

## Satisfaction, quality of life and lumbar pain following laparoscopic sacrocolpopexy: suture vs. tackers



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### ARTICLE INFO

#### Article history:

Received 30 October 2014

Received in revised form 5 January 2015

Accepted 6 February 2015

#### Keywords:

Dorsolumbar pain  
Genital prolapse  
Sacrocolpopexy  
Sacral colpopexy  
Tacker  
Pelvic organ prolapse

### ABSTRACT

**Objective:** To compare the operative results and rate of complications, in particular dorsolumbar pain, following laparoscopic sacrocolpopexy (LS) using sutures or tackers.

**Study design:** A case-control study: LS using tackers ( $n = 35$ , tacker group) compared with LS using sutures ( $n = 65$ , suture group). In addition to clinical evaluation of prolapse, all patients were evaluated for urinary incontinence (ICIQ-SF), dorsolumbar pain, overall quality of life (SF-36 score), and overall improvement in symptoms (PGI-I), one year after LS.

**Results:** The patient characteristics (age, initial stage of prolapse, ...) were comparable in the two groups, as was operating time (240 vs. 210 min,  $p = 0.18$ ). There was no significant between-group difference in terms of anatomical correction (median post-operative ICS stage: 0 in both groups,  $p = 0.26$ ) or post-operative complication rates. The incidence of de novo low back pain appearing after LS was equivalent in both groups (50% vs. 25%, in the tacker and suture groups, respectively,  $p = 0.11$ ). However, there was a significant difference in lumbar pain intensity evaluated using the visual analog scale (4 (IQR 0–6.5) vs. 0 (IQR 0–4) in the tacker and suture groups, respectively;  $p = 0.01$ ), and in post-operative quality of life, which was better in patients in the suture group according to all the questionnaires.

**Conclusion:** Our study suggests that the use of tackers for prosthesis fixation to the promontory does not increase the incidence of post-operative dorsolumbar pain, but may increase its intensity and decrease quality of life.

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### Introduction

Genital prolapse (cystocele, uterine prolapse, vaginal vault prolapse and/or rectocele) is a common condition that affects 30% of women [1]. Sacrocolpopexy is frequently performed to correct prolapse of the apical compartment (vaginal vault or uterine prolapse) and of the anterior compartment (cystocele). If in the same patient another compartment is found to be prolapsed (e.g. posterior compartment in rectocele), it can be corrected during the same surgery. Other methods to cure the prolapse include vaginal surgery (autologous techniques or synthetic mesh placement).

The standard treatment of genital prolapse via the abdominal route is laparoscopic sacrocolpopexy (LS), in which a prosthesis is attached to the anterior common vertebral ligament, in order to correct the anterior and/or posterior compartments. Various prosthesis fixation techniques can be used: nonabsorbable tackers, nonabsorbable sutures such as Mersuture<sup>®</sup>, and Arthrex AR-1925S titanium bone anchor fixations [2]. All of these means of fixation have been analyzed in non-comparative studies [3,4]. The incidence of de novo dorsolumbar pain following LS remains unclear, but some authors have hypothesized that the use of tackers for the fixation on the anterior vertebral ligament may be associated with an increase in complication rates [5]. However, none of these studies have taken a close look at the possibility of a correlation between the type of fixation used to attach the prosthesis to the promontory and the appearance of, or an increase in, dorsolumbar pain. The main objective of our study was thus to evaluate the impact of the type of promontory fixation (ProTack<sup>™</sup> 5 mm tackers vs. Mersuture<sup>®</sup> sutures) on the incidence of dorsolumbar pain.

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## Materials and methods

This was a case–control study of 228 patients who underwent LS between January 2006 and December 2012. A flow-chart is given in Fig. 1. The indication for surgery was symptomatic genital prolapse associated with discomfort, following failure of pelvic floor rehabilitation and/or a pessary. Two different promontory fixation techniques were available: prosthesis fixation to the promontory using a suture (Mersuture<sup>®</sup> 0) (suture group) or titanium tackers (ProTack<sup>™</sup> 5 mm) (tacker group). Patients with mixed promontory fixation (sutures + tackers) were not included in the study ( $n = 17$ ). Of the remaining 211 patients, 63 (30%) underwent prosthesis fixation to the promontory using tackers and 148 (70%) using sutures. Only those patients who had been followed up for more than one year and who returned questionnaires were kept in the study. We implemented a case–control study (LS using tackers (tacker group) vs. LS using a suture (suture group)). The number of subjects to be included was computed by estimating the prevalence of lumbar pain to be 25% in the suture group, whilst seeking to detect a 50% greater prevalence in the tacker group, based on an alpha level of 0.05 and a power of 80% in a one-sided test. The number of subjects required for the

study was estimated to be 100, with 35 subjects in the tacker group and 65 subjects in the suture group. The 65 women in the suture group were matched for age and body mass index (BMI), which are recognized risk factors for dorsolumbar pain.

For each patient, we recorded the following information: age, BMI ( $\text{kg}/\text{m}^2$ ), pregnancy, parity, previous surgery for prolapse, history of hysterectomy, history of perineal retraining, tobacco consumption. During the pre-operative visit, functional discomfort was evaluated by means of the following questions: Q2 (“Do you usually experience heaviness or dullness in the pelvic area?”), Q3 (“Do you usually have a bulge or something falling out that you can see or feel in your vaginal area?”) and Q17 (“Do you usually experience urine leakage related to coughing, sneezing or laughing?”) of the PFDI-20 (response scale: no: 0; scale of bother if “yes” (symptom present): not at all: 1; somewhat: 2; moderately: 3; quite a bit: 4). An objective assessment of POP was carried out using a split speculum during a Valsalva maneuver in the gynecological position, following the recommendations of the International Incontinence Society (ICS) POP-Q examination.

A trained senior surgeon performed the LS procedures. Either a prosthetic macroporous monofilament polypropylene mesh or a polyester mesh was used. A posterior mesh was placed only if there was a posterior compartment vault (elythrocele, rectocele or enterocele). Following identification of the right ureter, the left iliac vein, and the iliac vessel junction, the peritoneum above the sacral promontory was incised medially to the right ureter and laterally to the sigmoid colon. The bladder was dissected from the upper half of the anterior vaginal wall. Concerning the apical compartment: (i) when the uterus was left in the pelvis, the anterior mesh was attached to the anterior part of the uterine isthmus (junction between the cervix and the anterior part of the uterine isthmus), and the mesh was passed laterally in the right broad ligament; (ii) when a concomitant hysterectomy was performed, a subtotal hysterectomy was done and the anterior mesh was attached to the conserved cervix; (iii) in patients presenting with previous total hysterectomy, the mesh was attached directly to the vaginal wall. For the posterior mesh placement, a rectovaginal dissection was performed down to the level of the levator ani muscles, and a mesh was placed and sutured to the levator ani muscles using a non-absorbable suture along the full length of the posterior vaginal wall. Depending on the group to which the patient belonged, the cranial end of the anterior prosthesis was attached to the anterior vertebral ligament opposite to the promontory (S1), using either a non-absorbable multifilament suture (Mersuture<sup>®</sup> 0, Ethicon, Issy-les-Moulineaux, France), or one or more tackers (ProTack<sup>™</sup> 5 mm, Covidien, Elancourt, France). A complete closure of the peritoneum was achieved by joining the edges of peritoneum using an absorbable suture (Vicryl<sup>®</sup> 2-0). The operative and peri-operative data we recorded.

During routine follow-up visits, the anatomical correction was evaluated using the POP-Q classification. The association of the following criteria was used to define surgical success: the patient had to be very satisfied or satisfied, on a 3-level Likert scale (very satisfied, satisfied, not satisfied), and the stage of prolapse had to be strictly less than 2 for all compartments. Complications with the prosthesis were categorized according to the ICS/IUGA classification [6].

All patients were re-contacted concerning their surgery, by mailing them questionnaires designed to evaluate any lumbar pain/sciatica before and after sacrocolpopexy, as well as their quality of life. These corresponded to the ICIQ-SF questionnaire for urinary incontinence, the SF36 health questionnaire for the evaluation of the impact of lumbar pain on the patient's quality of life, a questionnaire on the patient's overall impression of her postoperative condition (PGI-1), and questions dealing with the direct impact of the sacrocolpopexy on low back pain (Appendix 1).

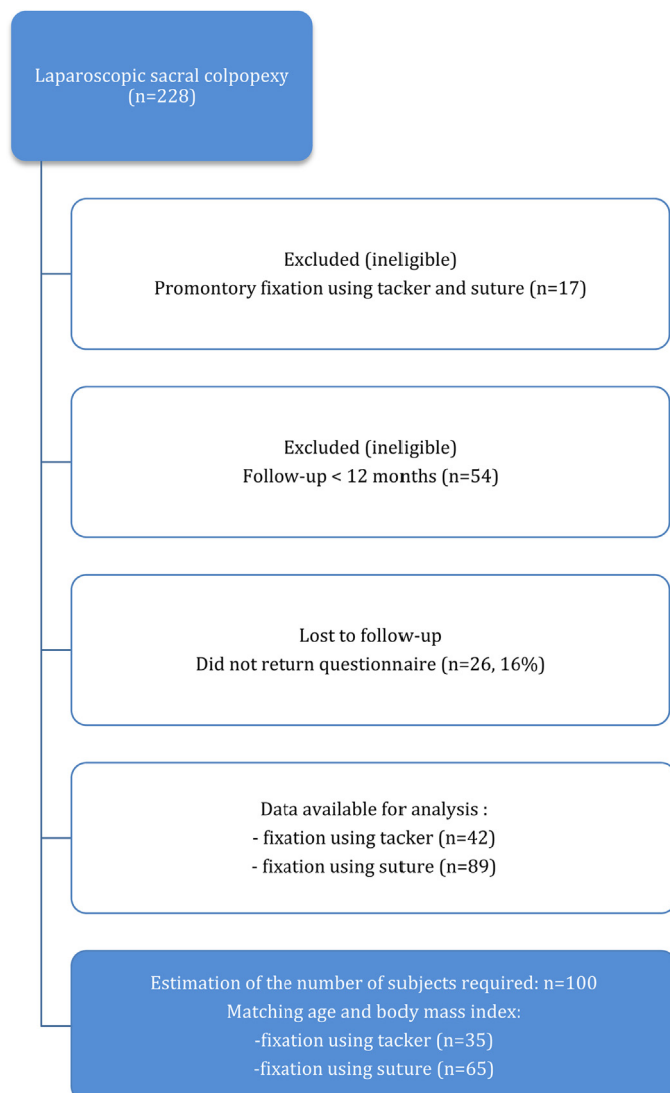


Fig. 1. Flow chart.

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