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Illiano E<sup>1</sup>, Porena M<sup>1</sup>, Mearini L<sup>1</sup>, Giannitsas K<sup>2</sup>, Natale F<sup>3</sup>, Balsamo R<sup>4</sup>, Lazzeri M<sup>5</sup>, Manasse G<sup>1</sup>, Maglia D<sup>1</sup>, Zucchi A<sup>1</sup>, Costantini E<sup>1</sup>

**1.** Urology and Andrology Clinic, Department of Surgical and Biomedical Science, University of Perugia Italy, **2.** Department of Urology, University Hospital of Patras, Rio, Greece., **3.** Urogynecologic Department, S.Carlo-IDI, Rome, Italy, **4.** Department of Urology, Magna Graecia University of Catanzaro, Catanzaro, Italy, **5.** Department of Urology, Humanitas Clinical and Research Center, Humanitas University, Rozzano (Milan) - Italy

# POLYVINYLIDENFLUORID (PVDF) VERSUS POLYPROPYLENE MESH FOR SACROCOLPOPEXY

### Hypothesis / aims of study

Polyvinylidenfluorid (PVDF) is a polymer mesh which has been successfully used for many years for hernia repairs. Favourable results in hernia surgery led to an adopted mesh design for use in urogynecology, but data on sacrocolpopexy (SC) for Pelvic Organ Prolapse (POP) using PVDF are limited. The aim of this study was to compare PVDF to polypropylene (PP), the mesh material most commonly used in POP surgical repair, in terms of anatomical and functional results as well as safety, in patients who underwent SC.

#### Study design, materials and methods

This retrospective series included women who underwent SC for stages III or IV POP, according to the POP- Quantification (POP-Q) system, from 2005 to 2015, using either PP (Cousin Biotech Sacromesh®) or PVDF (DynaMesh®-PRS) mesh.

All women were preoperatively evaluated with history, physical examination and urodynamics. Urinary and sexual symptoms were assessed with the Urogenital Distress Inventory (UDI), the Incontinence Impact Questionnaire (IIQ-7) and the Female Sexual Function Index (FSFI) questionnaire.

As many patients as possible, were brought into the clinic and re-assessed between January and March 2016. At re-assessment anatomical outcomes were evaluated using the POP-Q system. Functional outcomes included voiding and storage urinary symptoms, including incontinence, and sexual complaints that were diagnosed at history taking and were quantified with the validated questionnaires also used at baseline (UDI-6, IIQ-7 and FSFI). Global patient perception of improvement was recorded with the VAS score and the Patient Global Impression – Improvement (PGI-I) questionnaire. Mesh erosion was the focus of safety assessment.

The Mann-Whitney U and X2 tests were used for statistical analyses and a p-value <0.05 was considered significant.

The study was approved by the Local ethics committee and patients signed an informed consent document

#### Results

136 of 166 eligible women were re-assessed between January and May 2016: 73 of 93 who originally had polypropylene mesh POP repair (PP group) and 63 of 73 who had PVDF mesh repair (PVDF group). The two groups were comparable in terms of patient demographics and preoperative clinical characteristics. The only significant difference between the two groups was duration (mean ±SD) of follow-up: 94.93±21.67 months for the PP and 29.82±13.79 months for the PVDF group. The reason for this difference is that PVDF for prolapse repair was marketed more recently and patients were operated using it after 2010.

Successful postoperative anatomical correction rates (POP stages 0 or I), voiding and storage symptoms, including urgency and stress incontinence, questionnaire scores and mesh erosion rates are reported in Table 1. Most outcomes were not significantly different between the two groups with the exception of storage symptoms, sexual symptoms and UDI-6 scores that were better in the PVDF group.

Subjective patient satisfaction was high in both groups as demonstrated by the PGI-I and VAS scores (also in Table 1) with no significant differences between them

#### Interpretation of results

Our results suggest that PVDF is at least as safe and durable as polypropylene when used in POP repair. These results are in line with evidence from hernia repair series, where PVDF is already established, and can be attributed to PVDF mesh properties: it has been previously shown that PVDF filaments have excellent biocompatibility reducing adverse foreign body reactions such as granuloma formation, are associated with reduced bacterial colonization and maintain their tensile strength longer than polypropylene. Moreover, they are finer and smoother than conventional filaments. The aforementioned characteristics may also explain the superiority of PVDF in functional outcomes, such as urinary and sexual symptoms, observed in our series.

Nevertheless, our finding should be interpreted in light of the limitations of our work, mainly its retrospective, non-randomized nature and the difference in duration of follow-up between the two groups

#### Concluding message

Our data suggest that PDVF and PP are comparable in terms of anatomical correction of POP and mesh erosion rates. Interestingly, PVDF use was associated with significantly less storage symptoms and sexual dysfunction. Given the shorter follow-up in the PVDF group long-term data from prospective studies are needed to confirm these results.

#### Table 1: Postoperative outcome for PP and PVDF groups

Outcomes	PP group	PVDF group	P value
Apical compartment stages 0 & I [n (%)]	73/73(100)	63/63(100)	n.v
Anterior compartment stages 0 & I [n (%)]	67/73(91.7)	55/63(87.3)	0.67
Posterior compartment stages 0 & I [n (%)]	70/73(95.8)	62/63(98.4)	0.20
Storage symptoms (SS) [n (%)]	6/73 (8.2)	(0)	0.02*
Voiding Symptoms (VS) [n (%)]	5/73 (6.8)	7/63(11.1)	0.38
Urgency Urinary Incontinence (UUI) [n (%)]	5/73 (6.8)	10/63 (15.8)	0.09
Stress Urinary Incontinence (SUI) [n (%)]	14/73 (19.1)	6/63 (9.5)	0.5
Sexual dysfunction (SD) [n (%)]	12/73 (16.4)	(0)	0.001*
UDI-6 score [median(range)]	1 (0-14)	0 (0-4)	0.04*
IIQ-7 score [median(range)]	0 (0-17)	0 (0-10)	0.12
FSFI score [median(range)]	15.0 (1.2-30.3)	16.3 (1.2-34.8)	0.70
Mesh erosion rate [n (%)]	1/73 (1.3)	2/63 (3.1)	0.47
PGI-I score [mean± SD]	1.5±1.0	1.8±0.5	0.40
VAS score [mean± SD]	8.6±1.5	9.0±1.4	0.10

\*Significant p-value <0.05

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