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

Hypothesis / aims of study

The technique of cystocele repair by interposition of a subvesical transverse mesh has been shown to be effective and cause low morbidity in the medium term [1]. Techniques requiring transobturator passage carry risks of both intraoperative (neurovascular lesions) and postoperative complications (e.g., exposure and chronic pain due to retraction) [2,3]. A semirigid, semireabsorbable composite mesh would make it possible to avoid blind passages and the need for fixation in the anatomical obturator spaces; it would also limit the inflammatory reaction and the risks of prosthetic exposure as well as limit the prosthetic retraction responsible for postoperative pain and dyspareunia.

The aim is to study the characteristics of two semireabsorbable composite materials—polypropylene (PP) and poly-L-lactic acid (PLLA)—that are implantable by transvaginal methods for the surgical repair of cystoceles according to the exclusive "tension-free" principle. The stability of the arrangement depends on the transient rigidity of the mesh interposed between the bladder and the anterior vaginal wall.

Study design, materials and methods

Two composite materials (prototypes of PP and PLLA) 30 x 30 mm in size were subcutaneously implanted without fixation into animal models at INRA (Jouy and Josas). Histological and immunohistochemical (IHC) studies were used to compare these two implants to a control implant (macroporous PP monofilament). The materials were implanted in 17 female New Zealand white rabbits, INRA strain 1077, under general anaesthesia after an antibiotic prophylaxis was administered. Explantation after sacrifice was conducted 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). Precise 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 the 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 defects or cases of prosthetic exposure.

The results of the macroscopic examination of the 3 types of mesh (adhesion and surface shrinkage) were identical.

Retraction of the control mesh was significantly higher at 3 months.

The microscopic examination (fibrin, polynuclear neutrophiles (PNN), polynuclear eosinophiles (PNE), lymphocytes, plasmocytes, macrophages and giant cells and neovascularization) did not reveal any significant differences between the 3 types of meshes. Early tissue integration (fibrocytes, fibrosis and tissue colonization) was identical for the 3 types of meshes, with a net regression in fibrosis at 6 months for the composite mesh. A study of the inguinal ganglia did not reveal any abnormal inflammatory reactions.

Interpretation of results

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

Concluding message

These new semirigid, semiabsorbable materials are potentially very promising for exclusive vaginal repair of cystoceles because they provide in situ stability without fixation (tension free). Transvaginal animal implants followed by clinical trials are planned with the aim of testing this easy, reproducible and minimally invasive procedure.

References

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