



Efficacy of Pelvisoft® Biomesh for cystocele repair: assessment of long-term results

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ABSTRACT

Introduction and Hypothesis: To our knowledge a study regarding the efficacy of Pelvisoft® Biomesh for cystocele repair has not previously been reported in the literature. The aim of our study was to assess the long-term efficacy, subjective outcomes and complications in the use of a non-synthetic porcine skin mesh graft (Pelvisoft® Biomesh) associated with transvaginal anterior colporrhaphy in the treatment of cystocele prolapse.

Materials and Methods: A retrospective study was performed at a single centre. Thirty-three women aged 35-77 years underwent cystocele repair using Pelvisoft® graft between December 2005 and June 2009. Twenty-nine women who underwent transvaginal cystocele repair with Pelvisoft® Biomesh for over a 2 years period were assessed. Four patients were lost to follow-up. Cystocele repair was performed via the vaginal route using Pelvisoft®Biomesh implant by inserting it in the anterior vaginal wall.

Results: The median follow-up time was 54.0 months. The rate of recurrence was 17.3%. A total of 6.9% of patients presented early mesh exposure treated by conservative treatment. The mean PFDI-20 score was 72.2. Among sexually active women, the mean PISQ 12 was 33.9 but 56.2% had dyspareunia. After surgery, 6 patients had de novo intercourse.

Conclusions: Our results show that the use of Pelvisoft® biomaterial associated with anterior colporrhaphy for cystocele repair appears to be safe with acceptable failure and complication rates at long term. Nevertheless, an adverse impact on sexual function was reported by the majority of patients.

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INTRODUCTION

Pelvic organ prolapse is characterized by a descent of the pelvic organs into the vaginal wall. The most frequent occurrence is anterior vaginal wall prolapse or cystocele (1). It is a major health-care problem that affects about 40% of women over 50 (1). According to Olsen et al. approximately 11% of women will undergo reparative surgery for prolapse or stress urinary incontinence (SUI) and a second operation is estimate to be required

in 29.2 % of cases (2). Furthermore, 17% of women who undergo pelvic organ prolapse (POP) or SUI surgery may require re-operation in 10 years time (3). When conservative treatment has failed, surgery is the treatment of choice for women with symptomatic cystocele. Trans-vaginal cystocele repair by anterior colporrhaphy is associated with a high rate of failure reaching 40% or higher (4-6). In order to decrease this high recurrence rate, the use of meshes (synthetic polypropylene or non-synthetic biological materials) has been used to

repair POP during the past decade. Polypropylene monofilament and macroporous tissue is the most widely used. This material assures good anatomical repair, at short and median term, although there is a high rate of adverse events i.e. vaginal erosion, dyspareunia or pelvic pain. The use of biological biomaterials appears to have a lower complication rate, however few evaluations have been reported and most of them with short term follow-up. The aim of our study was to assess the long-term efficacy, subjective outcomes and complications in the use of a non synthetic porcine skin mesh graft (Pelvisoft® Biomesch) associated with transvaginal anterior colporrhaphy in the treatment of cystocele prolapse.

MATERIALS AND METHODS

Study population

Thirty-three women who underwent transvaginal cystocele repair with implantation of Pelvisoft®, from December 2005 to June 2009, were included in a retrospective study. Two experienced surgeons performed the repair surgery. Pre-operative urogynaecological examination was carried out with patients in the dorsal lithotomy position. Tests included a speculum valve examination, a cough test and Valsalva manoeuvre. The degree of prolapse was defined according to the POP-Q classification (7). All patients had a cystocele stage >1 with or without associated apical or posterior vaginal wall prolapse. Urodynamics, including flow rate measurement, urethrocystometry and profilometry were performed prior to cystocele repair if there were concurrent voiding abnormalities. All patients had a follow-up consultation at 2 months after surgery. Then, two years or more after surgery, all patients were examined by an independent blinded urologist and prolapse recurrence was defined as vaginal descent of the anterior wall POP-Q stage >1.

At each patient consultation, a questionnaire regarding subjective satisfaction to assess sexuality was completed. The French validated translation of the Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ-12) was used to assess the effects on sexual function (8) with a score range from 0 to 48, the higher score indicating better sexu-

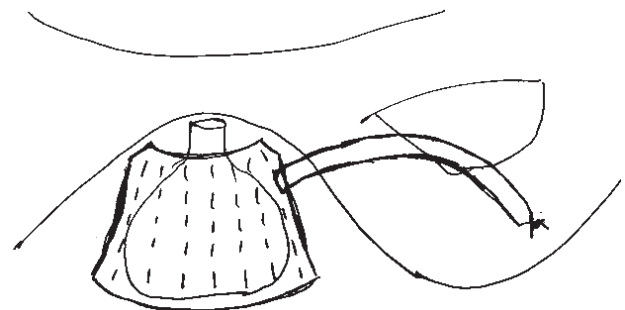
al function. The study was not submitted for Ethics Committee approval because this is standard clinical practice study with no randomization. The French validated translation of Pelvic Floor Distress Inventory (PFDI-20) evaluated pelvic floor disorders (9). It consists of 3 subscales: the pelvic organ prolapsed distress inventory (POPDI-6), the urinary distress inventory (UDI-6), and the colo-rectal-anal distress inventory (CRADI-8) The response of each item was rated from 0 to 4. The mean value of all of the answered items within the corresponding scale was then multiplied by 25. Each subscale ranges from 0 to 100, with a maximum summary score of 300.

Surgical technique

Pelvisoft® Biomesch (C.R. Bard, Cranston, R.I.) is a macroporous mesh material used for cystocele repair. It is a porcine dermal acellular matrix collagen biomesch consisting of fibrous, acellular collagen and elastin fibres. A 4 X 7cm size was used for the study. All women had negative urine culture before surgery and received prophylactic antibiotics (i.e. cefazoline) during surgery.

Initially an anterior colpotomy was performed with a dissection of the bladder from the vagina, opening the pelvis fascia on each side. The implant was inserted transversally over the bladder and attached with 3-0 monofilament polyglactin absorbable sutures on the median line proximal to the periurethral tissue and distal to the cervical ring. On each side, the implant was attached (Figure-1) with a 0 monofilament polypropylene transobturator non-absorbable suture, using a Hemet

Figure 1 – Lateral mesh fixation.



The prolene suture node is at the upper right part of the subcutaneous tissue. A transobturator route is used with a Hemet needle stitched from the outside to the inside.

needle back and forth. The colpotomy was sutured with a non interrupted 0 monofilament polyglactin. A vaginal pack and a Foley catheter were left indwelling for 24h.

An associated apical or posterior prolapse was treated respectively either by sacrospinous suspension or a posterior colporrhaphy. When preoperative SUI was associated, a transobturator tape (TOT) polypropylene sling procedure was performed. A hysterectomy was performed if associated with ≥ 2 uterus prolapse.

Statistical analysis

Values were reported at the mean plus or minus standard deviation (SD) or at the median and interquartile range (IQRs). Quantitative variables were analyzed using the Mann-Whitney test. For qualitative variables, Fisher's exact test was used. A $p < 0.05$ was considered to be statistically significant. Statistical analyses were performed with GraphPad Prism (version 5.01 for Windows).

RESULTS

Of the 33 patients who underwent cystocele repair, four patients were lost to follow-up. Patient's characteristics and prolapse staging are shown in Table-1.

Characteristics of surgery and early complications are listed in Table-2. The median duration of surgery was 58.0 min (IQR: 45.0-90.0), including all operative procedures. No per-operative complication was observed, except for a post-voiding residual in three patients ($>150\text{mL}$). Resolution occurred in all cases after intermittent self-catheterization. One patient presented a vaginal haematoma treated surgically. Two patients had early mesh exposure due to surgical dehiscence in the anterior wall which resolved conservatively and no recurrence occurred. These cases were associated with a vaginal hysterectomy. Urinary tract infection was treated by antibiotics. Mean hospital stay was 3.7 days (SD: 1.0).

Median follow-up period was 54.0 months (IQR: 37.0-57.0, range: 27.0-65.0). Pre and post-operative anatomical findings are shown in Table-3. Of the 29 patients, five of them had a cysto-

cele recurrence. At follow-up, among patients with recurrent prolapse, two had an early recurrence and had previously undergone laparoscopic sacral fixation. The recurrence rate was not statistically different in patients with or without an apical defect or rectocele repair ($p=0.6$). Median time to recurrence was 33.0 months (IQR: 10.5-49.0, range: 10.0-58.0).

Table 1 – Patients characteristics.

Characteristics	Patients (n=29)
Age, year, mean, (SD)	61.31 (12.01)
BMI, kg/m ² , mean (SD)	26.09 (4.47)
Surgical History, No (%):	
Prolapse repair	8 (27.6)
Suburethral sling	4 (13.8)
Hysterectomy	11 (37.9)
Intra vaginal surgery	9 (31.0)
Voiding abnormalities, No (%):	
Urgentury	10 (34.5)
SUI	14 (48.3)
Voiding difficulties	7 (24.1)
Constipation, No (%)	10 (34.5)
Anal incontinence, No (%)	3 (10.3)
Prolapse staging, No (%):	
Cystocele: First degree	0 (0.0)
Second degree	21 (72.4)
Third degree	8 (27.6)
Rectocele: First degree	7 (24.1)
Second degree	4 (13.8)
Third degree	0 (0.0)
Uterine/vaginal vault prolapse: First degree	2 (6.9)
Second degree	5 (17.2)
Third degree	1 (3.4)

BMI = body mass index.

SUI = stress urinary incontinence.

Table 2 – Characteristics of the surgery.

Characteristics	Patients, No. (%)
Concomitant procedure	
Vaginal hysterectomy	6 (20.7)
Posterior colporrhaphy	9 (31)
Suburethral sling	11 (37.9)
Uterine/Vaginal vault suspension	5 (17.2)
Post-operative complication	
Acute urine retention	3 (10.3)
Haematoma	1 (3.4)
Urinary tract infection	1 (3.4)
Mesh exposures	2 (6.9)

Table 3 – Anatomical outcomes.

	Pre-operative stage of cystocele, No. (%)	Post-operative stage of cystocele, No. (%)
Grade 0	0 (0)	15 (51.7)
Grade I	0 (0)	10 (34.4)
Grade II	21 (72.0)	3 (10.3)
Grade III	8 (28.0)	1 (3.4)
Grade IV	0 (0)	0 (0)

A de novo SUI occurred in 24.1% and de novo urgency in 13.7%. Urgency was resolved in 50.0%.

Our retrospective study regarding sexuality showed that 10 women still experienced sexual intercourse before surgery, with dyspareunia in 40.0 % of cases. After surgery, 16 patients had a sexual life showing an improvement in sexuality with 6 patients who had de novo sexual intercourse. The mean PISQ-12 score was 33.9 (SD: 8.7). The PISQ-12 showed that among women who had intercourse (16 patients), nine had pain during sexual activity. The mean PFDI-20 score was 72.2 (±61.7) (Table-4). It was significantly higher in patients with recurrence (p<0.05). Recurrence was associated with an adverse impact in quality of life, prolapse distress, colo-rectal and anal distress (p<0.05).

Table 4 – PFDI-20 Scores (recurrence vs no recurrence).

PFDI-20	Recurrence (n=3)	No recurrence (n=26)	p value
Total	174.9 (6.2)	60.3 (53.4)	0.009 ^Δ
POPDI-6	52.7 (31.3)	14.2 (14.1)	0.033 ^Δ
GRADI-8	57.3 (31.6)	19.7 (17.4)	0.024 ^Δ
UDI-6	65.3 (4.8)	26.4 (8.9)	0.078 ^Δ

Mann and Whitney Test: Δ

DISCUSSION

To our knowledge, our study is the first to evaluate outcomes of Pelvisoft® non synthetic bio-materials in cystocele treatment.

In the treatment of POP, the search for the “ideal graft” remains problematic. Currently, the most widely used material is macroporous low weight polypropylene. Synthetic meshes provide satisfactory anatomical results but side-effects and tolerance still remain a major concern. Therefore, studies regarding non-synthetic biomaterials are limited. Non-synthetic biomaterials have been reported to have a better biocompatibility and fewer side effects. As previously mentioned, Pelvisoft® biomesh, used in our study, is an acellular collagen matrix for tissue repair. Using a rat model, Konstantinovic et al. showed that there was no shrinkage of Pelvisoft® after a 90 day period although an increase in size of 17% has been observed (10). Macropores present in the material facilitate the integration of the implant into the surrounding tissue and provide a better resistance (11). In fact, in contrast with Pelvicol®, another porcine dermal collagen implant (not macroporated), the pores in Pelvisoft® permit new vessel generation as well as a better tensile strength (12). The tensile strength of Pelvisoft® is also similar to that of polypropylene (12). Fenestrations in the graft permit immediate contact between the vaginal mucosa and underlying host tissues and may improve long-term functional outcome. Moreover, in the absence of

pores, it can form a mesh encapsulation due to fibrotic tissue and allow dead space formation between native tissue and the graft. To date, only one clinical study has been reported in the literature assessing the properties of Pelvisoft® for rectocele repair. In a series of 35 patients, Dell et al. have shown that the use of these materials led to good anatomical results with sexual activity preservation (13). These authors observed that no graft exposure occurred due to fenestration.

In our study using Pelvisoft®, the recurrence rate was 17.2% and is less than the 40% reported with native-tissue colporrhaphy repair without mesh (4-6). However, this rate is higher than that reported with the use of polypropylene mesh. In recent prospective studies using synthetic meshes, the recurrence rate varies from 9.0% to 10.2% with a median follow-up of 12 months (14, 15). The incidence of cystocele recurrence increased over time with the follow-up. A 24.0% recurrence rate with 79 months follow-up was reported by Letouzey et al. (16). Two recent randomized trials have reported better results with a failure rate of 5.7% and 13% respectively for a follow-up of 24 to 60 months (5, 17). However, in these two studies the major concern was a mesh exposure rate of 11.1% and 19%. Vaginal mesh extrusions appear to be the most common complication observed with the use of a synthetic mesh graft and its management is often surgical. In the literature, with a follow-up higher or equal to 1 year, reported mesh-exposure was 4.0 to 14.4% (14-16). Two different processes may be involved. Early exposure could be caused by a healing defect resulting of the procedure. A late exposure may be a rejection phenomenon due to chronic tissue erosion depending on the material used (18). In our study, two patients presented early mesh exposure in the 15 days following surgery which was related to procedure (dehiscence of healing). They underwent concomitant hysterectomy which is a reported risk factor of exposure (19). However, we did not observe any late exposure. The hypothesis that may explain this result is that Pelvisoft® is composed of acellular collagen matrix which had minimal immunologic and inflammatory reaction compared to synthetic materials. The risk of mesh exposure could also result due to the friction during intercourse (18). Our rate of women

sexually active was low which may explain our good results on late exposure. Furthermore, among the women who had sexual intercourse, dyspareunia might have been a protective factor since pain can lead patients to avoid sexual intercourse. In fact, in our population 56.2% had dyspareunia. Moreover, the use of a synthetic mesh may lead to its shrinkage and consequently responsible for vaginal shortening and tightening. This may explain the better impact of surgery on quality of life and sexuality with Pelvicol® (biological graft) than with Gynemesh PS® (non absorbable mesh) observed in Natale et al. study (20). In our study, during follow-up, elasticity of the vagina was normal, with no shortening.

Some studies using other porcine dermis mesh have reported a low recurrence rates. Meschia et al. in a series of 201 women observed the lowest recurrence rate in the treatment of cystocele with Pelvicol® (7%) at 1 year follow-up, in comparison to patients treated with colporrhaphy (20 %) (21). Gomelsky et al. studied 70 patients over a 24 months period treated with Pelvicol® for POP and reported a 12.9% recurrence rate (22). In a retrospective study of 119 patients, Handel et al. compared anterior colporrhaphy, polypropylene meshes and porcine dermis meshes in cystocele repair with a 13.5 months mean follow-up (23). With the use of the porcine dermis graft, recurrence and erosion rates were 36% and 21% respectively, and this was significantly higher than in the two other groups. Two additional studies using Pelvicol® showed a high rate of recurrence: Dahlgren et al. reported a 58% recurrence at 3 years follow-up, while Natale et al. reported a 43.6% recurrence rate at 24 months follow-up (20, 24). These high recurrence rates can be explained due to the non-macroporous cross-linked structure of Pelvicol® which decreases strength and durability of tissue support owing to the limitation of neovascularization and encapsulation of the graft (20). Our lower failure rate may have been due to macroporations in the Pelvisoft® graft which allows a better incorporation of native tissue in grafts than the non macroporated meshes.

The de novo SUI rate is higher than usually reported in 6 to 12% of patients (5, 6). POP has an adverse effect on the functional quality of

life. Most women avoid sexual activity because of the presence of vaginal bulging (45.3-52.6%) (25). Surgery is an alternative which may improve sexuality; however, some vaginal functions might be altered. Also, the effect of surgery on sexual function remains contradictory. In our study, the impact on sexuality was not evaluated prospectively before surgery but based on a retrospective interview and compared to sexual activity after surgery at the follow-up visit. Our mean PISQ 12 score was 33.9, which was similar to that reported in the literature, i.e. 34.1 to 35.5 (25, 26). Our rate of inactive sexual patients after surgery was 44.8%. Two prospective studies with validated questionnaires showed an improvement of sexual function even if pain had been reported during intercourse after surgery for POP (27, 28), however the mean age of population was relatively young (36 and 51 years respectively). In other studies, sexual function was unchanged regardless of surgical procedure, with or without meshes or via the abdominal route (26, 29). A negative impact of the vaginal route on sexual function was described by Hellstrom and Nilsson, caused by a decreased elasticity of the vaginal wall and disturbance of the female erectile reflex (30). In our study, we observed a high rate of dyspareunia (56.2%) in comparison to other studies, (25, 26, 29), but the responsibility of Pelvisoft® seems to be less, since 40% of sexually active patients had already dyspareunia before the surgery. Further, we could not establish a de novo dyspareunia rate due to the absence of pre-operative evaluation. As regards, overall sexual satisfaction is difficult to evaluate due to a wide range of factors, i.e. age of two partners, widowhood, erectile dysfunction, however surgery seems to have only a limited impact.

CONCLUSIONS

This retrospective study on the use of Pelvisoft® in vaginal cystocele repair reassures this mesh as an interesting option. Our median 54 months follow-up showed positive functional outcomes with non recurrence of cystocele in 82% of patients. However, a long follow-up with a larger patient population is necessary, as well as future randomised controlled trials comparing non synthetic and synthetic meshes.

ABBREVIATIONS

SUI = Stress urinary incontinence
 POP = Pelvic organ prolapsed
 PISQ-12 = Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire
 SD = Standard deviation
 IQRs = Median and interquartile range
 TOT = Transobturator tape

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CONFLICT OF INTEREST

None declared.

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