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Original Article

Assessment of Synthetic Glue for Mesh Attachment in Laparoscopic Sacrocolpopexy: A Prospective Multicenter Pilot Study

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ABSTRACT **Study Objective:** To assess the anatomic efficacy and safety of synthetic glue to fix prosthetic material in laparoscopic sacrocolpopexy.

Design: A 1-year follow-up in a prospective multicenter pilot study between November 2013 and November 2014 (Canadian Task Force Classification II-2).

Setting: An academic urogynecology research hospital.

Patients: Seventy consecutive patients with Pelvic Organ Prolapse Quantification stage ≥ 3 anterior and/or medial prolapse underwent laparoscopic sacrocolpopexy.

Interventions: All women underwent laparoscopic sacrocolpopexy with the same standardized technique using a synthetic surgical glue to fix anterior and posterior meshes.

Measurements and Main Results: Patients were followed up at 1 month and 1 year, with anatomic and functional assessment (Pelvic Floor Distress Inventory-20, Pelvic Floor Impact Questionnaire-7, and Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire-12). Anatomic success was defined as 1-year Pelvic Organ Prolapse Quantification stage ≤ 1. Sixty-six patients were included; the mean age was 56.7 $\pm$ 1.2 years. The mean operative time was 145 $\pm$ 5 minutes. The mean glue fixation time was less than 2 minutes for both anterior and posterior meshes. The 1-year anatomic success rate was 87.5% in the anterior compartment (Ba at -2.3 cm, $p < .0001$) and 95.3% in the medial compartment (point C at -6.1 cm, $p < .0001$). There were no intra- or postoperative complications and no cases of mesh exposure; 5 cases of mesh shrinkage (7.8%) were observed at 1 year. The postoperative urinary stress incontinence rate was 29.7% at 1 year. Eight patients (12.1%) underwent revision surgery with transobturator tape. All quality of life scores showed significant improvement ($p < .0001$) at 1 year.

Conclusion: Synthetic glue attachment of prosthetic material in laparoscopic sacrocolpopexy proved straightforward, safe, time-saving, and effective at 1 year. Prospective randomized studies will be needed to confirm the long-term benefit. Journal of Minimally Invasive Gynecology (2017) 24, 41–47 © 2016 AAGL. All rights reserved.

Keywords: Cyanoacrylate; Laparoscopic sacrocolpopexy; Pelvic organ prolapse; Vaginal prosthetic glue

Genital prolapse affects 1 in 3 women of all ages and more than 60% of women aged over 60 years. It has a negative impact on quality of life [1,2]. Between 11% and 20% of women undergo prolapse surgery with a procedure that is effective and reproducible [3]. Laparoscopic or laparotomic sacrocolpopexy is presently the reference treatment for the correction of medial compartment prolapse [4,5], allowing lower dissection and more precise mesh attachment. Its limitations comprise an indispensable learning curve (15–30 procedures) to master suturing and laparoscopic dissection and a longer operative time compared with prosthetic reinforcement using a vaginal approach [6–8].

Synthetic surgical glue is already used to repair parietal hernia and shows results comparable with those of suture or staple fixation [9]. Application to laparoscopic sacrocolpopexy should simplify and optimize the procedure by reducing the suture time and thus the overall operative

Dr. Lamblin declares an interest in Peters Surgical (France), which provided the IFABond synthetic glue for the study.

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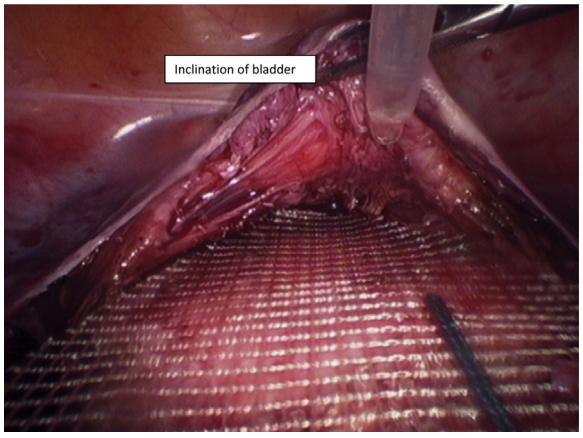
time. The main objective of the present pilot study was to assess 1-year anatomic success in laparoscopic sacrocolpopexy using synthetic tissue glue for mesh attachment. Secondary objectives were to assess 1-year functional results on quality of life, sexuality scores (Pelvic Floor Distress Inventory-20 [PFDI-20], Pelvic Floor Impact Questionnaire-7 [PFIQ-7], and Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire-12 [PISQ-12]), rates of complications (infection, erosion, and mesh shrinkage), and postoperative urinary stress incontinence.

Materials and Methods

A prospective multicenter study was performed between November 2013 and November 2014 in 3 University Urogynecology Centers: Hôpital Femme Mère Enfant, Centre Hospitalier Lyon Sud, and Hôpital de la Croix Rousse (all Hospices Civils de Lyon, France). The protocol was approved by the regional Institutional Review Board (Comité de Protection des Personnes Sud Est VI, Clermont Ferrand, France). The protocol was registered in the ClinicalTrials.gov registry under the following identifier: NCT02011373. All patients signed informed consent forms. The study data file was registered with the Commission Nationale de l'Informatique et des Libertés data protection commission. Seventy consecutive patients with Pelvic Organ Prolapse Quantification (POP-Q) stage ≥ 3 anterior and/or medial prolapse were eligible (Fig. 1). Exclusion criteria were POP-Q stage <3, an asymptomatic patient, previous total hysterectomy, pregnancy or pregnancy project during the study period, pelvic cancer or history of pelvic radiation therapy, and known cyanoacrylate hypersensitivity. Data were digitized and processed anonymously and confidentially. All patients underwent laparoscopic sacrocolpopexy with the same standardized technique in all 3 centers, with 2 gynecologic surgeons experienced in advanced laparoscopic surgery (more than 30 total laparoscopic hysterectomies) per center, using the same type of polyester mesh. IFABond synthetic surgical glue (Peters Surgical, Bobigny Cedex, France) was used in all cases following the same fixation procedure. Fixation time was assessed on 32 cases in the principal investigation center (Hôpital Femme Mère Enfant). Anatomic assessment was performed at 1 month and 1 year using the POP-Q terminology of the International Continence Society; concomitant quality of life assessment used the PFDI-20, PFIQ-7, and PISQ-12 questionnaires. Mesh shrinkage was defined as retraction of the stretched implant assessed on palpation during clinical examination according to the International Urogynecological Association classification [10].

Fig. 1

The anterior mesh glue fixation technique.



Surgical Technique

All patients underwent laparoscopic sacrocolpopexy with the same standardized technique in all 3 centers; all received anterior and posterior meshes using the same material—precut knitted polyester (Parietex; Covidien, Mansfield, MA). Second-generation cephalosporin antibiotic therapy was administered at the start of surgery. Three trocars (two 5 mm and one 10 mm) were positioned under visual control. The vagina was exposed using a rectangular vaginal valve held by an assistant. The first step of dissection consisted of posterior peritoneal opening, with access to the pouch of Douglas within the uterosacral ligament via an inverted U-shaped incision separating the rectum and vagina; dissection was continued up to the levator ani muscle on either side and down to the lower rectum. Glue was applied using a dedicated applicator (Fig. 1). A single 1.5-mL vial was enough for each procedure; a single droplet of about 0.2 mL was required at each anchorage. The posterior mesh was anchored as laterally as possible to the levator ani muscles to avoid tying the lower rectum and then laid without tension over the vaginal wall. The bladder and vagina were then separated within the vesicovaginal pillars until the collagen fiber was exposed at the vesical trigone. The anterior mesh was glued over the whole surface of the vagina and then fixed to the uterine isthmus with a single nonresorbable suture (Mersuture; Ethicon, Cincinnati, OH) and brought into the subperitoneal space via the parametrium. Only the anterior mesh was fixed to the anterior vertebral ligament of the promontory by a nonabsorbable suture (Mersuture, Ethicon). The 2 meshes were held entirely subperitoneally by a continuous absorbable suture (Vicryl 00; Johnson and Johnson, Cincinnati, OH) between the prerectal and retroisthmic peritoneum posteriorly and the vesical and preisthmic peritoneum anteriorly. Vaginal palpation was performed systematically at the end of surgery. Operative time was measured from incision to closure in a sample of 32 patients.

Physical and Chemical Properties of the Tissue Glue

IFABond synthetic solution is a liquid, translucent, nontoxic cyanoacrylate (patent: Fimed SAS; CE label, class