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EVALUATION OF THE SUCCESS RATE OF PELVIC FLOOR CORRECTIONS WITH COLLAGEN (PELVICOL® OR PELVISOFT®) VS POLYPROPYLENE (PROLIFT®) MESHES AT 3, 6 AND 12 MONTHS – A PROSPECTIVE STUDY

Hypothesis / aims of study

Pelvic organ prolapse (POP) surgery has undergone great developments in recent years, but there is still lack of scientific evidence that certifies the superiority of one technique over the other.
Objective: To evaluate cure, relapse and *de novo* prolapse rates at 3, 6 and 12 months after POP surgery using two different techniques - correction with collagen (Pelvicol® or Pelvisoft®) or with polypropylene (Prolift®) meshes.

Study design, materials and methods

Prospective study from January 2003 to December 2007. We recorded the POP-Q (Pelvic Organ Prolapse Quantification) at 0 (before surgery) and 3, 6 and 12 months after surgery of two groups of patients. Group A: collagen (Pelvicol® or Pelvisoft®) correction and Group B: polypropylene (Prolift®) correction. The groups were divided in three sub-groups A1 (n=23) and B1 (n=21) with previous hysterectomy, A2 (n=59) and B2 (n=28) with concomitant vaginal hysterectomy, A3 (n=42) and B3 (n=89) without hysterectomy. ***Cure*** was considered when all of the points Ba, C or Bp were at grade 0 or I (< - 2 cm**),** ***Failure or relapse*** when any of the points were in grade II or superior (≥-1 cm) and ***de novo prolapse*** in presence of POP in a compartment not submitted to surgery.
The Student's t test for parametric and Mann-Whitney U test for non parametric continuous variables and the chi-square test for categorical variables were used. P values less than 0.05 were considered statistically significant.

Results

Group A included 124 women and group B 138 women. There were no differences between the groups regarding to age, body mass index and race. The distribution of the surgeries performed in the group A and group B were the following: 58.4%/58.4% anterior compartment corrections, 28%/11.6% posterior compartment corrections, 7.2%/29% anterior and posterior compartments corrections.

	Cure (%)					
Months	A1	B1	A2	B2	A3	B3
3	75	76.2	70	67.9	82.5	69.3
6	78.9	84.2	47.2	60.7	68.4	64.4
12	70	77.8	43.6	46.4	62.9	57.5

	***De novo* prolapse (%)**					
Months	A1	B1	A2	B2	A3	B3
3	15	14.3	6	17.9	10	11.4
6	10.5	5.3	18.9	17.9	18.4	10,3
12	20	5.6	14.5	21.4	11.4	13.8

	Relapse (%)					
	A1	B1	A2	B2	A3	B3
	10	9.5	24	14.3	7.5	19.3
	10.5	10.5	34	21.4	13.2	25.3
	10	16.7	41.8	32.1	25.7	28.8

Interpretation of results

	Cure (%)			**Relapse (%)**			***De novo* prolapse (%)**		
	3	**6**	**12**	**3**	**6**	**12**	**3**	**6**	**12**
Collagen	75.5	60	54.5	15.5	22.7	30.9	9.1	17.3	14.5
Polypropylene	70.1	66.4	57.9	16.8	22.4	27.8	13.1	11.2	14.3

The highest cure rate at 12 months post surgery was in sub-goup B1 with polypropylene corrections in women with previous hysterectomy (77.8% versus 70%). The cure rate in each group was always inferior when vaginal hysterectomy was performed simultaneously with the POP correction. The group of women submitted to vaginal hysterectomy associated with collagen correction had the highest relapse rate at 12 months. *De novo* prolapse was more frequent in the group submitted to vaginal hysterectomy associated with polypropylene correction.

Concluding message

Globally, the cure rate at 12 months was superior with polypropylene meshes. With time, the decline of cure rate of collagen meshes is more evident.

Specify source of funding or grant	**no funding or grant**
Is this a clinical trial?	**No**
What were the subjects in the study?	**HUMAN**

Was this study approved by an ethics committee?	**No**
This study did not require eithics committee approval because	**Non-experimental, prospective study, with the normal clinical protocol follow-up. With a informed consent for clinical, investigation and teaching activities signed by the patients**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**