Effectiveness of transvaginal colporrhaphy with porcine acellular collagen matrix in the treatment of moderate to severe cystoceles

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Summary

Purpose: The aim of this study was to determine the effectiveness of transvaginal anterior colporrhaphy with the use of porcine acellular collagen matrix in the treatment of moderate to severe cystocele. *Materials and Methods:* This retrospective study included 95 patients who underwent anterior colporrhaphy with the use of porcine dermus from September 2003 through March 2008 at the Gynaecological Department of University General Hospital of Alexandroupolis in Greece. The inclusion criterion was a grade 2-4 cystocele by the Baden-Walker halfway system. Postoperatively patients were evaluated at one, six and 12 months. Objective cure was defined as no or grade 1 cystocele with an asymptomatic patient at 12 months postoperatively. Improved outcome was considered as an asymptomatic patient with a grade 2 cystocele and failure symptomatic patients or with grade 3 or 4 cystocele. *Results:* All of the patients had a 12-month postoperative follow-up or were noted as a failure prior to the 12-month assessment. The majority of the women were menopausal (88.4%) and overweight (mean BMI 26.1). The overall cure rate was 81.1%, the improvement of the cystocele was 10.5% while the failure rate was 8.4%. The complications we noted were vaginal erosion in 2.01% and graft extrusion in 1.05% of the patients. *Conclusion:* Transvaginal anterior colporrhaphy using porcine dermal in the treatment of moderate to severe cystocele is simple, safe, easily learned and performed with a high success rate and low morbidity.

Key words: Pelvic organ prolapse; Cystocele; Anterior colporrhaphy; Porcine collagen.

Introduction

Cystocele is defined as the extrusion of the bladder base beyond its original place towards the vaginal introitus with the patient in maximum straining. According to the level of the protruding anterior vaginal wall cystoceles are divided in grades 1-4 by using the Baden-Walker Halfway System [1]. Anterior vaginal wall prolapse results from increased weakness and laxity of periurethral, urethrovesical, and vesicovaginal ligaments or fascias. The collagen tissue is considered to be damaged along with the innervation of the perineal muscles resulting in malfunction [2]. The more severe cystoceles are less prone to cure and more prone to recurrence and represent a modern challenge to gynaecologists. These are accompanied with other prolapsed sites as rectocele, enterocele, lateral defects and vaginal vault prolapse [3, 4].

Many techniques have been used with unsatisfactory results such as the Marshall-Marchetti-Krantz urethropexy, the Burch colposuspension, paravaginal repairs and the typical anterior colporrhaphy with a Kelly suture. These stand especially for grade 3-4 prolapses. The recurrence rate is high and 18% of patients need a repeat operation. Cystoceles account for 70% of repair procedures in these women. Due to these facts surgeons used graft materials for the correction of pelvic organ prolapse transvaginally, as in abdominal hernias, to solve the problem [5]. A variety of grafts (Table 1) are used, but the most common are the synthetic polypropylene mesh and the xenograft porcine acellular collagen matrix [6, 7].

Permacol is one of the newest available materials in the past 20 years. Permacol is a natural, strong, biocompatible and permanent material. It is resistant to mineralisation, retains its shape despite stretching and is easily fixed to the underlying tissues by sutures. Once in place it is invaded by the host's fibroblasts within two weeks thus fixing it in place and subsequently it is vascularised within 60 days making it a permanent strong layer of fascia.

Pelvic floor reconstruction surgery is aimed to correct the various defective sites, restore the anatomy and mainly to maintain pelvic structural physiology and function. The aim of our study was to determine the effectiveness of anterior colporrhaphy with the use of porcine acellular collagen matrix (Permacol).

Materials and Methods

This study is a retrospective analysis of data that was collected on 95 women who underwent transvaginal anterior colporrhaphy with the use of porcine acellular collagen matrix between September 2003 and March 2008 in the Gynaecological Department of the University General Hospital of Alexandroupolis, Greece. The classification of cystocele was based on the Baden-Walker Halfway system. The inclusion criterion was a grade 2-4 cystocele without regard to the presence or absence of the uterus or whether there was recurrence of a cystocele. Table 2 shows patient demographics.

The operation was performed with spinal or general anaesthe-

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Table 1. — *Types of grafts*.

A. Synthetic non absorbable (Prolene, Mersilene, Gore-Tex)
B. Synthetic absorbable (Dexon, Vicryl)
C. Autologous (rectus fascia/fascia lata)
D. Xenografts - Porcine (acellular dermis, subintestinal mucosa)
E. Allografts - Donor (fascia lata, dura mater)

Table 2. — *Patient demographics*.

Age	Mean 66 (range 42-78)
Parity	Mean 3 (range 1-4)
BMI (kg/m^2)	Mean 26.1 (range 21.2-30.5)
Vaginal Deliveries	92/95 (96.8%)
Previous pelvic floor reconstruction	11/95 (11.6%)
Postmenopausal	84/95 (88.4%)

sia with the patient in the dorsal lithotomy position. Patients were given antibiotics intra- and postoperatively. The typical steps for anterior colporrhaphy were followed with the use of mixed vasopressin and normal saline at the preparation site under the vaginal mucosa for a better and bloodless dissection thereafter. A vertical suburethral incision was made after infiltration and the underlying vesicovaginal fascia was left on the vaginal site in order to leave the bladder free of any tissue to accept and fuse with the porcine matrix via infiltration and neovascularisation. Meticulous haemostasis, clean surgical gloves, a tension-free graft and wet porcine matrix are essentials for the overall success rate. In cases of a huge cystocele we use interrupted 2/0 vicryl sutures placed transversely 1 cm apart for bladder area shrinkage and a better end result. The vaginal mucosa trimming was limited offering the patient a normal length of vagina. Then a 5 x 8 cm piece of Permacol was anchored at the 12 o'clock position suburethrally and then laterally along the perivesical area at 2, 4, 8 and 10 o'clock with 2/0 vicryl sutures. This limits the chance of the graft slipping and furthermore extruding through the vaginal mucosa. A vaginal pack was placed for 24-48 hrs and a Folley catheter for 48-72 hrs according to the necessity of a tension free vaginal tape transobturator (TVT-O) placement.

Residual urine was measured on the third postoperative day and a volume of ≤ 50 ml was considered satisfactory for the woman to be discharged, whereas a volume of ≤ 80 ml warranted a second voiding measurement after adequate hydration. If the residual urine was ≥ 50 ml the catheter was reinserted for another 24 hrs along with antibiotics per os.

In cases of coexisting pathology, we performed posterior colporrhaphy (rectocele), vaginal hysterectomy (uterine prolapse), and placement of a TVT-O (SUI) or posterior IVS or Apogee tape (vault prolapse).

Regular follow-up was carried out at one, six and 12 months postoperatively. The pre- and postoperative examinations were carried out with the women in the Sim's position straining maximally. Surgical outcome was classified according to the repair of cystoceles as cured, improved and failed. The objective cure was defined as no or grade 1 cystocele with an asymptomatic patient at 12 months postoperatively. Improved outcome was considered an asymptomatic patient with a grade 2 cystocele. Failures could be reported at any time on follow-up and were considered symptomatic patients or with grade 3/4 cystocele.

Results

Ninety-five patients were included in this study. All of them had a 12-month postoperative follow-up or had failed prior to the 12-month assessment, thus qualifying them to be included in the analysis.

The majority of the women were menopausal (88.4%) due to the lack of estrogens as a supporting factor for pelvic floor endurance. Patient mean body mass index (BMI) was 26.1 kg/m^2 and placed the women within the overweight category (25-29.9).

Five women had a history of previous failed cystocele repairs. There were 11 patients with grade 2 cystoceles (11.6%), 61 with grade 3 (64.2%) and 23 patients with grade 4 cystoceles (24.2%). All of these women underwent anterior colporrhaphy with the use of Permacol.

Table 3 shows the coexisting surgical pathology and the procedures performed on our patients.

Table 3. — *Coexisting surgical pathology and operations performed respectively.*

Rectocele	17/95 (17.9%)	Posterior repair
Uterine Prolapse	54/95 (56.8%)	Vaginal hysterectomy
Vault Prolapse	6/95 (6.3%)	Infracoccygeal Sacrocolpopexy (posterior IVS)
SUI *	27/95 (28.4%)	Transobturator Vaginal Tape (TVT-O)

* Stress urinary incontinence.

Mean blood loss was 275 ml (200-350 ml) while mean operation time was 65 min (45-85 min) according to the presence or not of vaginal hysterectomy. As seen in Table 4, postoperative complications were low (9.47%). Most commonly erosions were observed (2.1%) after a local reaction to the vaginal epithelium. These were successfully treated with local antibiotics and estrogen cream. The extrusion was slight and after cutting a part of the graft and aseptic closure of the vagina the patient was cured without any further complications. A small haematoma was noted in one case of IVS insertion at the perineum which was successfully treated with antibiotics. The urinary catheter was reinserted in four cases (4.21%) because of increased residual urine ≥ 50 ml. After 24-48 hrs the catheter was removed and the patients were discharged after a normal voiding activity and residual volume. Delayed discharge beyond the third postoperative day was mainly for women who underwent total vaginal hysterectomy.

Table 4. — *Postoperative complications*.

Wound infection	0/95 (0%)
Urinary tract infection	1/95 (1.05%)
Pyrexia	0/95 (0%)
Hematoma	1/95 (1.05%)
Vaginal erosion	2/95 (2.10%)
Graft extrusion	1/95 (1.05%)
Catheter reinsertion	4/95 (4.21%)

Table 5. — *Postoperative outcomes*.

Cured, asymptomatic with no or grade 1 cystocele	77 (81.1%)
Improved, asymptomatic with a grade 2 cystocele	10 (10.5%)
Failure, symptomatic or with a grade 3 or 4 cystocele	8 (8.4%)
Total	95 (100%)

Using our definition for determining success, the overall failure rate was 8.4% (8 women) as shown in Table 5. Two were noticed at six months and six at 12 months of follow-up. Five patients had grade 3 cystoceles and three symptomatic grade 2 cystoceles. Seventy-seven women had no or asymptomatic grade 1 cystocele at 12 months after the anterior repair (overall cure rate 81.1%). Improvement of the cystocele was noticed in ten patients (10.5%). Of the 18 improved or failed outcomes, seven had coexisting apical prolapse and three of these patients requested and have undergone further surgical repair.

Discussion

The occurrence of severe cystoceles is associated with a few risk factors such as high parity, postmenopausal period, prolonged vaginal delivery and unsuccessful previous attempts for pelvic floor reconstruction. The main reason for cystocele and vaginal prolapse in all three compartments (anterior-middle-posterior) is believed to be due to the defective fascial support (urethrovesical-vesicovaginal-rectovaginal) along with ligament dysfunction owing to loose connective tissue [2, 8].

The paravaginal repairs and the typical anterior colporrhaphy had a high failure rate and low success rate. Fixing, reinforcing and placating the abnormal pelvic fascia have not been as successful as once thought accounting mainly for central defects or herniations of the bladder (cystocele) [9-11]. Interest in the use of synthetic and biologic materials in the anterior compartment is increasing. The use of mesh or porcine dermis decreases the failure rate (6-22%). However, permanent synthetic mesh causes erosion with rates ranging from 3% to 25% and xenograft use has the potential of an unpredictable immune reaction to the graft during tissue healing, manifested as early postoperative superficial dehiscence [12-17].

It is difficult to reach a consensus with regard to which graft to use in pelvic surgery. Even after a thorough review of the literature, most studies report outcomes that are based on small case series without control groups and short-term to medium-term follow-up. The variety of definitions of surgical success in these studies makes it difficult to interpret and compare results. The ideal graft has not yet been developed. Two general categories of graft materials have promising results with respect to restoring anatomic and functional outcomes – the synthetic grafts and the biomaterials (xenografts).

Conclusion

Transvaginal anterior colporrhaphy reinforced with a porcine acellular collagen matrix (Permacol) in the treatment of moderate to severe cystocele appears to be the best solution for the time being. It is a simple technique, easy to learn and applied with a high success rate and low morbidity.

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