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TOPIC PAPER

Do we need meshes in pelvic floor reconstruction?

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Abstract
Objectives Transvaginally placed mesh in pelvic reconstructive surgery for women with pelvic organ prolapse has gained popularity because of excellent anatomical outcomes, but postoperative mesh-related complications have lead to a number of cautious reviews and warnings. This review focuses on functional outcomes after synthetic transvaginal mesh placement.
Methods MEDLINE database was searched from 2010 to August 2011 for original articles on transvaginal mesh surgery for pelvic organ prolapse not included in recent reviews. The following search terms were used: pelvic organ prolapse, genital prolapse, cystocele, rectocele and mesh, synthetic graft, and repair. Studies were assessed and appropriate data extracted and tabularized. Studies were excluded if the follow-up time was less than 12 months and if studies did not contain original data or data on subjective outcome.
Results Eleven studies irregularly reported functional outcomes. After trocar-guided transobturator vaginal mesh surgery, symptomatic recurrence of pelvic organ prolapse was reported between 7 and 33%. If analyzed cumulatively, 76 of 370 patients (21%) complained of prolapse symptoms postoperatively. De novo stress urinary incontinence occurred in 12–17% and persisted in up to 68% after trocar-guided mesh surgery. De novo dyspareunia was present between 2 and 15%, worsened or de novo dyspareunia between 25 and 44%. Deteriorating coital incontinence was described in 6 of 16 women after anterior Prolift in one trial.
Conclusions When counseling women for pelvic reconstructive surgery, we should provide them with evidence-based information on functional outcomes and subsequently take the patient's concerns and preferences into account. Pelvic floor symptoms were scarcely reported in reviewed trials, but demonstrated a worse scenario than anatomical outcomes.

Keywords Pelvic organ prolapse · Pelvic reconstructive surgery · Pelvic floor symptoms and function · Quality of life · Mesh

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Introduction

Do we need meshes in pelvic floor reconstruction? The answer is 'Yes', we need meshes, but not in every patient, not routinely. Not many people will argue about the enormous advantages the development of synthetic mid-urethral slings have brought to patients (and surgeons and industry); not even the success of synthetic mesh in abdominal sacrocolpopexies is doubted. The partially public and arduous dispute is more on the value of mesh in vaginal pelvic floor surgery, as many complications or problems are caused by the vaginally placed mesh to treat pelvic organ prolapse. The most recent FDA notification emphasizes to cautiously employ vaginal meshes in likely to be beneficial circumstances (http://www.fda.gov/cdrh/safety/102008-surgicalmesh.html). Most mesh erosions are not serious, and many do not require a surgical intervention. However, there are no studies investigating the patients view and quality of life regarding mesh erosion symptoms, re-operations to trim mesh, and oversewing. Therefore, we can only say that many surgeons do not consider these complications serious. Intractable pain

syndromes, however, are serious and further surgery may be difficult, complicated, and unsuccessful. Now the FDA has again informed the public about risks of vaginal mesh procedures, has asked health care providers to be cautious, and also makes them responsible for indications, appropriate counseling, and surgery of the patients. Although industry should provide scientific evidence to support the use of their mesh, the clinician has to ensure that the correct procedure and material has been selected, that the operation can be performed with a high standard, that the patient has been informed and counseled according to her needs and abilities, and that an audit is in place.

There is no scarcity of current reviews on the use of mesh for pelvic organ prolapse repair [1–17]. Conclusions of recent reviews are relatively consistent: Although there is now evidence to use mesh in the anterior compartment, long-term efficacy and safety are not known, and data on pelvic floor function is limited. Surgeons should carefully select patients and procedures and above all should adequately counsel patients.

While it is known that anatomical success does not necessarily correlate with functional outcome, we operate on patients with POP because of their symptomatic pelvic organ support defects. We repair these defects and restore anatomy, while hopefully restoring or maintaining function as well. Restored anatomy deems an operation successful, and it is unlikely that a woman with stage 0 or 1 will have typical prolapse symptoms like prolapse sensation or feeling a bulge [18]. On the contrary, she might not be aware of a prolapse stage 2 [18]. Certainly, for a surgeon, it is comforting to look at a patient complaining of lower urinary tract symptoms postoperatively when she has no recurrent prolapse.

The following review will focus on functional outcomes like prolapse symptoms (subjective outcome), stress urinary incontinence, overactive bladder, voiding difficulties, bowel function, and dyspareunia, as well as on advantages and disadvantages, evidence and eminence, and aptitudes and attitudes with regard to synthetic transvaginal mesh placement in urogynecology and pelvic floor reconstructive surgery. Examples for changes in the decision-making process are given.

Methods

Given the existing reviews covering studies partially up to 2010, the MEDLINE database was searched from 2010 to August 2011 for original articles not included in these reviews with the following keywords: pelvic organ prolapse, genital prolapse, cystocele, rectocele and mesh, synthetic graft, and repair. Studies were assessed and appropriate data extracted and tabularized. Studies were excluded if the follow-up time was less than 12 months and if studies did not contain original data or data on subjective outcome.

If reported, data on the following outcomes were summarized in Tables: prolapse symptoms or subjective outcome, stress urinary incontinence, overactive bladder, voiding difficulties, anal incontinence, obstructed defaecation, dyschezia, pain, and dyspareunia.

Functional outcome: patient-centered

Literature review

Eleven original studies employing transvaginal mesh to treat pelvic organ prolapse were found according to the above-mentioned inclusion and exclusion criteria. However, functional outcomes were irregularly reported (Table 1). There were no studies that provided information explicitly on bowel function.

Questionnaires: symptoms versus scores

Self-administered symptom-specific pelvic floor function and quality of life questionnaires are the gold standard when assessing the patient's perspective after pelvic floor reconstructive surgery [19]. There are several validated questionnaires assessing different or all aspects of pelvic floor dysfunction [20–25]. Especially, the ICI questionnaires (http://www.iciq.net) are robust measures of symptoms and quality of life [26]. Although it is to be commended that these questionnaires are increasingly used, the simple report of scores does not necessarily help when counseling women for pelvic floor surgery. The rates of persistent stress urinary incontinence or de novo overactive bladder or dyspareunia also seem very relevant issues to be discussed and presented. This issue is corroborated by one trial on anterior Prolift [27]: Bladder Function Questionnaire scores significantly decreased 12 months after surgery, but 39/57 (68%) had persistent and 9/52 (17%) had de novo stress urinary incontinence [27].

Subjective cure of prolapse symptoms

After trocar-guided transobturator vaginal mesh surgery, symptomatic recurrence of pelvic organ prolapse was reported between 7 and 33%. If analyzed cumulatively, 76 of 370 operated patients (21%) complained of prolapse symptoms postoperatively [28–32]. Still, although 17/36 women in one trial [31] using anterior Prolift to treat recurrent cystocele had stage 2 or more recurrent anterior prolapse after a mean follow-up time of 24 months, most

Table 1 Included studies and their functional outcomes

Study	Design	Operation	Follow-up months	Inclusion criteria	Subjective failure	SUI	UUI	Pain	Sexual function
Altman et al. [28]	RCT	Anterior colporrhaphy	12	Stage 2+ anterior POP	66/174 (38%)	De novo SUI 11/176 (6.2%)		0	Pain: 2% Satisfaction: 40%
		Anterior prolift	12	Stage 2+ anterior POP	44/179 (25%)	De novo SUI 22/179 (12.3%)		1 (0.5%)	Pain: 7.3% Satisfaction: 48%
Maher et al. [30]	RCT	Laparoscopic sacrocolpopexy	24	Symptomatic vault prolapse stage 2+	1/53 (2%)	Urodynamic SUI: 7 (16%)			
		Prolift	24	Symptomatic vault prolapse stage 2+	4/55 (7%)	Urodynamic SUI: 14 (33%)			
Milani et al. [29]	Prospective follow-up	Prolift +M	12	POP stage III or IV	8.9%	SUI worsening/de novo: 17 (13.3)		5 (3.9%), in 3 pain only elicited during pelvic examination	De novo dyspareunia 1/49 (2.0%)
Zyczynski et al. [33]	Prospective follow-up	Prosima	12	Symptomatic POP stage 2+	14% ($n = 130$)				De novo dyspareunia 3
Alcalay et al. [37]	Prospective	Trocarless mesh attached near SSL and laterally	12	POP	1/20 (5%)	De novo 2/20 (10%)	3/20 (15%)		2/8 dyspareunia 1/8 device-related Dyspareunia (too medial "fastener")
Ek et al. [27]	Prospective follow-up	Anterior prolift	12	Stage 2+ anterior POP		39/57 68% persistent 32/57 worsend 9/52 de novo 17%	UDI irritative scores improved significantly	UDI pain scores improved significantly	Not reported
Fayyad et al. [31]	Prospective follow-up	Anterior prolift	24+	Recurrent anterior POP	12/36 (33%)	4 improved 5 unchanged 4 deteriorated 5 de novo	6 improved 9 unchanged		7/16 worsening dyspareunia 5/16 improvement in dyspareunia 6/16 deteriorated coital incontinence
Feiner et al. [32]	Prospective follow-up	Prolift + sacrospinous ligament fixation	12	Stage 2+ anterior POP, stage 1+ uterine/posterior POP	84% (84/100)	De novo 2 (2%)	7 (7%)	Persisting thigh pain 1	3 dyspareunia related to mesh contraction
Jacquetin et al. [35]	Prospective follow up	Prolift	36	Leading edge of POP ≥ -1 cm					De novo dyspareunia: 5/33 (15%)
Moore et al. [34]	Prospective follow-up	Perigee	24	Symptomatic stage2+ anterior POP			De novo urge incontinence 4/87 (3.5%)	5 (4.4%): 2 groin/pelvic, 2 vaginal, 1 with sitting	Overall dyspareunia rate post-op: 19/65 (29%) De novo dyspareunia: 6/94 (6.4%), 2 required surgical intervention
Long et al. [36]	Retrospective follow-up	Perigee +- SUS	Mean 20	Stage 2+ anterior POP		Unclear preop data	Unclear preop data		De novo or worsened dyspareunia: 10 (17%)
		Anterior Prolift +- SUS	Mean 12	Stage 2+ anterior POP		Unclear preop data	Unclear preop data		De novo or worsened dyspareunia 12 (25%)

POP pelvic organ prolapse, *SUI* stress urinary incontinence, *UUI* urge urinary incontinence, *RCT* randomized controlled trial

women (28/36) considered themselves "very much better" or "much better". The global impression on improvement did neither correlate with the POPQ nor with dyspareunia nor with mesh erosion [31]. Laparoscopic sacrocolpopexy resulted in considerably less symptomatic prolapse at 2% [30]. In one trial, the trocar-less Prosima system was evaluated demonstrating a 14% symptomatic recurrence rate at 12 months [33].

Urinary incontinence

De novo stress urinary incontinence occurred in 12–17% [28, 31, 32] and persisted in up to 68% [27] after trocar-guided surgery, which is significantly more than after anterior colporrhaphy (6%) in one randomized controlled trial [28].

Although overactive bladder symptoms should be considered a very important outcome, urge incontinence is rarely reported separately. De novo urge incontinence was described in 3.5% after anterior transobturator mesh (Perigee) in one study [34].

Sexual function

Apart from symptoms scores, which usually improve after prolapse surgery, dyspareunia was the only relatively consistently communicated outcome. De novo dyspareunia was present between 2 and 15% [29, 33–35] after transobturator mesh. Some studies described worsened or de novo dyspareunia in 25% [36] and 44% [31]. There was also dyspareunia related specifically to the mesh (mesh contraction [32]) or the mesh attachment device [37]. Deteriorating coital incontinence was described in 6 of 16 women after anterior Prolift [31].

Evidence for or against meshes

The short summary version of the most recent Cochrane review on surgical management of pelvic organ prolapse states: "The inclusion of new randomised controlled trials showed that the use of mesh at the time of anterior vaginal wall repair reduces the risk of recurrent anterior vaginal wall prolapse on examination. However, this was not translated into improved functional or quality of life outcome [17]." Reviews including non-randomized trials are in agreement with this conclusion [11, 19]. For apical support defects, vaginal mesh kits might be beneficial, but mesh-related complications have to be considered [4].

Although data are scarce, the current Cochrane and other reviews including non-randomized trials [11, 17, 38] do not support the use of vaginal mesh in the posterior compartment. Outcomes were not superior to native tissue repairs, neither anatomically nor functionally.

Eminence-based opinions

Most current studies employ modern meshes and established operations. Presently, vaginal mesh kits or self-styled meshes are meant to replace insufficient endopelvic fascia and have arms or anchors to attach them apically, distally, and laterally. They are rarely placed as an overlay in addition to an anterior or posterior repair. A literature review on studies employing self-cut anterior meshes that only provide distal transobturator or arcus tendineous fascia pelvis attachment [39–42] reveals low anatomical success rates between 12 and 36% when compared to mesh kits [3, 4]. Apical and lateral or distal mesh attachment, therefore, seems important rendering armed or anchored mesh applications more successful anatomically. However, mesh arms under tension are responsible for a significant number of dyspareunia. [43] Likewise, anchoring the repaired endopelvic fascia apically to the sacrospinous or uterosacral ligaments may yield better results.

Aptitude and attitudes

Surgeons placing transvaginal mesh should be sufficiently trained and experienced in general pelvic floor surgery. In most areas of life, adequate training is a prerequisite of a success. Surgeon-credentialing efforts are underway (IUGA Grafts Roundtable 2010). However, so far, these are not binding laws, and things are handled differently all over the world. In some countries, urogynecology is a subspecialty, and in others, there are not even scheduled lectures for students at medical schools. There is some evidence showing that surgical skill is associated with success or failure and complications of the procedures [44]. Whether patients should be informed of the case load and personal experience of a surgeon remains debatable. However, informed consent and shared decision-making have to include information on the diagnosis, the planned procedure, its success rates, as well as its risks and complications including further surgery and alternative management, including observation. The simple solution is to have the right attitude toward the patients: information and counseling and risk–benefit estimation taking the surgical skills, the material and the procedure as well as patient-related factors like obesity into account. Figure 1 provides an illustration of factors likely to influence a decision-making process. While the surgeon's expertise is a combination of knowledge of the diagnosis, etiology, pathogenesis, probable progress with and without treatment, and therapeutical options and outcomes based on experience and scientific data, the patient's view concerns more the impact of the condition on her daily life, her own risk–benefit estimation, values, and preferences. The more the

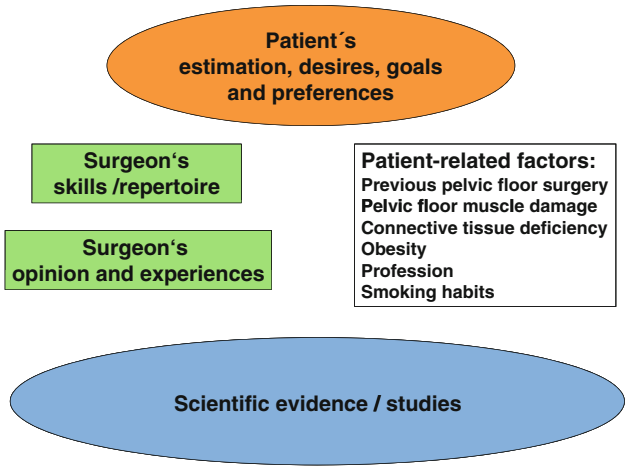

Fig. 1 Factors likely to influence the decision-making process

aspects patient, surgeon, and scientific evidence overlap (Fig. 2), the less difficult the decision should be. If we are to take the patient's concerns and preferences into account, the shared decision-making process might result in easy or comfortable agreements on the best care for this particular patient. The following two examples will illustrate this issue.

Example 1 (Fig. 3): *complete uterovaginal eversion, no clinical or occult stress urinary incontinence*

Surgical options in various combinations depending on surgeon's repertoire

- anterior and posterior repair
- paravaginal repair
- sacrospinous fixation, enterocele repair
- uterosacral ligament fixation
- Armed or anchored transvaginal mesh
- Sacrohysteropexy

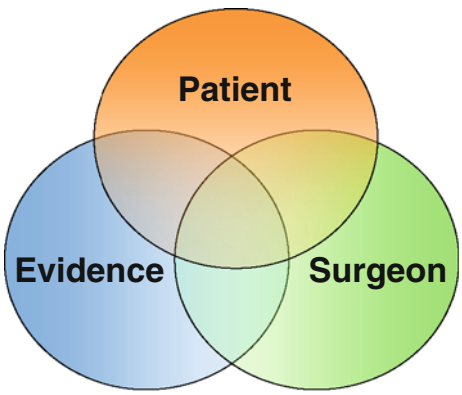

Fig. 2 The more the surgeon's and the patient's views as well as the scientific evidence overlap, the easier the decision-making process should be

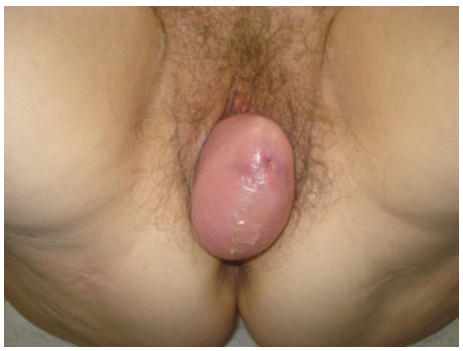

Fig. 3 Example 1: Complete uterovaginal eversion, no clinical or occult stress urinary incontinence

- +- hysterectomy, +- anti-stress incontinence procedure
- Sacrocolpopexy after hysterectomy, +- prophylactic Burch colposuspension

Data

Sacrocolpopexy may provide best anatomical results [1], but concomitant hysterectomy may increase the risk for erosion [30, 45, 46]. The risk for erosion may also apply for vaginal mesh placement, although data for both procedures are ambiguous [47–49]. Vaginal sacrospinous fixation with or without hysterectomy offers a good chance of success [1, 50], especially with the placement of anterior mesh [32]. Uterine preservation is a viable option [1, 50–52].

Patient's choice #1

- Spinal anesthesia → vaginal or open abdominal procedure
- Preference no abdominal incision → vaginal surgery
- Desire to have sexual intercourse without intractable pain → omit vaginal mesh placement and levator plication
- Prefers to keep uterus as asymptomatic → vaginal hysteropexy
- Prefers risk of recurrence over risk of pain syndrome → omit vaginal mesh and levator plication

→ Vaginal sacrospinous hysteropexy, anterior and posterior fascial repair.

Patient's choice #2

- Prefers risk of pain syndrome or mesh erosion over recurrence, would like to minimize risk to ever require further pelvic organ prolapse surgery → mesh placement possible
- Desires hysterectomy including bilateral salpingoophorectomy because of fear of cancer as sister has

breast cancer → vaginal or laparoscopic or open abdominal hysterectomy with BSO
- Prefers laparoscopic over open procedure and over vaginal approach to safely remove ovaries
- Obstructed defecation symptoms bothersome → vaginal rectocele repair

→ Laparoscopic hysterectomy and bilateral salpingoophorectomy, sacrocolpopexy using polypropylene mesh, posterior repair for low rectocele.

Example 2 (Fig. 4): *anterior vaginal wall and uterine prolapse stage 2 with stress urinary incontinence, small rectocele (stage 1).*

Surgical options in various combinations depending on surgeon's repertoire

- Anterior repair
- Paravaginal repair
- Sacrospinous fixation
- Uterosacral ligament fixation
- Armed or anchored transvaginal mesh
- Sacrohysteropexy
- +- Hysterectomy
- Sacrocolpopexy after hysterectomy

Data

The review of RCT's on anterior vaginal wall prolapse demonstrated lower anatomical failure rates when transvaginal meshes are used [1]. However, native tissue repair is feasible, especially in a primary prolapse [1, 17, 53]. Although the Cochrane review did not support concomitant stress incontinence procedures, the insertion of a suburethral tape at the time of an anterior repair improved postoperative continence rates [1, 17]. As in Example 1, uterine preservation is a viable option in selected patients [51, 54]. Laparoscopic Burch colposuspension provides similar success rates compared to suburethral tapes if performed by an experiences surgeon [55].

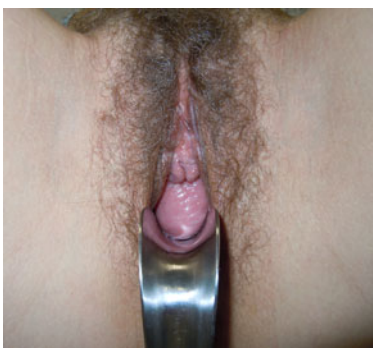

Fig. 4 Example 2: Anterior vaginal wall and uterine prolapse stage 2 with stress urinary incontinence

Patient's view #1

- Preservation of sexual sensitivity (wish for G-spot sparing surgery) → avoid vaginal surgery
- Prefers preservation of the uterus → laparoscopic or open abdominal hysteropexy
- Prefers laparoscopy over abdominal incision
- Stress urinary incontinence bothersome, prefers concomitant procedure → Burch colposuspension as suburethral tape might interfere with sensible vaginal tissue (G-spot)

→ Laparoscopic Burch colposuspension, paravaginal repair, and sacrohysteropexy using mesh.

Patient's view #2

- Prefers enhancement of sexual sensitivity by narrowing vaginal diameter → posterior repair
- Prefers risk of pain syndrome or mesh erosion over recurrence, would like to minimize risk to ever require further pelvic organ prolapse surgery → mesh insertion an option
- Is afraid of adductor muscle injury/necrotizing fasciitis → avoid transobturator mesh
- Desires hysterectomy without bilateral salpingoophorectomy to reduce risk of uterine cancer, but keep ovaries because of ongoing testosterone production

→ Vaginal hysterectomy and high uterosacral ligament vault fixation, posterior repair, anterior vaginal mesh with attachment at sacrospinous ligaments, and arcus tendineous fascial pelvis.

Conclusion

In selected cases, we do need meshes in vaginal reconstructive surgery. However, the selection process is not at all clear. There are some factors that deem the use of transvaginal mesh possibly to be beneficial as far as anatomical outcome is concerned: previous failed pelvic floor surgery, large prolapse, obesity, chronic pelvic floor stress (e.g., asthma), deficient connective tissue, and a combination of these factors. Regarding function, this short review demonstrated a high cumulative subjective failure rate of 21%, which appears considerably lower than promising reports on anatomical success. Although this review was unable to provide new information, the stated rates of recurrent prolapse symptoms as well as dyspareunia might be helpful when counseling women. Worsening or de novo

dyspareunia rates as high as 44% appear disturbing. Also, coital incontinence was found to have deteriorated in 37% [31]. There was only this one study reporting this very common and bothersome symptom. However, the impact of these symptoms on the women's quality of life has not been assessed in these trials.

The most important contributor to the decision-making process is the informed patient. A large proportion of the current discussion on vaginal meshes appears redundant if we would regard the woman with pelvic organ prolapse a collaborator to reach the ultimate goal: reconstructive surgery that results in best possible pelvic floor anatomy and function.

Conflict of interest No conflicts of interest, no disclosures.

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