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Rate of re-interventions after transvaginal pelvic organ prolapse repair using partially absorbable mesh: 20 months median follow-up outcomes

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ABSTRACT

Objective: To report our experience regarding the use of partially absorbable mesh, evaluating the nature and rate of re-intervention after transvaginal pelvic organ prolapse repair.
Materials and methods: We retrospectively collected data on 269 consecutive patients who underwent partially absorbable mesh repair between January 2009 and January 2011. Data were obtained from our hospital medical records and we phoned patients to check if they had surgery in another hospital since then.
Results: 250 patients were included, with a median follow-up duration of 20 months (range 8–34 months). The global rate of re-interventions was 8%. The main indications were mesh exposure (2%), prolapse recurrence (1.2%), and urinary complications such as de novo stress urinary incontinence (4.8%). Afterwards, we compared these data with those previously obtained in our centre with non-absorbable mesh.
Conclusion: Our study shows that the use of a partially absorbable mesh is efficient and reliable with relatively low rates of re-intervention. According to the available literature data, a partially absorbable mesh does not seem to give advantages in comparison with classic non-absorbable mesh regarding rates of re-intervention.

1. Introduction

During their lifetime, 30–50% of women will suffer from pelvic organ prolapse (POP), with an incidence of surgery of 11%. Sacrocolpopexy has long been considered the gold standard in the matter. The development of laparoscopy allowed a less invasive approach, with good anatomic and functional results [1,2]. Nevertheless, the vaginal route has many advantages (less post-surgical pain, shorter interventions, and much quicker return to daily activities) [3,4], and it is now widely used. The use of mesh provides a better rate of success than conventional techniques [5–9]. However, specific complications were reported, mainly exposure and sometimes pain and dyspareunia [3,4,10–12], that led the U.S. Food and Drug Administration in July 2011 to publish a warning regarding the use of mesh for vaginal prolapse repair [13].

Studies in hernia surgery showed that reduction of mesh density allowed a reduction of mesh retraction and post-operative pain [14,15]. Therefore, the hypothesis was that using mesh which has lower density after partial resorption might reduce the rate of mesh exposure and dyspareunia after vaginal prolapse repair. The aim of our study is to report our experience using partially absorbable mesh for vaginal prolapse repair and to assess the rates of reintervention observed, with a median follow-up duration of 20 months.

2. Materials and methods

This was a retrospective single-centre study. It registered 269 consecutive patients who were treated by transvaginal partially absorbable mesh (Prolift + M®, Ethicon Women's Health and Urology, Sommerville, NJ) for a symptomatic POP stage 2 or more, in the gynaecologic surgical unit of Lille University Hospital between January 2009 and January 2011. At the time of pre-surgical consultation, each patient underwent thorough clinical examination: symptoms, type of prolapse (anterior, median or posterior), its stage, and symptoms of stress urinary incontinence (SUI), were registered. Stage of prolapse was determined using a simplified version of the International Continence Society (ICS) Pelvic Organ Prolapse Quantification (POP-Q) staging system as

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described by Swift et al. [16]. A cough stress test was performed to detect SUI, or occult urinary incontinence if the urine leakage was only revealed after prolapse reduction. Urodynamic evaluation was performed only when symptoms suggested concomitant SUI.

Surgery was standardized following the description by Fatton et al. [17] of the tension-free vaginal mesh (TVM) procedure. Anterior mesh was placed between bladder and uterus, held on both sides by its two arms passing through obturator membrane and foramen, with the superficial arm anterior and median, and the deep posterior arm postero-lateral. Posterior mesh was placed in the recto-vaginal space. On each side, an arm crossed the sacro-spinous ligament in the ischio-anal fossa. The Prolift + M mesh is made up of half polypropylene and half poliglecaprone 25, which is totally absorbed after 90 or 120 days. The mesh then weighs 31 g/m^2 compared to 45 g/m^2 for classic non-absorbable polypropylene Prolift mesh. It also has a certain longitudinal elasticity. In our centre it had replaced classical Prolift since January 2009. The procedure itself (isolated anterior repair, posterior alone or total repair) varied with the type and stage of the prolapse. During the same surgical time, the surgeon could add additional procedures if necessary: sacrospinous fixation, posterior myorrhaphy, hysterectomy, or surgery for SUI by suburethral sling insertion if concomitant SUI was diagnosed during pre-operative period.

Patients' data were obtained from electronic hospital medical records. Each patient's data were computerized: age, parity, history, stage of POP and compartment involved, type of repair, concomitant surgery, intraoperative complications and their management, and date and type of re-intervention, if any. The characteristics of included patients are summarized in Table 1. The surgeon saw all the patients again two months after the operation. In addition, each patient had a phone call to find out if re-intervention had been done in another centre, with a median phone call follow-up duration of 20 months (range 8–34).

Afterwards, the data obtained were compared to previous data on 524 patients who had undergone POP repair in our centre between January 2005 and January 2009 by placing classic non-absorbable Prolift mesh. The patients were operated by the same surgeons using the same surgical technique, and data were obtained following the same methodology [18]. The aim was to assess if the use of a partially absorbable mesh might reduce the rate of complications requiring re-intervention in comparison with non-absorbable mesh.

Analysis was done with the help of the biostatistics department of Lille University hospital. Categorical variables were compared with the chi-squared or Fisher's exact test. Continuous variables were compared with Student's *t* test. Survival distribution function for Prolift and Prolift + M was obtained using Kaplan–Meier method, and the log-rank test was performed to compare rates of re-intervention between meshes. Statistical significance was set at $p < 0.05$.

Table 1
Characteristics of included patients.

Characteristics	*n* = 250
Age, median (± DS)	66 years (±8.5 DS)
Parity, median (± DS)	3 (±2 DS)
History, n (%)	95 (38)
Hysterectomy	64 (25.6)
Prolapse surgery	54 (21.6)
Surgery for SUI	38 (15.2)
Concomitant surgery, n (%)	102 (40.8)
Prolapse repair without mesh	19 (7.6)
Surgery for SUI	68 (27.2)
Hysterectomy	7 (2.8)
Type of Prolift, n (%)	
Anterior only	17 (6.8)
Posterior only	42 (16.8)
Anterior and posterior	191 (76.4)
with uterine preservation	155 (62)
previous hysterectomy	31 (12.4)
with concomitant hysterectomy	5 (2.8)

3. Results

A total of 269 consecutive patients were surgically treated between January 2009 and January 2011. Of these, 250 (93%) could be included and 19 were excluded: 13 patients were lost to follow-up, 3 refused to participate in the study, 2 died from no reason linked to surgery and one, a 22 year old woman, was excluded due to a very long surgical history of vesical exstrophy. Characteristics of the patients are summed up in Table 1: 208 (83%) had a cystocele stage ≥ 2, 149 (60%) had a uterine prolapse stage ≥ 2, 162 (65%) had a rectocele stage ≥ 2, and 33 (13%) had an enterocele. Intraoperative complication occurred with two patients (0.8%). It consisted in bladder injury, immediately stitched up, and involving immediate removal of the mesh for one patient.

Twenty patients out of the 250 had re-intervention, with a global rate of 8%. The nature and number of re-interventions are detailed in Table 2. Three patients (1.2%) had post-surgical haemorrhage: one patient had intraoperative bleeding in the right pararectal fossa, the origin of which was not identified. Immediately after surgery, a scan was done which showed a right lateral pelvic haematoma with active bleeding from the cervico-vaginal artery. Selective embolisation of this artery allowed complete haemostasis. A second patient presented a pre-rectal and pre-sacral haematoma on day 3 after total mesh repair. This patient was being treated with anticoagulants for atrial fibrillation. Surgical drainage was performed by the vaginal route without allowing identification of the source of bleeding. A few days later, dehiscence of the vaginal scar allowed evacuation of a second, infected haematoma and the evolution was favorable with antibiotics. Finally, a third patient with a serious cardiovascular history presented a pelvic retroperitoneal haematoma on day 2 after a posterior mesh repair. She was treated by embolisation of hypogastric arteries. The source of bleeding was not identified during the embolisation. This haematoma was complicated by haemorrhagic shock that required transfer to the intensive care unit, and then by multi-organ failure which ended in death on day 28.

Five patients (2%) had a re-intervention for anterior mesh exposure. This always occurred after total mesh. All patients were treated by partial mesh excision. Using the International Urogynecological Association (IUGA) classification, the exposures after vaginal route insertion of the mesh can be classified as 2A, 2B, 3A, 3B/T3/S1 [19]. The median delay of re-intervention was five months.

Three patients (1.2%) had re-intervention for prolapse recurrence, with a median delay of seven months. In our study, recurrence was defined by post-operative symptomatic prolapse stage 2 or more. The recurrence could also occur in the untreated compartments. Among the 42 patients who only had a posterior mesh, two (4.8%) had a prolapse recurrence. One had a uterine prolapse treated by total vaginal hysterectomy, seven months after initial surgery. The second one had a direct and early relapse, after three months, in the form of a low rectocele, the rectum being no longer covered by the mesh. She had two more re-interventions, initially to place a second pre-rectal mesh of Ultrapro (Ultrapro Hernia System®; Johnson and Johnson, Somerville, NJ) with rectopexy, then transanal surgery following the Delorme technique. Of the 191 patients treated by total mesh, only one (0.5%), had a relapse after 16 months (cystocele stage 2 and uterine prolapse stage 3), treated by hysterectomy and sacrocolpopexy.