Clinicopathological Study of Patients Requiring Reintervention After Sacrocolpopexy With Xenogenic Acellular Collagen Grafts

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Purpose: We describe the operative and histopathological findings of patients requiring reintervention because of symptomatic vault prolapse or graft related complications following sacrocolpopexy using xenografts.

Materials and Methods: A total of 13 patients underwent secondary sacrocolpopexy because of failure (8) or vaginal revision (5) because of a graft related complication after the initial sacrocolpopexy with porcine dermal collagen (9) or small intestinal submucosa (4). Outcome measures were operative findings and histology of specimens obtained at reintervention. Sections were semiquantitatively scored for the presence of infection, foreign body reaction and fibrosis by a pathologist blinded to the outcome and graft type.

Results: Reinterventions for failure and graft related complications were performed a median of 33 and 15 months, respectively, after the initial operation. Pathology of porcine dermal collagen failures (6) revealed local degradation associated with a minimal foreign body reaction. Porcine dermal collagen remnants were surrounded by minimal fibrosis and neovascularization. Small intestinal submucosa implants of failures (2) were entirely replaced by collagen rich and moderately vascularized connective tissue. Pathology of 3 erosions (all 3 porcine dermal collagen) revealed a locally degraded implant that was surrounded by histiocytes and a polymorphonuclear infiltrate. Pathology of 2 early infections, both small intestinal submucosa, revealed a massive polymorphonuclear infiltration with the implant material remodeled and replaced by loose connective tissue.

Conclusions: In these clinical recurrences porcine dermal collagen implants were usually locally degraded but still recognizable several years after implantation. Small intestinal submucosa implants were fully replaced by connective tissue. Therefore, the cause of recurrence remains unclear. Porcine dermal collagen erosions displayed features of infection and degradation.

Key Words: pathology; pelvic organ prolapse; transplantation, heterologous

Abbreviations and Acronyms

FBR = foreign body reaction
GRC = graft related complication
LSC = laparoscopic sacrocolpopexy
PMN = polymorphonuclear cells
PP = polypropylene
SC = sacrocolpopexy

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Study received local ethics committee approval.

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Sacrocolpopexy is the gold standard procedure for the surgical treatment of vaginal vault prolapse,[1] and it can be done abdominally or laparoscopically.[2–4] SC requires the use of an implant to enable suspension of the vaginal vault to the anterior longitudinal ligament, substituting deficient level I support.[5] Macroporous PP grafts are typically used for this purpose, providing excellent long-term anatomical results.[2] However, the occurrence of graft related complications such as erosion and pain has resulted in an

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ongoing quest for alternative materials.[2,4,6,7] Biological grafts have been suggested as alternatives because they would be better compatible to the host. Autologous materials were quickly abandoned because of poor results and inherent morbidity due to graft prelevation.[8] Allografts overcame the latter limitation but carry the risk for transmission of diseases and remain prone to implant degradation.[9,10] FitzGerald et al reported 83% failures after SC using fascia lata allografts.[10] In 81% of patients no residual graft material was found during repeat SC.

More recently heterologous acellular grafts were introduced. Commercially available products include porcine small intestinal submucosa (eg Surgisis®), which is resorbable, or cross-linked porcine dermal collagen (eg Pelvicol®). They have been shown to induce a mild inflammatory reaction associated with an anti-inflammatory cytokine profile.[11] Xenografts have been used successfully to augment anterior repairs.[12] However, when used for SC there seems to be an increased recurrence rate without a reduction in GRCs, the reason for which remains unclear.[13–15] Experimental studies have demonstrated that Pelvicol can be locally degraded over time which may be associated with decreased strength of the repair.[16–19] Surgisis seems to be remodeled within a few months but the strength of the replacing scar tissue has been questioned by several authors.[16,19–21]

These studies are experimental, and are no substitute for clinical observations. Clinicopathological studies on xenografts are scarce and to our knowledge no data are available on patients who required reintervention after SC using xenografts.[22] Such studies may provide insight into the mechanisms leading to GRCs and recurrence.[23]

MATERIALS AND METHODS

Study Design and Patients

This is a single center, consecutive case series performed in the Pelvic Floor Unit of the University Hospital of Leuven, Belgium. Patients included are part of a prospective cohort undergoing LSC with a xenograft (Surgisis, 29 or Pelvicol, 43).[14,15] Patients were operated on because of symptomatic stage II or greater vault prolapse and were followed with a standardized long-term followup program documenting anatomical and functional outcome. Briefly this involves anatomical assessment, and obtaining a standardized interview 3 months postoperatively and annually thereafter, or whenever they were symptomatic. These assessments were done by a single assessor independent from the surgeon (FC). Patients undergoing LSC were part of a longitudinal followup study approved by the local Ethics Committee on Clinical Studies of the University Hospitals of Leuven (ML2750).

We previously reported on the setting and the clinical outcome of this cohort.[14,15] Recurrent vaginal vault prolapse developed in 13 (18%) patients and a GRC developed in 8 (9.2%). Eligible cases for the present study were those which required reintervention because of recurrent symptomatic vault prolapse (8) or a GRC (5). At reintervention the surgical findings were recorded and whenever possible specimens for histology were retrieved where the implant was initially located.

Clinical Evaluation

The parameters recorded were preoperative characteristics, prolapse, bladder, bowel and sexual symptoms assessed with a standardized interview described earlier,[4] and anatomical examination classified according to the Pelvic Organ Prolapse Quantification System.[24] Anatomical failure was defined as the presence of stage II or greater at any anatomical site.[24] Subjective failure was defined when the patient often or always reported prolapse symptoms.[4] The anatomical and functional data of the entire cohort have been previously reported.[14,15] GRCs included the presence of granulation tissue, erosion, or infection or sinus tract formation in the implant area.[13] Outcome following reintervention was documented using the same standardized followup protocol.

Technique of Laparoscopic Tissue Sampling and Secondary SC

The operative setting for redo LSC using a macroporous PP mesh was identical to that used for the primary procedure, previously described in detail.[4,14,15] In addition, we inspected the peritoneal cavity for the presence of adhesions and visible remnants of previously used graft material. The density of adhesions was graded on a scale from 0 to III, with 0—absence of adhesions, I—minimal adhesions that can easily be separated, II—mild adhesions difficult to separate and III—dense adhesions that can only be separated with sharp dissection.[25] Biopsies were systematically taken along the presumed trajectory of the xenograft (promontory, paracolic gutter, anterior and posterior wall of the vagina). For tissue sampling during vaginal revision unhealthy vaginal tissue was resected and visibly infected material removed, and sent for culture and pathology.

Bacteriology and Histopathology

All specimens were read by an expert pathologist (BK) who was independent of the treatment center, and who was blinded to the material used and clinical outcomes of patients. Formalin fixed tissue samples were either completely, or in case of larger specimens, slices of 0.3 to 1.0 cm, embedded in paraffin. Ten to 15 sections of 4 μm thickness were cut, stained with hematoxylin and eosin, Movat and elastica van Gieson. Parameters analyzed included infection, FBR and fibrosis. The presence of infection was defined as more than 50 PMN per 10 high power fields (400 x).[26] FBR and fibrosis were scored by a 4-scale ordinal system (no— −, mild—+, moderate—++ and severe—+++). In terms of statistical analysis data were collected in a MS Access® database and statistics were analyzed with SPSS® 15. Data are reported as median (range) or number (%).