

## SUCCESS RATE OF PELVIC FLOOR CORRECTIONS WITH COLLAGEN (PELVICOL® OR PELVISOFT®) MESHES AT 12 AND 48 MONTHS – A PROSPECTIVE STUDY

### Hypothesis / aims of study

Since 1996, prosthetic meshes have become popular for transvaginal surgical cure of pelvic organ prolapse (POP). There is still lack of sufficient evidence regarding the best type of mesh, rate of complications and patient quality of life to draw any definite conclusions. Objective: To evaluate cure, relapse and *de novo* prolapse rates at 12 and 48 months after POP surgery using collagen (Pelvicol® or Pelvisoft®) meshes in our Department.

### Study design, materials and methods

We have conducted a prospective study from January 2003 to March 2010. We recorded the POP-Q (Pelvic Organ Prolapse Quantification) by ICS staging at 0 (before surgery), 12 and 48 months after surgery. Three groups of patients were submitted to POP correction with collagen meshes (symptomatic stage II or ≥ stage III): group A with previous hysterectomy, group B with concomitant vaginal hysterectomy and group C without hysterectomy. Optimal anatomical outcome (**Cure**) was considered when all of the points Ba, C or Bp were at stage 0 or I (< -2 cm), unsatisfactory anatomical outcome (**failure or relapse**) when any of the points were in stage II or superior (≥-1 cm) and **de novo prolapse** in presence of POP in a compartment not submitted to surgery (1). We used descriptive statistics for evaluating the results.

### Results

Ninety-seven patients were included (group A n=16, group B n=55, group C n= 26). Global cure rate was 54.1% at 12 months and 44.4% at 48 months. Reoperation rate at 12 months was 1.1% and null at 48 months. 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, B and C was the following: 68% / 83.6% / 73.1% anterior compartment corrections, 25% / 3.6% / 19.2% posterior compartment corrections, 6.3% / 12.7% / 7.7% anterior and posterior compartments corrections.

Group A: had foreign material granulomas in 3/13 patients with stitch removed in two of them; two (15.4%) failures which were asymptomatic stage II cystoceles at 12 months; 3 (42.9%) failures at 48 months, two asymptomatic (stage II) and one resolved with a pessary (82 years-old with stage IV vaginal cupule).

Group B: had one case of vaginal cupule infection and hematoma with surgical removal of the mesh; one case of foreign material granuloma; 12 (23.1%) anatomical failures at 12 months (10 stage II, two stage III) both stage III needed reoperation; one case of ureter stenosis with hydronephrosis diagnosed 2 months after surgery with consequent reimplantation; 36.8% (7/19) failures at 48 months (six stage II, one stage III), none reoperated.

Group C: had foreign material granulomas in 3/24 patients with stitch removed in one of them; five (29.2%) failures at 12 months (four stage II, one stage III) none reoperated; five (33.3%) failures at 48 months (all stage II) none reoperated.

Groups	12 Months			48 Months		
	Cure (%)	Failure (%)	de novo prolapse (%)	Cure (%)	Failure (%)	de novo prolapse (%)
<b>A</b>	9 (69.2)	2 (15.4)	2 (15.4)	4 (57.1)	3 (42.9)	0(0)
<b>B</b>	26 (50.0)	12 (23.1)	14 (26.9)	7 (36.8)	7 (36.8)	5 (26.3)
<b>C</b>	18 (75.0)	5 (20.8)	1 (4.2)	9 (60.0)	5 (33.3)	1 (6.7)
<b>Global</b>	<b>53 (59.6)</b>	<b>19 (21.3)</b>	<b>17 (19.1)</b>	<b>20 (48.8)</b>	<b>15 (36.6)</b>	<b>6 (14.6)</b>

### Interpretation of results

The group of women with past hysterectomy had the highest failure rate at 48 months. The best cure rate was achieved in the group of corrections without past or concomitant hysterectomy. The cure rate declines with time. Failure rate was high and reoperation rate was very low because the anatomical criteria used to evaluate the outcome are very strict. The majority of the patients who had failure referred no bother and felt no need to be reoperated (stage II POP). *De novo* prolapse rate declined with time because several patients were not present at 48 months evaluation.

### Concluding message

Anatomical cure rate with collagen meshes was 59.6% at 12 months and 48.8% at 48 months. This decline is not reflected in the reoperation rate. Anatomical failure most of the times does not correspond to clinical failure. Patients became very satisfied when the POP stage IV or III became stage I or II after surgical correction.

### References

1. Weber AM, Abrams P, Brubaker L, et al. The standardization of terminology for researchers in female pelvic floor disorders. Int Urogynecol J Pelvic Floor Dysfunct 2001;12:178-86.

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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 ethics committee approval because	Anonymous data included in the patient informed consent form.
Was the Declaration of Helsinki followed?	Yes
Was informed consent obtained from the patients?	Yes

