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Original article

# Laparoscopic sacrocolpopexy with a vaginal prosthetic adhesive

## *Scacrocolpopexie laparoscopique avec encollage prothétique vaginal*

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ABSTRACT

*Study objective.* – To evaluate the efficacy and safety of vaginal prosthetic adhesive (VPA) during laparoscopic sacrocolpopexy.
*Design.* – Retrospective analysis of 35 first consecutive cases.
*Setting.* – Gynecology Surgery Unit, Bouchard Clinic, Marseille, France.
*Patients.* – Thirty-five women (age range: 35–85 years; average 60.8 years) presenting a genital prolapse assessed by a Pelvic Organ Prolapse Quantification (POP-Q) Score (stage 2 to 4).
*Procedures.* – Modified laparoscopic sacrocolpopexy using a synthetic glue (Ifabond™, Peters Surgical®) to fix the mesh to the vagina (anterior and posterior) and to the levator ani. Two non-absorbable knots are used to secure the anterior mesh to the isthmus and to the promontory.
*Measurements and main results.* – The average operating time was 68.4 minutes (45–115 min). No complications occurred during the procedure and early postoperative course. One patient (2.8%) experienced mesh exposure, and one patient (2.8%) experienced a subacute intestinal obstruction, which was resolved by a medical treatment. During a median follow-up at 13.2 months (range: 6–24.7 months), the surgical success rate (POP-Q $< 2$) was 94.2% (two recurrences). The patient satisfaction rate was 87%.
*Conclusions.* – The VPA during laparoscopic sacrocolpopexy seems to be safe and effective at short term. This new procedure due to adhesive opens up a new path for the widespread use of sacrocolpopexy and for reduced operating times, which is often one obstacle with the dissection in the development of this technique.



*Mots clés :*
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RÉSUMÉ

*Objectif.* – Évaluer l'efficacité et l'innocuité d'emploi d'une prothèse vaginale encollée (PVE) par colle synthétique (Ifabond™, Peters Surgical®) dans le cadre d'une sacrocolpopexie laparoscopique.
*Méthodes.* – Analyse rétrospective des 35 premiers cas consécutifs colligés à la clinique Bouchard de Marseille. Les 35 patientes incluses (tranche d'âge : 35–85 ans ; moyenne 60,8 années) présentaient un prolapsus génital de stade 2–4 selon la classification Pelvic Organ Prolapse Quantification (POP-Q). Une sacrocolpopexie laparosopique modifiée utilisant de la colle chirurgicale pour fixer le treillis au vagin (antérieur et postérieur) et au releveur de l'anus a été pratiquée. Deux nœuds non-résorbables étaient utilisés pour fixer la prothèse antérieure à l'isthme et au promontoire.
*Résultats.* – La durée moyenne de l'intervention était de 68,4 minutes (de 45 à 115 min). Aucune complication n'est survenue pendant la procédure ou dans les suites immédiates. Une exposition de prothèse (2,8 %) a été notée ; un cas (2,8 %) d'obstruction intestinale subaiguë a été déploré et traité médicalement. Sur un suivi médian à 13,2 mois (extrêmes : 6 à 24,7 mois), le taux de réussite chirurgicale (POP-Q $< 2$) était de 94,2 % (deux récidives). Le taux de satisfaction des patientes était de 87 %.

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*Conclusions.* – L'usage de PVE au cours d'une sacrocolpopexie laparoscopique semble être sûr et efficace à court terme. Grâce à la colle, cette nouvelle procédure ouvre une nouvelle voie à l'utilisation démocratisée de la sacrocolpopexie par laparoscopie en favorisant notamment la réduction du temps opératoire, ce qui est souvent avec la dissection l'un des obstacles au développement de cette technique.


## 1. Introduction

The growing number of patients affected by symptomatic genital prolapse requires discussing around the subject in order to determine an effective, reproducible and safe procedure. It is currently estimated that the highest prevalence of this pathology is 30% among women of age 60 [1–3] and that the reason for consulting is to be multiplied by 10 [4] in just a few years.

From a purely technical point of view, laparoscopic sacrocolpopexy is more complicated than treating a prolapse vaginally, with a longer learning curve. This laparoscopic procedure is a fairly recent technique in the history of surgery [5]. Many practitioners have had to convert technically and philosophically to laparoscopy, and this difficulty has delayed its application, especially among gynecologists [6]. The widespread use of this procedure in educational establishments should allow laparoscopic sacrocolpopexy to become a common practice [7,8].

With the mesh fixation, the difficulty and the fear of the dissection stay one of the time consuming and challenging steps limiting the sacrocolpopexy diffusion.

In order to optimize the sacrocolpopexy procedure, we have developed a new technique of prosthetic fixation called vaginal prosthetic adhesive (VPA). By limiting the number of nodes and making the fixation procedure easier, it is conceivable to believe that the application of the adhesive will reduce the operating time, the number of vaginal complications (explosion, erosion) and improve the learning curve.

The clinical study received an authorization (No. 1615954 v 0) from the National Commission for Data Protection and Liberties (CNIL, France), and a favorable opinion (No. 12.652bis) from the Advisory Committee for Processing of Health-related Data (CCTIRS, France). As a retrospective study, the non-oppositions were orally expressed and a copy of the signature form was sent to patients in which essential informations (e.g. subjects' rights) were mentioned.

## 2. Materials and methods

We conducted a retrospective study from August 2010 to June 2012, including data from 35 patients who consecutively underwent a dual laparoscopic sacrocolpopexy (VPA operation) to treat various stages of prolapse. The patients with a symptomatic prolapse were at least at POP-Q stage 2 [9] and on at least one of the compartments (anterior, middle or posterior). All the patients were treated in the exact same manner and procedure, and operated on by the same surgeon at the Bouchard Clinic (Marseille, France). All of the patients received Ifabond™, a synthetic adhesive cyanoacrylate solution, during the VPA time of the surgical procedure.

### 2.1. Population

The average age of the patients was 60.8 years (34–85 years) and the average Body Mass Index was 24.6 (17.7–32.3). Their gynecological and obstetrical history included: three hysterectomies (9%), six cases of adnexal surgery (17.1%), and an average parity of 2.4 [1–6].

The anatomical evaluation of the prolapse was done using the preoperative POP-Q classification according to two methods:

- Compartment-by-compartment average (Fig. 1): Aa: $0.1 \pm 0.8$ (−3; +1); Ba: $0.1 \pm 0.8$ (−3; +1); C: $-0.2 \pm 0.8$ (−2; +1); D: $-0.8 \pm 1.3$ (−3; +1); Ap: $-2.0 \pm 1.2$ (−3; 0); Bp: $-2.1 \pm 1.1$ (−3; 0);
- General staging: POP-Q stage 2, $n = 27$ (77.1%), POP-Q stage 3, $n = 8$ (22.9%).

### 2.2. Characteristics of the adhesive

The adhesive used in the study is a translucent and non-toxic synthetic liquid solution (n-Hexyl cyanoacrylate) Ifabond™ [10] applied in laparoscopy using a syringe (1,5 ml) and an MB3 applicator (Microtek™). Designed and manufactured in France (Fimed SAS), this medical device has a class III CE mark. Once applied to living tissue, this low viscosity sterile mesh adhesive polymerizes in just a few seconds to create a flexible poly (n-Hexyl cyanoacrylate) adhesive, with no risk of further unwanted gluing. All of the biocompatibility tests were conducted according to the European regulations and are compliant with ISO 10993 (cytotoxicity, sensitivity, Ames test, toxicity, etc.) [11–15].

A histological examination showed that the n-Hexyl cyanoacrylate polymer was still present 3 months after its use [16]. The lifespan of the polymer in the mesh is of approximately 6 months [17].

### 2.3. Operative technique

All of the patients underwent a standard laparoscopic sacrocolpopexy according to several reproducible steps [18,19]. During surgery, the patients are placed in a supine position, with their arms along the body and their legs slightly bent. A 30° Trendelenburg position is set up after completing the safety measures. The laparoscopic approach is done by placing a 10-mm umbilical trocar, 5-mm left and right para-umbilical trocars (6–8 cm) and a 10-mm trocar placed midway between the umbilicus and the pubis, shifted 2 cm to the right. The epiploic appendages of the sigmoid colon and the uterine fundus are suspended (no suspension for patients with a history of hysterectomy) using a transparietal suture to ensure a suitable

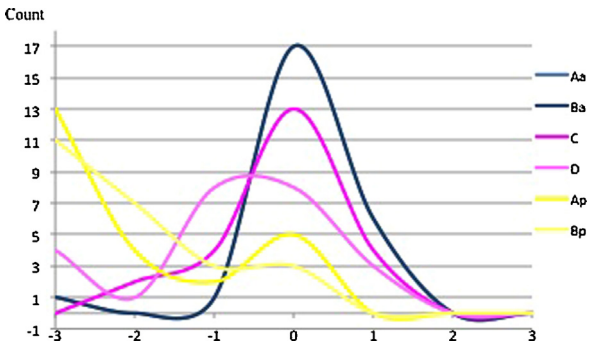


**Fig. 1.** Clinical examination and preoperative POP-Q quantification.