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Original Research

Transvaginal PVDF-mesh for cystocele repair: A cohort study

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HIGHLIGHTS

- PVDF- mesh is feasible for transvaginal application for cystocele repair.
- 15% of patients presented any kind of complications and 8.8% needed a resurgery for SUI or POP during the follow-up.
- Improvement of quality of life was reported by 87.5% according the PGI-I.
- The preliminary results support the initiation of prospective trial and registry according to IDEAL.

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ABSTRACT

Introduction: Optimized biocompatibility of new materials is a major requirement for transvaginal meshes for pelvic organ prolapse (POP) repair. Polyvinylidene fluoride (PVDF) presented good characteristics in prior animal experiments and clinical use in humans.
Methods: Between 01/2012 and 04/2016 37 women underwent transvaginal repair of symptomatic prolapse of the anterior vaginal wall (cystocele) with PVDF-mesh in a single institution. A chart review for recurrence, continence, peri- and early postoperative complications was performed. Referring practitioners were interviewed by telephone and mail. Additionally patient reported outcome and satisfaction were measured by Patient Global Improvement Inventory (PGI-I) scale.
Results: 34 women were eligible for a mean follow up of 19 months. The functional outcome improved significantly. One symptomatic vault prolapse (2.9%) and two reoperations for incontinence (5.9%) occurred. Two mesh exposures (5.9%) occurred and were treated conservatively. No other severe complications were registered. 87.5% of treated women felt very much better or much better and would undergo the surgery again. A cohort study including development steps in accordance with the IDEAL system is presented.
Conclusions: For the first time we report on effectivity and safety of transvaginal application of PVDF-mesh in real-life practice. A prospective long-term evaluation in a registry is justified.
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1. Introduction

Recently there has been a rising interest in new surgical techniques and materials that may improve outcome after cystocele repair. Standardised trocar-guided meshes are applied in prolapse surgery to reduce the recurrence of prolapse for decades. Polypropylene (PP) meshes (Type 1, Amid-classification) are the most used [1]. New modifications with light-weight meshes, coatings and partly resorbable materials have been proposed lately. However, there are no standards and less evidence on relevant biological and physical parameters of materials [2]. Due to insufficient medical product controls a lot of me-too meshes got approval without the provision of studies first. Food and Drug

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Administration (FDA) changed the requirements for mesh approval due to the number of serious complications related to mesh insertion. In January 2016 an FDA amendment was released, which requires studies and clinical data before the application of transvaginal meshes [3]. Postmarket-surveillance is required by the European regulatory authorities. Alloplastic materials potentially add to the complication profile the aspects of trauma of insertion, foreign body reaction to the implant in terms of inflammation, infection and/or rejection, and the stability of the prosthesis over time [4]. The rate of mesh-related complications after the implantation of transvaginal mesh is about 15–25% and especially mesh erosion up to 10% [5,6]. Other complications are obstruction, de novo urge, chronic pain, dyspareunia and mesh erosion [7]. Biocompatibility is an important requirement for the perfect ingrowth of the material. It is determined by the foreign body reaction and inflammation and depends on different parameters like type of polymer, pore size, material weight and others [8,9]. An optimized surgical mesh permits the transmigration and localisation of immune cells and prevents adherence and inflammation if directly exposed to visceral organs, vessels or nerves.

In reaction to FDA warnings, our international scientific collaboration group has recently developed and concluded preliminary studies in order to investigate and improve biocompatibility of surgical meshes [3,9–11]. Our entire innovative approach has been conducted following the five stage IDEAL-D method of surgical innovations (Idea, Development, Exploration, Assessment, and Long-term study of Device) with the aim of comparability and reproducibility at every single step of development [12,13]. Experimental studies have been conducted first and can be assigned to preclinical stage 0 according to IDEAL-D [13]. For the first time a validated in vitro test system to compare the biocompatibility of different meshes was developed [9]. Series of commonly used meshes were incubated with patient tissue culture (muscle, connective tissue and endothelium) and the adhesion and ingrowth of tissue over time were assessed. The score system was then validated in a longterm animal [11]. Different meshes were inserted intraperitoneally and as a fascia and muscle onlay in a sheep and were explanted after hours, 3, 6, 12 and 24 mos. Complications were evaluated and connective tissue and inflammatory reaction were examined histologically. The study revealed comparable ranking characteristics at every time point after explantation. The in vivo performance of these meshes in a sheep model was predictable with a previously developed in vitro test system. The early inflammatory reaction determined the outcome and mesh biocompatibility [10].

After preliminary positive results on PVDF-mesh in vitro and in a longterm animal study consecutive human application is presented in the current study according to the first stage of IDEAL-D. The aim of the study is to proof the efficacy and safety of a new mesh material in a real-life practice. Additional focus of the study was on the Patient-Reported Outcome (PRO).

2. Methods

2.1. Patients

The study was carried out in accordance with the 1964 Helsinki Declaration and its later amendments. An ethics vote has not been applied for due to the retrospective design. 37 women were retrospectively enrolled who underwent transvaginal anterior PVDF mesh repair for POP between 2012 and 2016 in a single center cohort study(Marienhospital Bottrop, Germany). All women gave their signed informed consent for participation in this study. Study methods and definitions were applied according to recommendations by the International Urogynecological Association (IUGA) and the International Continence Society (ICS) [4,14]. Women in reproductive age, planning of pregnancy were excluded for mesh usage. Women with uterovaginal prolapse were recommended to concomitant hysterectomy. The study group included parous women with symptomatic grade II-IV anterior/apical prolapse based on Pelvic Organ Prolapse Quantification (POP-Q). All grade II cystoceles were recurrent and symptomatic after previous surgery for prolapse. Risk factors like recurrent or high grade cystocele, obesity, chronic obstructive pulmonary disease, heavy physical labour, previous pelvic floor surgeries and preference of the patients were considered in cases of vaginal mesh insertion [5]. PVDF-mesh was used due to beneficial material characteristics found in previous studies [9–11]. From January 2012 through April 2016, patients were screened by the participating surgeons for prolapse of the anterior vaginal wall after referral by their Gynecologist. All patients experienced an unsuccessful conservative treatment prior to operation. Exclusion criteria were previous cancer of any pelvic organ, previous mesh implantation at the operation site, infection at the operation site, chemo- or immunological therapy during the last three months, pregnancy or wish for child. All patients selected for the surgery underwent preoperative and postoperative clinical examination and pelvic floor ultrasound by the referring Gynecologist. Table 1 presents the clinical characteristics of the study group. Additionally the study was registered at German Clinical Trials Register (DRKS), registration number DRKS00011264 and Research Registry, registration number researchregistry2097.

2.2. Surgical procedure

All surgeries were performed by one experienced Urogynecologist (HCK). The surgical procedures were standardised before initiation of the study. All mesh procedures involved use of the PVDF mesh (DynaMesh®-PR4, FEG Textiltechnik, Germany) (Fig. 1). The material is a pre-cut non-absorbable monofilament soft PVDF mesh (6 × 4 cm) with four arms. This procedure may be performed under spinal or general anesthesia. All patients had an intravenous perioperative antibiotic prophylaxis. All patients were placed in the lithotomy position with thighs flexed at approximately 90°. After cleaning the entire surgical area with antiseptic, a suprapubic catheter is placed. The anterior vaginal wall is cut and the cystocele

Table 1
Baseline characteristics of 37 patients undergoing cystocele repair with PVDF-mesh.

Mean age, years ± SD (range)	66 (±11.5)
Parity	
Median	2
Range	0–5
Cesarean deliveries, no. of patients (%)	1 (2.7)
Current smokers, no. of patients (%)	5 (13.5)
Body mass index, mean ± SD (range)	27 (±4.1)
Menopause, no. of patients (%)	33 (89.2)
Current use of hormone therapy, no. of patients (%)	11 (29.7)
Risk factors (diabetes mellitus, immunosuppression, recurrent UTIs, PVR>100 ml), no. of patients (%)	14 (37.8)
Previous surgery for cystocele, no. of patients (%)	8 (21.6)
Prior pelvic surgery, no. of patients (%)	
hysterectomy	13 (35.1)
sacrospinal fixation	4 (10.8)
suburethral tape	1 (2.7)
Mean POP-Q grade, n ± SD (range)	3 ± 0.4 (2–4)
Grade II, n (%)	6 (16.2)
Grade III, n (%)	26 (70.3)
Grade IV, n (%)	5 (13.5)
Symptoms, no. of patients (%)	
vaginal bulge	29 (78.4)
episodes of incontinence	13 (40.5)
pelvic pain	3 (8.1)

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