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Bader G[1], Koskas M[2], Wassef M[3], Fauconnier A[1]
***1.*** *Poissy University Medical Center,* ***2.*** *Hopital Bichat Ap-Hp, Paris,* ***3.*** *Hopital Lariboisiere, Paris*

# ANIMAL STUDY FOR THE EVALUATION OF A NEW SEMI-RIGID AND SEMI-ABSORBABLE COMPOSITE MESH (POLYPROPYLENE, POLY-L-LACTIC ACID) FOR TRANSVAGINAL CYSTOCELE REPAIR.

Hypothesis / aims of study
The technique of transvaginal cystocele repair using a sub-vesical transverse mesh has shown effectiveness and low morbidity in the medium term [1]. Techniques requiring transobturator passages carry risks of both intra-operative (neuro-vascular lesions) and post-operative complications (exposure, chronic pain due to retraction) [2,3]. A semi-rigid, semi-absorbable composite mesh would permit to avoid blind passages and fixation in the anatomical obturator spaces. Such materials may limit the inflammatory reaction responsible for postoperative pain and dyspareunia and the risk of prosthetic exposure.
The aim of the study was to assess the characteristic of two composite semi-absorbable materials of PP and PLLA, implantable by transvaginal route for cystocele repair according to the exclusive “tension-free” principle. The stability of the arrangement depends on the transient rigidity of the mesh placed between the bladder and the anterior vaginal wall.

Study design, materials and methods
Two composite materials (PP and PLLA) of 30 x 30 mm were subcutaneously implanted without fixation into animal models at INRA (Jouy en Josas). Histological and immuno-histochemical studies were used to compare these two implants to a control implant (macroporous PP monofilament). Implantation in 17 female rabbits of the White New Zealand type, INRA strain 1077, under general anaesthesia after antibiotic prophylaxis was done. Explantation after sacrifice was made at 1 week, 1 month, 3 months and 6 months, following the recommendations of the ISO 10993-6 standard to evaluate the biological reaction and tolerance of the implants. All rules governing animal experimentation were respected (order 87-848, 19 Oct. 1987). Morphometric and histological criteria (macro + micro + IHC) were defined prior to the study. Particular attention was given to the study of the inflammatory reaction and tissue integration.

Results
The general state of the animals was conserved at the moment of explantation. No systemic complications were found during the period of follow-up. There were no cutaneous wound defect or mesh exposure.
Macroscopic examination of the 3 types of meshes (adherence and shrinkage) was identical.
Retraction of the control mesh (PP) was significantly higher at 3 months.
Microscopic examination (fibrin, PNN, PNE, lymphocytes, plasmocytes, macrophages and giant cells, neo-vascularisation) did not reveal any significant difference between the 3 types of meshes. Early tissue integration (fibrocytes, fibrosis, tissue colonisation) was identical for the 3 types of meshes with a net regression in fibrosis at 6 months for the composite mesh (PP + PLLA). Study of the inguinal ganglia did not reveal any abnormal inflammatory reaction.

Interpretation of results
The composite meshes tested (PP + PLLA) have properties comparable to those of the control mesh (PP) and did not produce any sign of local intolerance of an inflammatory, infectious or necrotic nature at 6 months.

Concluding message
These new semi-rigid, semi-absorbable hybrid materials are potentially promising for exclusive vaginal use in the repair of cystoceles because they provide in situ stability without fixation (tension free) and less inflammatory reaction. Transvaginal animal implants followed by clinical trials are planned with the aim of testing this minimally-invasive, easy and reproducible procedure.

References
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