The patients were evaluated for a mean of 8.1 months in the Prolene soft® group and 8.8 months in the Pelvicol® group respectively. There were no significant differences between the two groups regarding storage and voiding symptoms, urodynamic parameters and grade of prolapse. Post-operatively, 58% of the Prolene Soft® and 68% of the Pelvicol® group were considered anatomically cured. The procedure reduced symptoms associated with pelvic organ prolapse (feeling of a lump, heaviness, dragging sensation) in both groups (72.8% pre-op. vs 8% post-op. for Prolene soft®; 73% vs 2.8% for Pelvicol®, $p< 0.001$). There were no significant variations in storage symptoms in either group (42% vs 35% in Prolene soft, $p=0.283$; 44% vs 25% in Pelvicol®, $p=0.085$). The Prolene soft® group demonstrated a statistically significant reduction in voiding symptoms compared to the Pelvicol® group (57.5% vs 13% in Prolene soft®, $p< 0.001$; 44% vs 11.7% in Pelvicol®, $p=0.010$). The results of urodynamic studies are reported in table 1. The incidence of mesh erosions was 3 pats. (8.3%) for Prolene soft® while in the Pelvicol® group there was only 1 case (2.7%).

Table1- **Pre and post-op. urodymanic findings**

		Prolene soft®			**Pelvicol®**	
	Pre-op	**Post-op**	**P**	**Pre-op**	**Post-op**	**P**
Mean maximun cystometric capacity (ml)	410.72	396.75	0.29	424.30	416.21	0.38
Mean first sensation of bladder filling (ml)	188.46	186.87	0.43	190.29	182.9	0.29
Mean pressure at maximum flow (cmH2O)	37.36	23.51	0.12	28.40	28.94	0.37
Mean maximum flow rate (ml/sec)	12.67	11.91	0.31	12.47	12.64	0.16
Detrusor overactivity	24%	12.5%	0.02	19%	24%	0.39
"de novo" detrusor overactivity		3%			7%	NS
Reduced Compliance	8%	12.5%	0.12	5.5%	0%	0.02
Obstruction*	8%	9%	0.80	8%	9%	0.80

Interpretation of results

From the anatomical point of view there was no statistically significant difference between the two groups regarding cystocele correction rate. The procedure resolved symptoms associated with pelvic organ prolapse in both groups, but storage symptoms remained unchanged. Prolene soft® demonstrated a statistically significant reduction in voiding symptoms compared to Pelvicol®. Urodynamic studies did not show significant differences in functional parameters (maximum cystometric capacity, compliance and bladder sensation), but the pressure/flow study demonstrated a reduction in the percentage of obstructed patients in the Prolene soft® group.

Concluding message

Prolene soft® did not demonstrate any advantage compared with traditional Prolene with respect to correction rate or mesh erosion rate [1]. Pelvicol® on the other hand presents correction rates comparable to traditional surgery, with the advantage of biocompatibility which reduces the rate of erosions. A long-term follow up is needed for further evaluation of the role of new soft prosthetic materials in pelvic floor reconstructive surgery.

References

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2. Bladder outlet obstruction nomogram for women with lower urinary tract symptomatology. Neurourol Urodyn 2000; 19: 553.