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ORIGINAL ARTICLE

Ultrasound visualization of sacrocolpopexy polyvinylidene fluoride meshes containing paramagnetic Fe particles compared with polypropylene mesh

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Abstract

Introduction and hypothesis Paramagnetic Fe particles can be added during synthetic mesh production to allow visibility on magnetic resonance imaging. Our aim was to evaluate whether transperineal ultrasound (TPUS) allows visualization, measurement, and characterization of polyvinylidene fluoride (PVDF mesh) containing Fe particles compared with regular polypropylene (PP) meshes used for sacrocolpopexy.

Methods Women up to 1.5 years after laparoscopic sacrocolpopexy who were implanted with a PP or PVDF mesh underwent clinical examination and 2D, 3D, and 4D TPUS. Acquired volumes were analyzed offline for mesh position at rest and maximal Valsalva and for mesh dimensions and characteristics, with the operator blinded to group assignment. The two groups were compared.

Results There were 17 women in the PP and 25 in the PVDF mesh group, without differences in baseline demographics. None had significant prolapse, recurrence, symptoms, or complications. On TPUS, mesh was visible in all patients both caudally (perineal) and cranially but was more echogenic in the PVDF mesh group. Mesh length from distal to proximal that was visible on TPUS was longer for PVDF mesh, for both anterior and posterior vaginal arms (all $P < 0.05$), and for mesh above the vaginal apex ($P = 0.002$). The inferior aspects of the mesh showed areas of double mesh layers, suggesting folding in 80% of women in both groups, without symptoms.

Conclusions PVDF mesh permits clearer visualization and is seen over a longer stretch on TPUS, with longer visible mesh arms. The latter can be due to differences in operative technique, presence of microparticles, implant textile structure, or patient characteristics.

Keywords 4D transperineal ultrasound · Laparoscopy · MRI visible mesh · Mesh folding · Pelvic organ prolapse · Sacrocolpopexy mesh · PVDF mesh

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Introduction

The lifetime risk to undergo surgery for pelvic organ prolapse (POP) is ~20% [1–3]. For some procedures, such as sacrocolpopexy, a mesh is required; for others, implants may be used as an alternative or complementary to native tissue repair. Most implants used today are made of monofilamentary woven and knitted fibers of polymers, including polypropylene (PP), polyamide, and polyvinylidene fluoride (PVDF). They are typically available as macroporous textile constructs (Fig. 1). The use of implants for incontinence or prolapse has recently come under scrutiny because of the frequent occurrence of graft-related complications (GRC). As these are potentially debilitating and difficult to treat [4, 5] and more frequent after vaginal insertion, their use via this route has come into

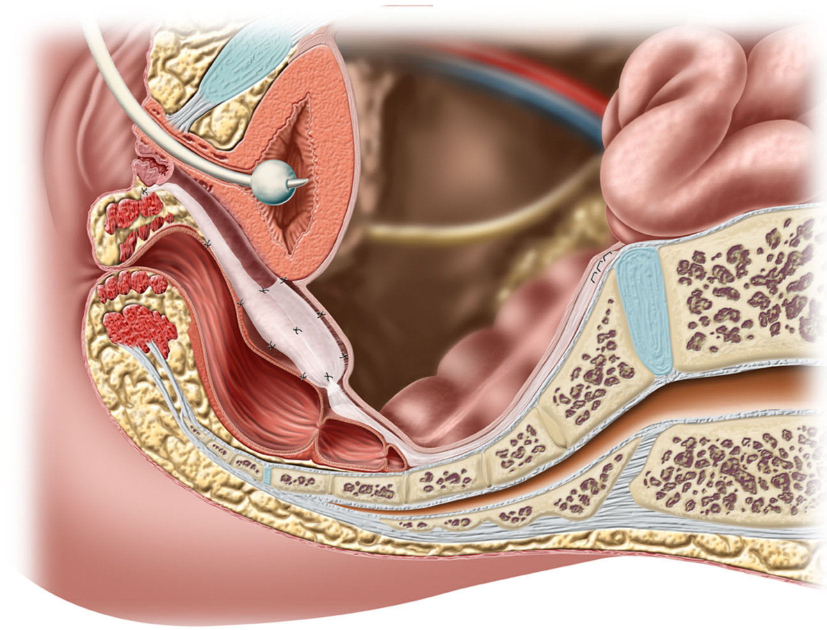

Fig. 1 Sacrocolpopexy with mesh fixation over the anterior third of the vagina, the entire posterior wall, and down to the anal sphincter. Copyright: UZ Leuven. Drawing: Dreamteam, Lubbeek, Belgium. The mesh is depicted in *white* lining the surfaces

question [6]. GRC are, however, not unique to this approach, as up to 10% of patients undergoing abdominal sacrocolpopexy presented with GRC up to 7 years postoperatively [7]. Also, patients previously operated with durable mesh may still develop recurrence, leading to the questions why and on what site the prolapse is developing. There is, therefore, an urgent need for appropriate tools for objective assessment of such patients.

Medical imaging is an attractive option because of its non- or limited invasive nature. It would also be acceptable for the prospective study of patients, permitting a better understanding of the pathogenesis of GRC and in vivo documentation of what occurs with the implant at the host site over time. Ultrasound has already been suggested for the assessment of patients with durable implants, which appear as a hyperechoic area [8, 9]. The textile structure of the constituting mesh fibers has been evaluated using 2D and 3D ultrasound (US) by some authors, including us. Ultrasound has been used to visualize slings [10], vaginal mesh [11], and sacrocolpopexy meshes [12, 13]. However, transperineal US has a limited imaging depth, which makes it difficult to see the sacral arm, and there can be interference by adjacent rectoceles or intussusceptions. Other clinical imaging methods are less likely to visualize mesh, such as computed tomography (CT) or magnetic resonance imaging (MRI) [8, 14]. MRI is to be preferred because it does not use ionizing radiation and has a higher soft tissue resolution; however, since implants do not spontaneously induce contrast or provoke a signal void, they are not visible on MRI. This issue can be solved by coating filaments with contrast agents or by mixing paramagnetic microparticles, such as Fe_3O_4, into the polymer [15]. These microparticles cause a signal void on T1- or T2-weighted images [16, 17]. We speculated that the addition of iron oxide particles to PVDF mesh would also enhance mesh visualization on 2D and 3D transperineal US, compared with non-iron-oxide-containing implants. To compare visualization of such sacrocolpopexy implants we teamed up with those who first described visualization of double-armed PP sacrocolpopexy implants [12, 13]. We designed a single blinded controlled comparison of images obtained in unselected women having undergone subjective and objective cure for vault prolapse by uncomplicated sacrocolpopexy.

Our aim was to evaluate whether transperineal ultrasound (TPUS) following sacrocolpopexy allows visualization, measurement, and characterization of commercially available PVDF mesh containing paramagnetic iron oxide microparticles (Dynamesh Visible, FEG Textiltechniken, Aachen, Germany), as compared with polypropylene (PP; Alyte, Bard Medical Division, Covington, GA, USA) meshes without such particles.

Materials and Methods

Study design and operative technique

Women after laparoscopic abdominal sacrocolpopexy were invited for a clinical audit at two participating centers. In each center, all women were operated in a standardized manner by the same surgeon, and patients were matched for time elapsed from surgery. Women were included if they had had a sacrocolpopexy procedure up to a maximum of 1.5 years prior to recruitment. In both centers, sacrocolpopexy is offered to women with symptomatic prolapse due to level I support defects of either the vault or uterine cervix. The operative endoscopic technique of both teams was previously described in detail [12, 18]. In essence, the vesicovaginal and rectovaginal spaces are dissected in proportion to the individual degree of anterior, posterior, and apical vaginal prolapse. Both vaginal walls, vault, or cervical stump (after subtotal hysterectomy) are covered by mesh for as far as the prolapse stretches. The upper arm is suspended to the sacral promontory with a degree of tension visually controlled by the surgeon. Obvious differences between centers were, in essence, the operator (both highly experienced) and mesh used. Individual preferences in terms of extent of dissection, suturing and fixation methods, and degree of tension with which the mesh is fixed to the sacral promontory, also exist. Additionally, the implant was adjusted to the anatomy and presentation of the individual (Fig. 1).

In Group 1 (PP) (Fig. 2a), the surgeon (LL) performed sacrocolpopexy with an ALYTE® Y-Mesh Graft PP mesh (Alyte® Y-Mesh Graft Bard Medical Division, Covington, Georgia, USA; pore diameter 2.9 mm^2; mesh width 5 cm). This mesh consists of two single-knit vaginal flaps (weight, 16.5 g/m^2) and one dual-knit sacral flap (33.5 g/m^2). The initial 27-cm length of the mesh is tailored to the individual's needs. The mesh was sutured in place along the anteroposterior vaginal wall and vaginal apex/cervix using nondissolvable polyester 2.0 sutures (TiCron™, Tyco, Waltham, MA, USA). Transverse mesh dimensions were not altered. The cranial aspect of the mesh was secured to the sacral promontory with three to four 5-mm tackers (ProTack; Tyco Healthcare, Norwalk, CT, USA) without tension.

a

b

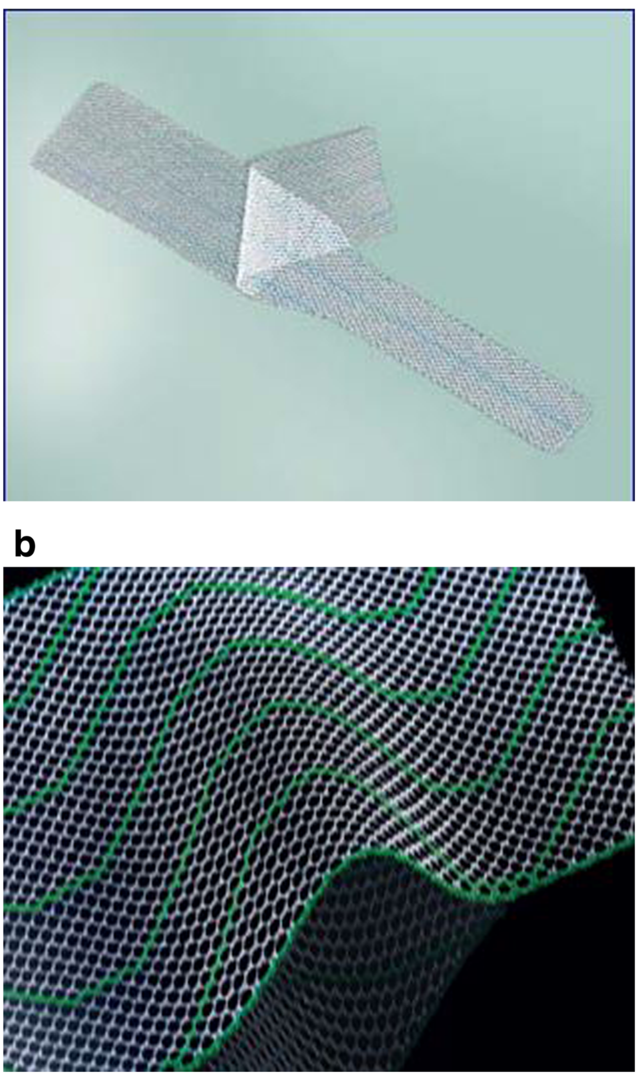

Fig. 2 In vivo appearance of sacrocolpopexy meshes compared in this study: **a** Group 1, polypropylene (PP) ALYTE Y-Mesh graft; **b** Group 2 polivinylidene fluoride mesh with paramagnetic particles (PVDF-Fe)

The surgeon in Group 2 (Fig. 2b) (JD) used MR-visible PR4-1B soft meshes (DynaMesh Visible™). This mesh is constructed from arms of knitted monofilament PVDF mesh fibers containing paramagnetic Fe microparticles with a pore size of 1.3 × 2.3 mm, weight, 83.0 g/m^2, and an effective porosity of 61.1%. PVDF meshes have been studied extensively for their biocompatibility both in animal models [19] and clinical trials, and the product is widely used in Germany [17, 20, 21]. For sacrocolpopexy, a large sheet of mesh was customized to the patient anatomy, with one shorter anterior vaginal flap and a longer posterior implant covering the posterior vagina and extending to the promontory. The anterior flap was fixed to the sacral part of the posterior leaf by several slowly resorbable sutures (PDS II 0, polydioxanone; Ethicon, Zaventem, Belgium). The sacral flap was fixed to the promontory by metallic staples (EMS, Ethicon). After securing the mesh to the vaginal wall and sacral promontory, the free edges were trimmed. For both groups, differences in mesh amount were minor and mainly dependent on total vaginal length (TVL). With more advanced prolapse, TVL is longer and anterior and posterior leaves of the mesh are expected to be longer; the sacral arm connecting to the promontory is expected to be shorter. Overall, differences were minor and unrelated to the image quality of mesh presented by US. In both groups, following sacrocolpopexy completion, the peritoneum was closed and additional concomitant procedures performed, as indicated, such as midurethral slings for stress urinary incontinence.

Patient evaluation

Consenting women underwent a clinical assessment using the International Continence Society (ICS) Pelvic Organ Prolapse Quantification system (POP-Q) the day of the US [22]. The clinical examination was performed after voiding, with the patient in a dorsal lithotomy position with the hips flexed and abducted (LL in Group 1 and GC in Group 2). Pelvic floor imaging was performed in a standardized manner using a 2D/3D/4D transperineal pelvic floor US (Voluson 730, E6 or E8, GE Kretz Medical Ultrasound, Zipf, Austria) with a 4- to 8-MHz RAB curved-array volume transducer. Volume acquisition was obtained at rest, maximal Valsalva maneuver, and maximal pelvic floor contraction, as previously described by Eisenberg et al. [12, 13]. US examinations at both centers were performed by the same operator (VHE), who was not involved in the surgery or patient follow-up. Also, while blinded to patient identification and group assignment, she performed the offline postprocessing analysis of the TPUS volume data sets at a much later date using proprietary software GE Kretz 4D view (GE Medical Systems). Though the assessor operating the TPUS equipment was meant to be blinded to clinical data, due to geographical location, she could not be blinded to surgical technique and implant type. However, postprocessing analysis was blinded to the source of the image set.

Outcome measures

The following parameters were retrieved from the medical records: age, body mass index (BMI), previous pelvic surgery, menopausal status, parity, concomitant procedures, operation time, and the occurrence of complications, if any. Complications were classified as intra- or postoperative (within 3 months of surgery). Prolapse recurrence was defined as a cystocele, rectocele, or cervical/apical prolapse descent down to the hymen or further. On US, prolapse recurrence was defined as bladder descent ≥10 mm below the symphysis pubis (SP), descent to the SP of the vaginal cuff or cervix, and descent ≥15 mm below the SP for the rectum at maximum valsalva [8]. Measurements on the US volumes included mesh position and dimension, levator hiatal dimensions, and presence of mesh folding, as we previously described [12]. The lowest (caudal) anterior and posterior mesh positions were determined in the midsagittal plane at rest and on maximal Valsalva maneuver. The urinary bladder was considered as the anterior landmark for mesh position with the bladder neck as the craniocaudal landmark. The anterior rectal wall was considered as the landmark for the posterior mesh. Mesh extremities were considered as those where the typical hyperechoic mesh appearance could no longer be seen. Folding was defined as visualization of several mesh layers one over the other, which is commonly observed in the extremities of the mesh arms, in the vagina, the sacral area, and the vaginal apex. Mesh mobility was defined as the difference in position of the most distal point of the mesh between rest and maximal valsalva.

Statistical analysis and ethics

Statistical analysis was performed with SPSS for Windows version 21 (SPSS, Inc., Chicago, IL, USA). Repeatability testing of this imaging method was tested in the original study [12]. Continuous parameters were checked for normality using Kolmogorov–Smirnov testing, as it is sensitive to differences in both location and shape of the empirical cumulative distribution functions of the two samples. In the special case of testing for normality of distribution, samples were standardized and compared with a standard normal distribution. The independent Student *t* test and chi-square test were used to compare continuous and categorical repeated values, respectively. All tests were considered significant at the $p < 0.05$ level and were two sided. This study was approved by the local Ethics Committees of both hospitals, and written consent was obtained from all participants (Rambam Healthcare Campus and UZ Leuven ML 7932).

Results

Forty-two women were audited: 17 in the PP and 25 in the PVDF group, respectively. There were no statistically significant differences for age, BMI, parity, menopausal status, duration of surgical procedure, or time elapsed from surgery between the groups. These variables are represented in Table 1. At evaluation, no patient presented with complications or recurrent prolapse to the hymen or beyond. In women in Group 2, individual Aa, Ap, Ba, Bp, C, Gh, and Pb values of the POP-Q score were larger than in Group 1; conversely the TVL was shorter. Again, this did not correspond with any difference in subjective findings.

Figures 3a (regular Y-mesh) and b (PVDF mesh) depict mesh appearance on TPUS. Figure 4 depicts a multiplanar volume of the PVDF mesh. On TPUS, levator hiatal areas at rest, maximal Valsalva maneuver, and maximal pelvic floor contraction were larger in the PVDF group (all $P < 0.05$). Women in that group tended to have a more caudal implant location, yet the difference was not statistically significant (Table 2). Mesh mobility at maximal Valsalva was greater in

Table 1 Demographic data comparing the two groups (*t* test)

Parameter	Group 1: PP (regular mesh) ($n = 17$)			Group 2: PVDF (MRI mesh) ($n = 25$)			*P* value
	Mean	SD	Range	Mean	SD	Range	
Age (years)	56.82	5.15	43–68	62.16	10.79	45–86	0.068
BMI (kg/m^2)	26.02	2.67	21.5–31.9	25.77	3.7	18.7–34.3	0.809
Parity	2.7	1.4	1–7	2.11	0.76	1–3	0.126
Time since surgery (months)	11.29	3.75	7–20	10.36	2	6–13	0.301
Surgery duration (minutes)	203.4	46.94	110–300	204	52.8	121–288	0.969

PP ALYTE® Y-Mesh Graft polypropylene mesh, *PVDF* polyvinylidene fluoride mesh, *BMI* body mass index

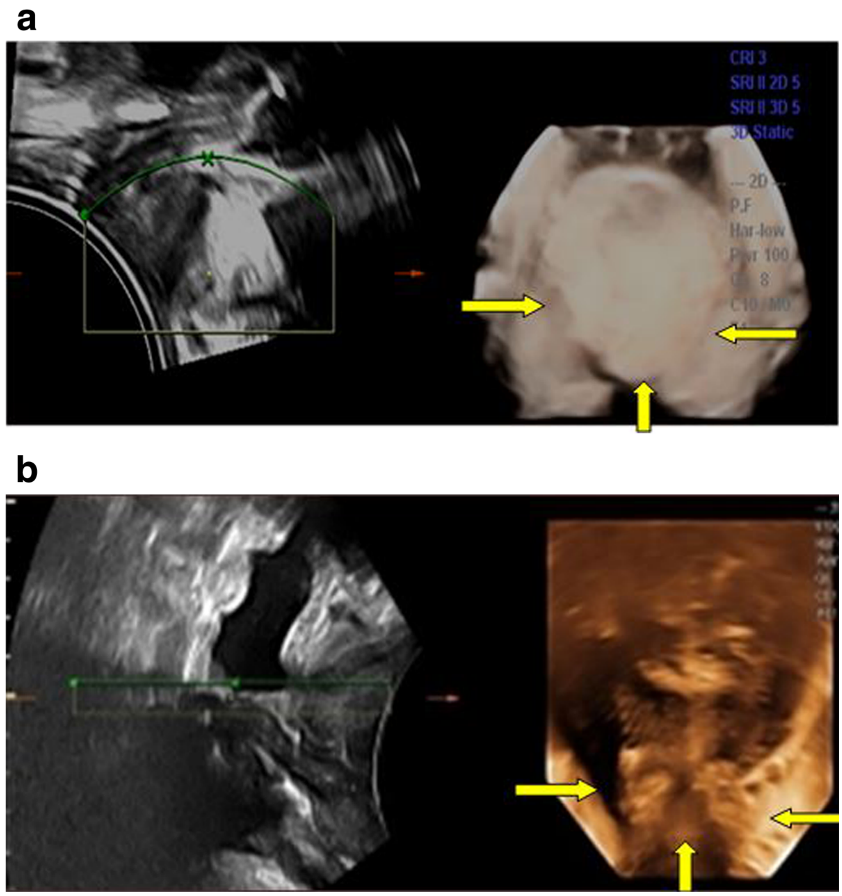

Fig. 3 Three-dimensional rendered views depicting the appearance of the two mesh types on transperoneal ultrasound (TPUS). In the *left panel* of *each image*, the mesh is seen as an echogenic structure, whereas in the *right panel,* a rendered image is highlighted by *yellow arrows*. Note the clear delineation of mesh aspects in the multiplanar image. **a** ALYTE® Y-Mesh Graft polypropylene mesh, **b** polyvinylidene fluoride (PVDF)-Fe mesh

PVDF patients for the anterior and posterior mesh arms but only statistically significant for the anterior arm ($P = 0.042$ and $P = 0.058$, respectively).

The length of the anterior and posterior arms surrounding the colpos and heading toward the promontory and visible on US was significantly longer in the PVDF group [those with a longer vaginal length ($P = 0.002$)] (Table 3). There were no differences in the width of the mesh flaps anteriorily or posteriorily. Folding at the inferior aspects of the mesh was observed in ~80% of women in both groups, but this was not associated with adverse symptoms (Fig. 5). There were no mesh exposures in either group. Visualization of all mesh arms in the same patient can be seen in Fig. 6.

Discussion

In this study, we set out to evaluate whether TPUS allows different visualization, measurement, and characterization of PVDF meshes containing paramagnetic iron oxide microparticles when compared with PP meshes without such particles—both used for sacrocolpopexy. To the best of our knowledge, this is the first study to describe the visibility of PVDF mesh containing paramagnetic iron oxide microparticles on TPUS.

We were able to visualize and measure sacrocolpopexy implants in all patients, in both caudal (perineal) and cranial (colpos) aspects. PVDF mesh implants can be more clearly visualized, as they are more echogenic, particularly with regard to the sacral arm component. Patients who underwent PVDF mesh insertion also had a lower insertion point of the vaginal flap relative to the symphysis pubis, and longer mesh arms. There was no difference in the width of the vaginal flaps. Mesh folding (caudal or elsewhere) was present in 80% of patients in both groups without causing any symptoms. This coincides with smaller mesh dimensions as compared with preoperative values. The implant size in most cases was large enough to support both anterior and posterior vaginal cuffs. During the operation, surgeons usually try to avoid mesh folding by adapting the size of the anterior and posterior mesh according to vaginal length and stage of prolapse. Nonetheless, folding may still occur as a result of either surgical technique or changes that occur to vaginal tissue over time. This is usually unavoidable. We described this earlier for vaginal mesh and demonstrated experimentally that these dimensional changes happen in the early postoperative period [17, 23]. Additionally, folding seems to be a frequent finding and usually is not symptomatic [24]. Furthermore, the differences between the two mesh types are not only related to the iron particles but also to the properties inherent in PVDF mesh. It has been

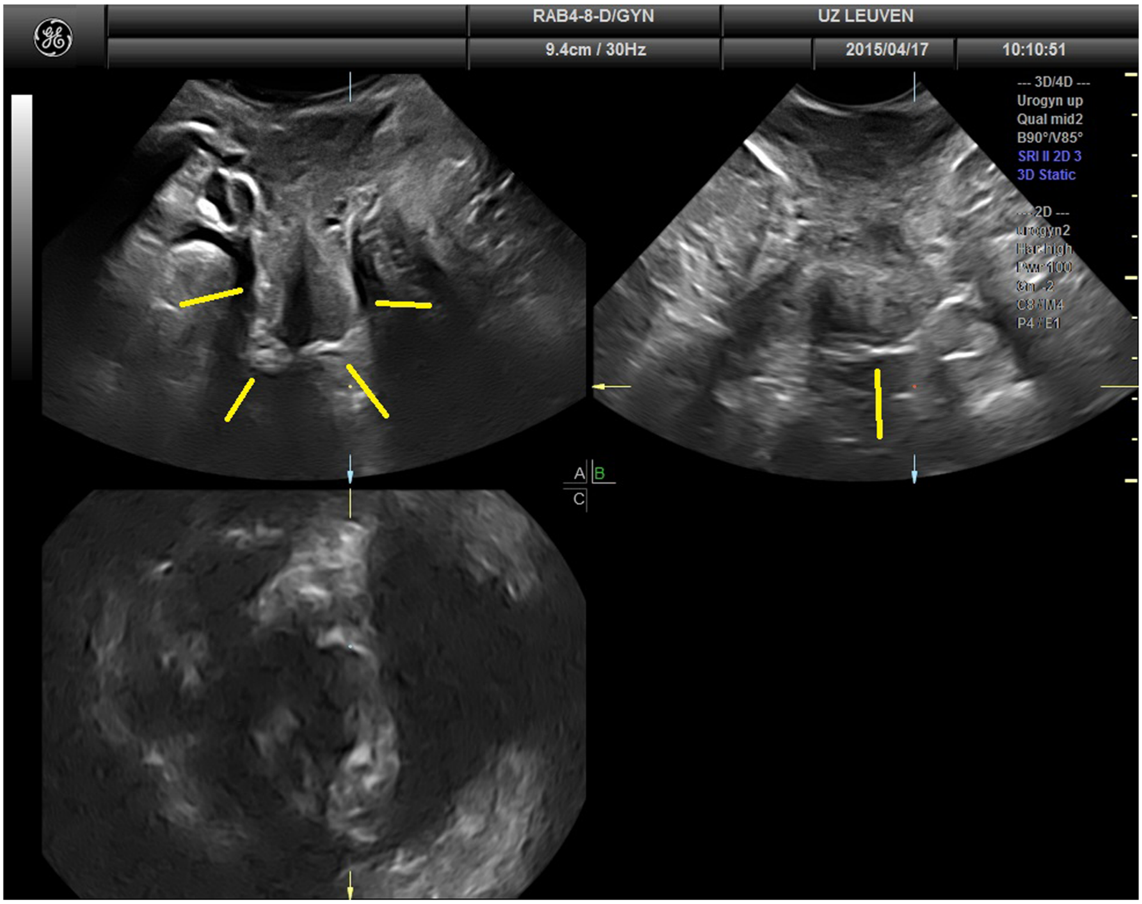

Fig. 4 Multiplanar image of polyvinylidene fluoride (PVDF)-Fe mesh. Note clear delineation of mesh aspects (arrows). The mesh is seen as an echogenic structure and is highlighted by *yellow arrows*. Note clear delineation of mesh aspects in the multiplanar image

previously shown that PVDF mesh filaments have excellent biocompatibility, reducing adverse foreign-body reactions such as granuloma formation; they are associated with reduced bacterial colonization and maintain their tensile strength longer than polypropylene. Moreover, they are finer and smoother than conventional filaments [16, 17].

There were no cases of clinically significant prolapse recurrence. This is quite logical, since the follow-up period was short and hence cure rates should be high, even though patient selection may have played a role [18]. Mesh exposures were not observed in any of our participants, which may also be a coincidence, though exposures following this

Table 2 Compartment descent and levator hiatal area measurements on transperineal ultrasound (TPUS) in the two groups (*t* test)

Parameter	Group 1 = PP (regular mesh) ($n = 17$)			Group 2 = PVDF (MRI mesh) ($n = 25$)			*P* value
	Mean	SD	Range	Mean	SD	Range	
Bladder-neck descent (mm)	15.84	9.36	1.90–37.70	15.18	9.72	.00–37.70	0.828
Bladder descent (mm)	16.56	9.65	1.9–41.4	18.72	14.56	.0–54.7	0.595
Central compartment descent (mm)	14.32	8.78	1–37	14.02	8.46	-2–31	0.911
Rectal ampulla descent (mm)	18.5	9.7	0.2–42.6	13.53	9.7	0.8–37.4	0.11
Levator hiatal area at rest (cm^2)	22.9	5.86	12.22–34.02	28.82	6.92	17.48–40.98	0.006*
Levator hiatal area on Valsalva (cm^2)	32.42	7.66	23.44–49.71	41.33	11.8	23.88–77.22	0.009*
Levator hiatal area on contraction (cm^2)	18.52	5.77	9.67–28.16	23.25	7.93	11.60–40.06	0.046*

PP ALYTE® Y-Mesh Graft polypropylene mesh, *PVDF* polyvinylidene fluoride mesh visible on magnetic resonance imaging (MRI), *TPUS* transperineal ultrasound

*Statistically significant, $P < 0.05$

Table 3 Mesh dimensions on transperineal ultrasound (TPUS) comparing groups

Parameter	Group 1, PP (regular mesh) ($n = 17$)			Group 2, PVDF (MRI mesh) ($n = 25$)			*P* value
	Mean	SD	Range	Mean	SD	Range	
Length of colpos from introitus (cm)	6.52	.66	5.31–7.57	7.35	.88	5.30–8.87	0.002*
Anterior mesh arm length (cm)	3.81	.9	2.45–5.47	5.62	1.08	3.62–7.86	<0.001*
Anterior mesh arm maximal width (cm)	3.39	.53	2.11–3.99	3.66	.64	2.24–4.70	0.160
Anterior mesh arm minimal width (cm)	2.43	.64	1.44–3.44	2.31	.52	1.53–3.48	0.485
Posterior mesh arm length (cm)	4.65	.87	3.30–6.26	5.36	1.23	3.42–8.37	0.046*
Posterior mesh arm maximal width (cm)	3.3	.55	2.23–4.0	3.5	.82	1.71–5.50	0.388
Posterior mesh arm minimal width (cm)	2.38	.65	1.06–3.22	2.17	.74	.98–3.23	0.336
Sacral arm length (cm)	1.79	.39	1.27–2.51	1.75	.44	1.07–2.45	0.775

PP ALYTE® Y-Mesh Graft polypropylene mesh, *PVDF* polyvinylidene fluoride mesh visible on magnetic resonance imaging (MRI), *TPUS* transperineal ultrasound

abdominal operation typically arise later [16]. There were no patients with other types of GRC, such as pain or symptomatic folding. The use of mesh in vaginal prolapse repair is crucial, especially for women with advanced prolapse. Future research is needed to evaluate the long-term difference between these two types of meshes and to investigate whether Fe particles can reduce the complications rate following their use.

There are several limitations that must be addressed. The retrospective design means all measurements were from a single postoperative evaluation, and patients were not examined preoperatively by TPUS. However, since the same issue

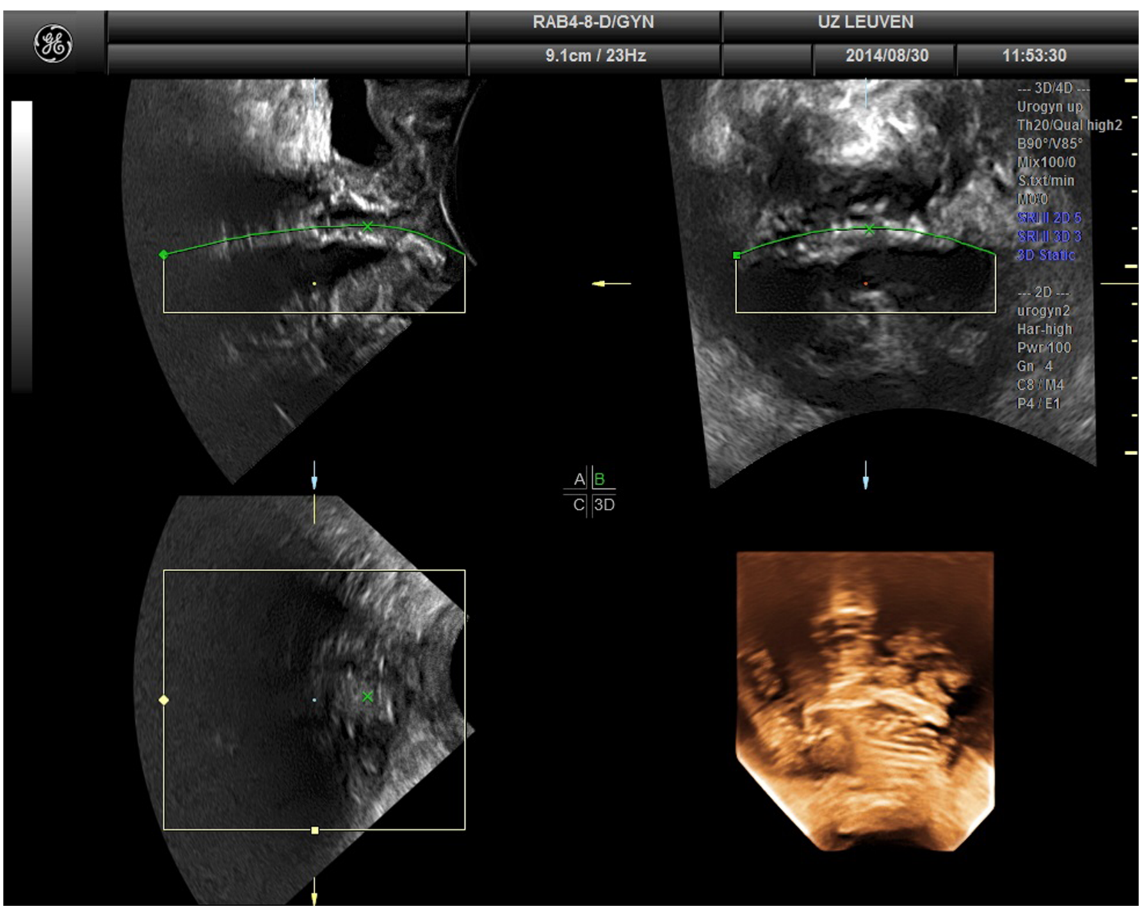

Fig. 5 Multiplanar image and rendered view of polyvinylidene fluoride (PVDF)-Fe mesh. There is folding of the posterior arm, seen on the *lower right panel* as *echogenic transverse lines*. The patient was asymptomatic

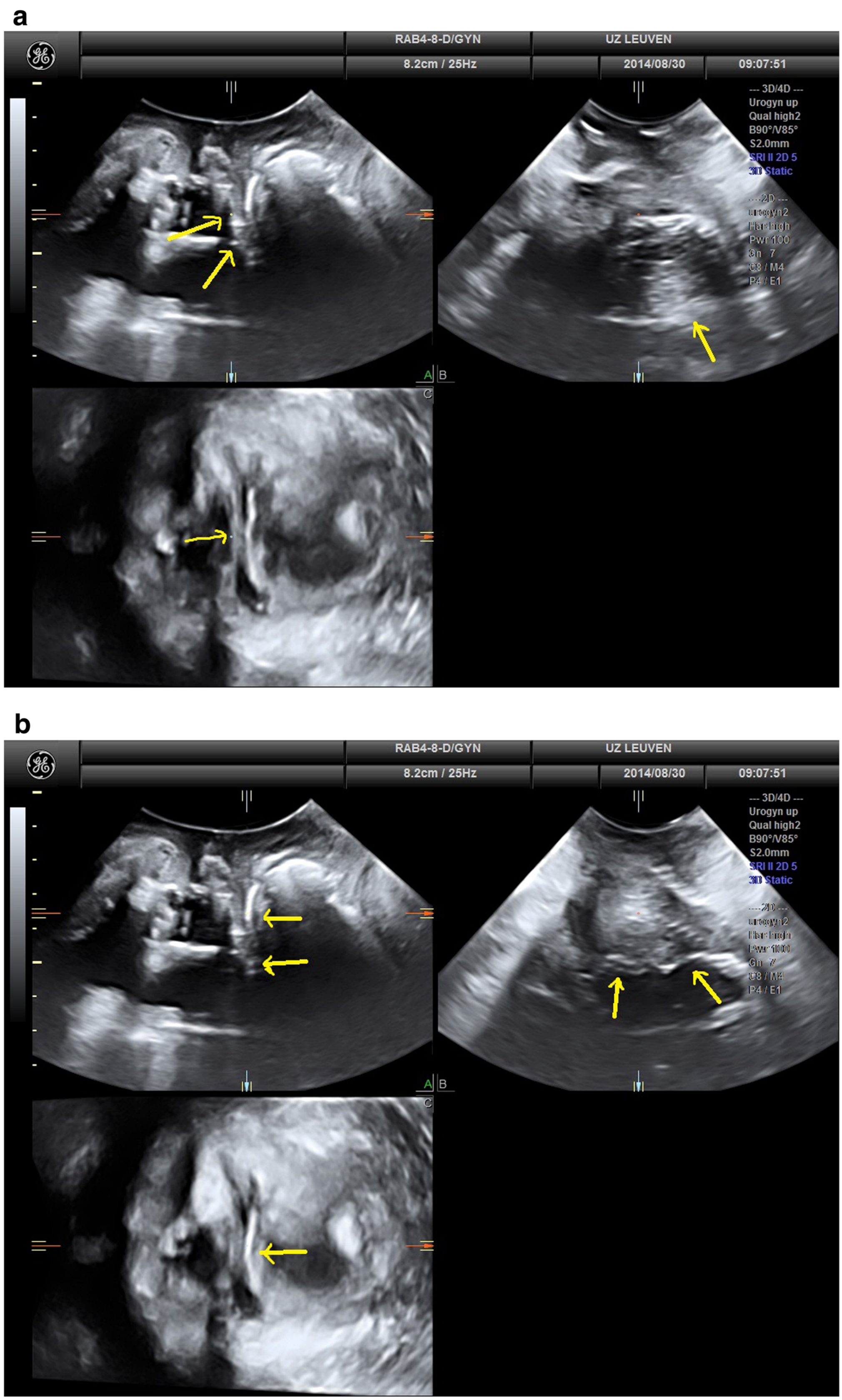

Fig. 6 Multiplanar image of polyvinylidene fluoride (PVDF)-Fe mesh in the same patient as in Fig. 5 (arrows). The mesh is seen as an echogenic structure and is highlighted by *yellow arrows*. Note clear delineation of mesh aspects in the multiplanar image. **a** Anterior arm, **b** posterior arm, **c** colpos and sacral arm extension

c

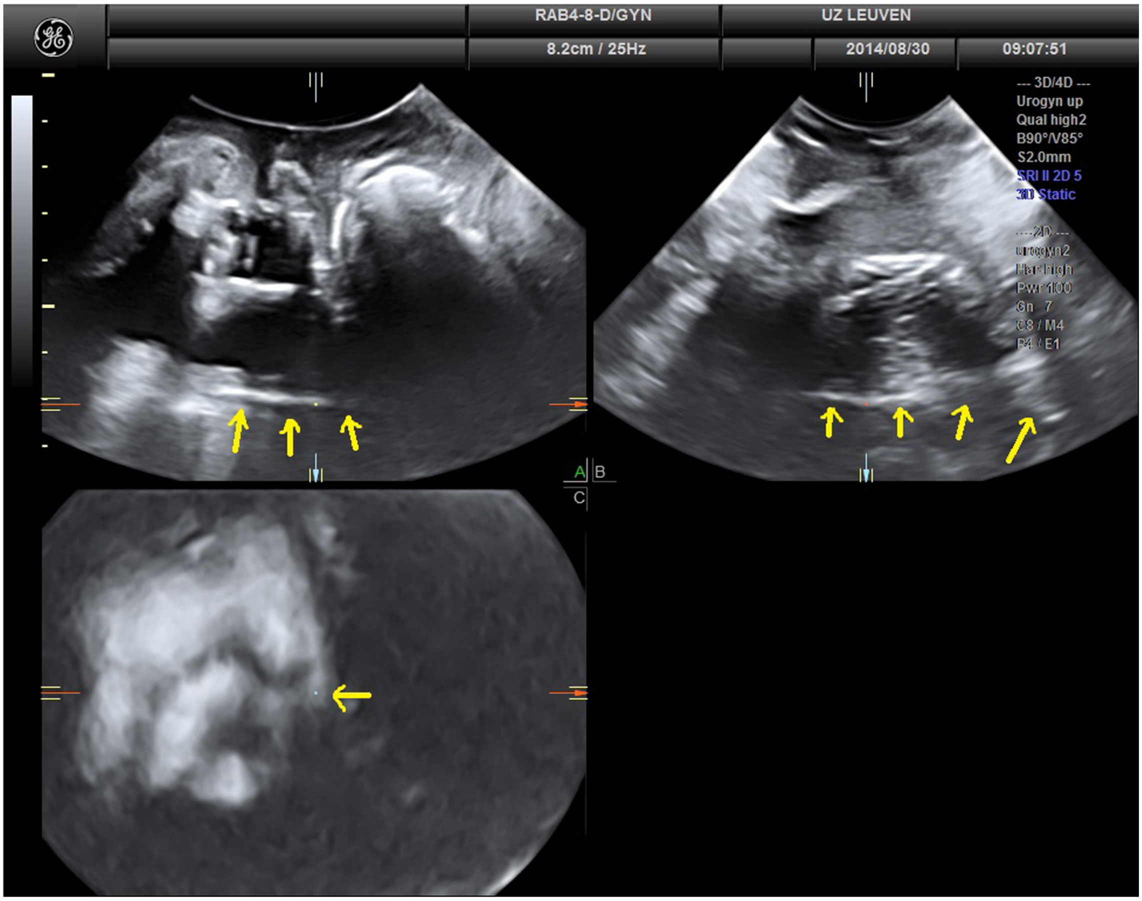

Fig. 6 continued.

applies to both groups, this bias would have been mitigated. The fact that women in both groups were operated by two different surgeons may have introduced differences resulting from varying surgical techniques and skills. However, both surgeons were highly experienced and way beyond their learning curve, which may alleviate some of this bias. Hence, differences may be due in part to the difference in technique as well as the choice of material used. Therefore, these meshes, along with different surgical handling properties, may perform differently. We also think that the extent of the dissection and subsequent suturing location of the mesh may have been different between surgeons.

A significant strength is that all TPUS examinations were performed and analyzed by the same operator, who has extensive experience in visualzing sacrocolpopexy mesh implants [12, 13]. Mesh visualization requires significant experience in 3D and 4D volume manipulation and may be difficult to learn. The use of PVDF mesh containing paramagnetic iron oxide microparticles does seem to improve visualization. Alternatively, MRI may be used to visualize these meshes and for operative audit [17, 23]. However, TPUS has certain advantages over MRI: TPUS is cheaper and more readily available in a clinical setting. Additionally, at present, mesh mobility measurement on dynamic MRI sequences has poor repeatability and may not be reliable for quantitative analysis, which may limit its usability [8, 11–13]. The presence of bowel air, large rectoceles, movement artefacts, and lack of depth of the transperineal probe may likewise limit visibility on TPUS, but these issues can often be overcome by changing transducer plane and bowel emptying. Transvaginal or transrectal probes are also an option but may be less acceptable due to their invasive nature. Also, they may also put pressure on the implants, distorting their view and hampering measurements [11, 12].

Conclusion

In conclusion, sacrocolpopexy implants, both regular PP and PVDF mesh containing paramagnetic iron oxide microparticles, can be easily visualized on TPUS. PVDF mesh permits clearer visualization and is seen over a longer stretch on TPUS, with longer visible mesh arms, allowing the operator to distinguish the different mesh types on TPUS. This may be due to differences in operative technique, presence of iron microparticles, implant textile structure, or patient characteristics. PVDF mesh patients had a lower vaginal flap insertion point relative to the symphysis pubis and longer mesh arms, but there was no difference in the width of vaginal flaps. Mesh folding (caudal or elsewhere) was present in 80% of these asymptomatic patients. Since all patients were asymptomatic, we cannot confirm or refute whether our observations have any clinical relevance. We therefore suggest that TPUS can be used for surgical audit following sacrocolpopexy surgery in both symptomatic and asymptomatic women.

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Compliance with ethical standards

Conflicts of interest Prof. Jan Deprest was a clinical scientist for the Fonds Wetenschappelijk Vlaanderen (G069715 N). NS received a doctoral grant in the Bip-Upy project (NMP3-LA-2012-310,389; FP7) funded by the European Commission. His clinical research on sacrocolpopexy has previously been, in part, supported by an unconditional grant by Johnson & Johnson. He has previously been consulting for AMS, Johnson & Johnson, and Bard. The others have nothing to disclose.

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