Chapter 14
Outcomes of Vaginal Mesh Surgeries

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Introduction

The transvaginal placement of synthetic mesh has been used for over 20 years in an attempt to increase the durability of pelvic reconstruction, particularly in cases where the risk of failure/recurrence is high [1]. The idea of using synthetic materials to augment a defect in compromised native tissues is not unique to pelvic floor reconstruction. Synthetic materials are used to reconstruct great vessel aneurysms, orthopedic joints, and most similarly in abdominal wall hernias. The pelvic floor, however, presents atypical challenges due to the fact that the vagina is so intimately connected to sexual health and cannot be completely sterilized.

As a result, synthetic meshes have traditionally been reserved for recurrent or severe defects. Furthermore, their use has historically been restricted to physicians who sub-specialize in pelvic floor reconstruction (i.e., specialists in urogynecology or female urology). That changed with the advent of the tension-free vaginal tape (TVT) procedure in the late 1990s [2]. This procedure not only revolutionized the way female stress urinary incontinence (SUI) is treated around the world, but it changed the way people learned how to do surgery in gynecology. It was very effective in treating SUI and appeared to be relatively easy to learn to perform without extensive training. While there are some surgeons who feel that any use of mesh

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S. A. Shobeiri (ed.), *The Innovation and Evolution of Medical Devices*,
https://doi.org/10.1007/978-3-319-97073-8_14

placed through a vaginal incision is inappropriate, the vast majority of those who treat SUI on a regular basis feel that a transvaginally placed midurethral is the standard of care for female SUI.

Within 5–10 years of the introduction and success of the TVT, many surgeons sought to marry the benefits of transvaginal surgery with the durability of abdominal mesh in the treatment of pelvic organ prolapse (POP). These procedures came to be known as tension-free or transvaginal mesh (TVM) surgeries [3]. The hope was that the innovative success of TVT could be translated to POP repair. These procedures were often taught in the same manner as TVT had been taught. The success of this approach has been fervently debated. There was great enthusiasm for these TVM procedures, but some felt that innovation was moving faster than the supporting data [4].

Some surgeons still harbor these concerns. They feel that we should continue to perform traditional procedures until the scientific data that support the traditional procedures are matched by the data for the more innovative approaches. Many people with this view regard the abdominal placement of mesh, such as is done in the sacral colpopexy procedure, as the standard of care for advanced POP. And indeed, the conventional wisdom is that there are more data on abdominally placed mesh than there are on vaginally placed mesh, but the argument can be made that the opposite is true. Examination of two recent systematic reviews of these two procedures reveals 33 comparative studies of TVM versus native tissue repairs, while there were only 13 such studies of abdominal mesh [5, 6]. The goal of this chapter will be to examine the outcomes of vaginal mesh surgeries in detail.

Vaginal Mesh for Urinary Incontinence

One of the most studied procedures in all of gynecology is the 3-incision, synthetic, tension-free midurethral sling (MUS). It is widely regarded as the recommended surgical procedure for the treatment of female SUI in routine cases. As such, further studies have not been ordered by the US Food and Drug Administration (FDA) for these products to remain on the market. Outcomes for this well-established procedure will not be covered in this chapter. However, the FDA determined that single-incision slings (SIS) were different enough from the standard MUS that manufacturers must conduct further clinical (FDA 522, postmarket surveillance) trials if they want to continue marketing these types of slings.

Currently the SIS procedure is completed through one vaginal incision using polypropylene tape, which fixates into the internal obturator muscle bilaterally. These slings differ in the type/robustness of the anchorage mechanism used [7]. Several recently developed slings also allow for post-anchorage adjustment of the sling's tension. There are some theoretical advantages with SIS when compared to their retropubic and transobturator MUS. By not penetrating the space of Retzius or the obturator fossa, the limited surgical approach used to delivery single-incision slings eliminates the need for external incisions and reduces the risk of potential injury to surrounding structures. This simplified dissection reduces surgical time

and anesthetic requirements, potentially allowing the procedure to be performed in an outpatient office-based setting [8].

The landscape and availability of SIS are constantly shifting, given the challenging medicolegal climate, industry changes, and FDA requirements [9]. As a result the outcome data currently available are often of shorter follow-up duration and include products that have been discontinued, which make comparisons difficult. However two recent comprehensive reviews are available.

The Cochrane database review in 2014 evaluated 31 trials involving 32,290 women. This large meta-analysis revealed that women were more likely to remain incontinent after surgery with SIS than with retropubic slings or with inside-out transobturator slings. The authors of the review acknowledge that most of these conclusions were derived from trials involving TVT Secur™ (Gynecare, Ethicon, Somerville NJ, USA) and that the higher risk of incontinence was principally associated with use of this specific device, which had been withdrawn from clinical use in March 2013. The data also were insufficient to suggest a significant difference between any of the SIS in any of the comparisons made [10].

A similar comprehensive review was also performed in 2014 by Mostafa et al. [11]. This analysis excluded data from TVT Secur™ clinical trials. The authors found no evidence of significant differences between SIS and MUS in patient-reported cure rates and objective cure rates at a mean follow-up of 18.6 months. There was also no evidence of significant differences in most perioperative complications between both groups after excluding TVT Secur™. SIS also had significantly lower postoperative pain scores and earlier return to normal activities and to work. The analysis also demonstrated a nonsignificant trend toward higher rates of repeat continence surgery, less postoperative voiding dysfunction, more de novo urgency, and/or worsening of pre-existing urgency within the SIS group.

Since the release of these two meta-analyses in 2014, several small trials with short-term follow-up have published their findings. Some of the best data available for SIS are those involving a sling that is no longer being marketed, MiniArc™ (American Medical Systems, Minnetoka MN, USA). The data include a randomized control trial (RCT) of 225 women who were randomized to receive either the MiniArc™ (SIS) or Monarc™ (American Medical Systems) transobturator MUS [12]. Objective cure was defined as negative cough stress test with a comfortably full bladder. Subjective cure was defined as no report of leakage with coughing or exercise on questionnaire. There was no statistically significant difference in the subjective or objective cure rates between MiniArc™ and Monarc™ at 12 months, respectively, with a significant improvement in overactive bladder outcomes and incontinence impact from baseline in both arms.

Medium-term outcome measures have also been collected. These data include a cohort study of 381 women with primary SUI in a single tertiary referral center [13]. Median length of follow-up was 60 months. Of 381 patients, 215 were treated with Monarc™ slings and 166 with MiniArc™. The two groups were comparable in terms of preoperative characteristics. No difference was found in cure rates between Monarc™ and Miniarc™ patients at 5-year follow-up. Monarc™ showed better overactive bladder-free rates (97% vs. 92%). No significant differences have been found in terms of sexual function, mesh exposure, and objective cure rates.

Of products still remaining on the market, 2-year data for the Altis® (Coloplast, Minneapolis MN, USA) adjustable SIS system for treatment of SUI comes from an industry-sponsored, multicenter, single-arm trial of 113 patients with primary efficacy defined as ≥50% reduction in 24 h pad weight from baseline at 6 months [14]. In this study 90.0% of patients achieved ≥50% reduction in pad weight, 81.1% were dry (pad weight ≤4.0 g), and 87.9% had a negative cough stress test. The investigators also observed significant median reductions in the Urogenital Distress Inventory and Incontinence Impact Questionnaire scores.

Finally, one retrospective trial has evaluated the safety and efficacy of the Solyx™ (Boston Scientific, Marlborough MA, USA) SIS on 69 patients with a mean follow-up of 43 months [15]. In this study, the investigators stated that 93% of the patients were subjectively dry by questionnaire and were satisfied with their outcome. Also 91% of the patients stated that they would undergo the procedure again. There were no serious adverse events and no mesh erosions or extrusions during the reported period.

For later generation SIS, long-term efficacy has not yet been determined, but short-term efficacy rates seem to be comparable to traditional MUS. Long-term follow-up is warranted, and comparative studies will help to determine their relative efficacy.

Vaginal Mesh for Pelvic Organ Prolapse

Postoperative recurrence of POP has plagued pelvic reconstructive surgeons for decades [16]. There are multiple risk factors that have been shown to be associated with prolapse recurrence. These include advanced stage (III or IV) prolapse and younger age at the time of surgery (<60 years) [17]. Furthermore, anterior compartment defects tend to be the most prone to recurrence. We now know that anterior compartment defects are often closely associated with apical defects, and failure to address the apical component of these defects may be partially responsible for the high recurrence rate seen with traditional anterior repairs [18]. The rationale for using vaginally placed synthetic mesh for the treatment of prolapse is to minimize the risk of recurrence while at the same time minimizing the greater morbidity and length of hospital stay often associated with laparotomy/laparoscopy [19, 20].

Types of Transvaginal Mesh Procedures and Associated Outcomes

One can divide TVM procedures into two basic categories: trocar-assisted placement and nontrocar-assisted repairs. For the most part, trocar-assisted procedures come packaged and are marketed by surgical device companies. Nontrocar-assisted procedures can also come as packaged “kits” but are often performed by suturing in hand-cut mesh.

Techniques for suturing mesh in place vary. Likewise there have been many varied packaged mesh delivery systems marketed for the treatment of POP. This chapter will only report on nonabsorbable synthetic mesh and will focus on the most studied systems, with special focus on those currently being marketed as of the drafting of this chapter. It will also be limited to comparative studies or series with large numbers and at least 1 year of follow-up. Later in the chapter, outcomes for all TVMs when grouped together in systematic reviews and meta-analyses will be reviewed; first, the most studied procedures and their specific outcomes will be reviewed.

Sutured-In Hand-Cut Vaginal Mesh

There is great variation in the procedures that encompass this heading. Because the meshes and their associated delivery systems are not standardized in a manufacturing process, it is hard to lump the results together. Nonetheless, this group includes the original vaginal mesh procedures and other procedures that have served as the prototypes for those performed to this day.

The first comparative study on vaginal mesh for prolapse was published by Julian in 1996 [1]. Twenty-four women with two or more postsurgical recurrences of "severe" anterior vaginal prolapse were divided into two groups (no randomization was performed). The control group underwent suture-based anterior colporrhaphy and vaginal paravaginal repair. The treatment group underwent the same repair, but the repair was augmented by sewing synthetic nonabsorbable polypropylene mesh (PPM) from the urethrovesical junction to the vaginal apex and from the junction of the obturator and lavatory fascia from one side to the other. The author followed these patients for 2 years and noted a significantly higher recurrence rate in the control group (33% vs. 0%, $P < 0.05$). However, there was a 25% mesh complication rate (2 erosions and 1 prolonged granulation tissue). Of note, while it is still considered a Type I PPM, the graft used in this series (Marlex) has a more tightly knitted pattern and heavier weight than most of the "low-weight" PPMs used in the treatment of POP today.

The first large randomized trial to compare the transvaginal use of hand-cut, low-weight PPM to native tissue repair in the treatment of anterior vaginal wall prolapse was published in 2007 [21]. In this trial the mesh had a body with four extending arms sutured into place over plicated fascia. This technique is often referred to now as a split-thickness dissection, with the mesh being placed between the vaginal epithelium and the endopelvic fascia, as opposed to a full-thickness dissection in which the mesh is placed in the vesicovaginal space as it would be in abdominally placed mesh. Over 200 patients were randomized, and the authors found that the recurrence rate was significantly higher in the no-mesh group (38.5% vs. 6.7%, $P < 0.001$) at 12 months. The erosion rate was 17.3%. The authors subsequently published 2- and 3-year follow-up studies. At 2 years, not only did the approximately 30% higher recurrence rate in the no-mesh group persist ($P < 0.001$), but they also found a

greater sensation of bulge as well (17% vs. 5%, $P = 0.003$). There was one de novo mesh exposure [22]. At 3 years of follow-up, the proportion of symptomatic patients was similar between groups. However, the percentage of patients with an optimal outcome (defined as absence of anatomic recurrence and sensation of vaginal bulge) was greater in the mesh group (82% vs. 55%, $P < 0.001$). By the end of 3 years, 19% of patients had been diagnosed with mesh exposure at any visit; none experienced erosion of mesh into the bladder or other serious complications. The overall reoperation rate for POP or UI was 18% in the no-mesh and 11% in the mesh group (no *P* value given). No patients in the mesh group required reoperation for repeat anterior prolapse [23].

The most recent RCT of hand-cut vaginal mesh is the largest population studied to date [24]. In this study 1352 women were randomized to one of three arms: (a) standard repair of anterior or posterior compartment prolapse surgery (i.e., native tissue), (b) standard repair augmented with synthetic mesh, or (c) standard repair augmented with biological graft. The weights of mesh ranged from 19 g/m^2 to 44 g/m^2, and hybrid (coated) mesh was allowed. The biological graft materials were porcine acellular collagen matrix, porcine small intestinal submucosa, or bovine dermal grafts. The grafts were inserted below the fascial layer "if possible" and secured with peripheral sutures. Thirty-five centers recruited patients into the trial, and patients were reassessed at 6, 12, and 24 months. Augmentation with mesh or biological graft did not improve outcomes in terms of effectiveness, quality of life, adverse effects, or any other outcome in the short term, but the cumulative number of women with a mesh complication over 2 years was 12% (51 of 434). The authors note that only one woman had total mesh removal because of infection (0.2%). In most women the exposure of mesh into the vagina was small or asymptomatic, requiring only partial removal as a day case.

Trocar-Based Kits

The first generation of marketed kits manufactured by surgical device companies was influenced by the success of full-length, 3-incision midurethral slings in which trocars were used to deliver the implants. There were a number of different systems marketed, but this chapter will focus on the two most popularly used systems in the United States: Apogee™/Perigee™ (American Medical Systems) and Prolift® (Ethicon). These procedures involved placement of a body of mesh through a vaginal incision. These bodies of mesh were secured in place by extending arms of mesh that were placed in a tension-free manner. For anterior compartment defects, these mesh arms were placed through the distal and proximal arcus tendineus using a trocar and exiting through the obturator fossa via two small groin incisions per side. For posterior compartment defects, these mesh arms were placed through the sacrospinous ligament using a trocar and exiting through the ischiorectal fossa via one small buttock incision per side. These systems are not currently being marketed.

The Perigee™ system is used for anterior compartment defects. The first high-quality study of the Perigee™ system was a prospective clinical trial in which 76 women were randomized to either a standard anterior colporrhaphy or anterior repair with Perigee™ and followed for 1 year [25]. In this trial, the investigators found a higher rate of prolapse recurrence (≥ pelvic organ prolapse quantification system [POP-Q] stage II) in the native tissue arm, 45% vs. 13% ($P = 0.005$). Quality of life and sexual symptom score improvements were comparable in both groups. A 5% mesh extrusion rate was found. The authors concluded that nine native tissue patients would have to have recurrent prolapse to prevent one mesh extrusion.

The rest of the data on Perigee™ and Apogee™ (the posterior compartment system) is observational, composed mostly of cohort studies and case series. Some of the notable data in this vein include two studies by Moore and colleagues. The first study by Moore et al. is a 2-year prospective, multicenter trial of Perigee™ [26]. In this study of 114 women the authors found the 2-year anatomic cure rate to be 88.5% with significant improvement in domain-specific quality of life and sexual function questionnaires. The erosion rate was 10.5%, and the groin, pelvic, or vaginal pain rate was 4.4%. The second study, by Moore and Lubkan, is a retrospective cohort study of the Perigee™/Apogee™ mesh delivery system using mesh of two different densities (50 g/m^2 vs. 25.2 g/m^2) [27]. The traditional mesh was used in 371 cases and the lightweight mesh in 116. While the difference in mesh erosion was not statistically significant between the two groups, there was a 46% reduction in the lightweight arm (11.1% vs. 6.0%, $P = 0.12$). The most recent prospective study of the Perigee™/Apogee™ mesh delivery system is a single-center study of 158 patients in which both traditional and lightweight meshes were implanted [28]. The median follow-up times were 105 and 138 weeks for the anterior and posterior kits, respectively. Approximately half of the cases were for recurrent prolapse; the cure rates for these patients were 90.9% in the anterior compartment and 95.7% in the posterior. Overall success rates were 81.4% and 74.7%, respectively. The exposure rate was noted to be significantly lower in the lightweight mesh group ($P = 0.04$ for Perigee™ and $P < 0.001$ for Apogee™) in this study.

The Prolift® mesh delivery system is based on the "TVM technique," which was first described in 2004 [3] and is one of the most studied vaginal mesh procedures designed to correct prolapse. The Prolift® trocar-based mesh delivery system was marketed with three different kit options: anterior, posterior, and total. The first published report of outcomes of the Prolift® system was a French multicenter retrospective series of 110 patients [29]. Many of the surgeons involved in this study were involved in the original development of the TVM technique. All of the patients in this study had ≥ stage III prolapse: 54% underwent the total Prolift®, 26% the posterior Prolift®, and 20% the anterior Prolift® procedure. In this initial series, there were one bladder injury and two hematomas that required surgical intervention. At short-term follow-up, the mesh exposure and prolapse recurrence rates were both 4.7%. The results of this original investigation were promising enough to stimulate great interest in this technique, and soon other centers began reporting their outcomes.

One of the first and largest studies was conducted by the Nordic Transvaginal Mesh Group, a multinational group of surgeons from Sweden, Denmark, Finland,

and Norway. Between 2006 and 2007, they recruited 261 patients from 26 centers to enroll in a prospective study: 48% underwent the anterior Prolift®, 27% the posterior Prolift®, and 25% the total Prolift® procedure [30]. At 1-year the respective anatomic cure rates were 81%, 82%, and 79%. Visceral (bladder and rectal) perforations occurred in 9 of 252 (3.4%) of patients, and the 1-year erosion rate was 11% of which 7 (2.8%) required surgical intervention.

Other centers looked at specific clinical applications such as posthysterectomy and advanced prolapse. A retrospective series of 97 patients undergoing repair of posthysterectomy prolapse with the Prolift® (47% anterior, 29% posterior, and 24% total) reported on ≥1-year outcomes [31]. Anatomic success (≤ stage I in the treated compartment, including the apex) was noted in 87%, and there were significant improvements in domain-specific quality of life questionnaires. No mesh exposures were seen in this population. The same center carried out a retrospective cohort study of 90 (45 per arm) older patients (≥65 years) with severe prolapse (leading edge ≥4 cm beyond the hymen) undergoing either Prolift® of obliterative surgery (LeFort colpocleisis or total colpectomy) [32]. The rates of recurrence (prolapse beyond the hymen) (2.2% vs. 6.7%, respectively, $P = 0.30$) and patient satisfaction (86% vs. 92%, respectively, $P = 0.38$) were comparable between groups. Operative time, estimated blood loss, and complication rates were either equal or lower in the Prolift® group.

Six randomized clinical trials have been published comparing the Prolift® procedure to native tissue repair; the anatomic outcome results of these RCTs are compiled in Table 14.1 [33–38]. Overall, all but one showed a statistically significant difference in anatomic cure favoring the mesh-based repair. The Gutman et al. study [35] was the smallest study and did not meet its predetermined sample size, which may be why the difference in anatomic outcomes (14% lower cure rate in the native tissue arm) was not found to be statistically significant. Most of these differences were noted in the anterior compartment. However, two studies noted a difference in posterior compartment anatomic outcomes as well. A study of surgery only for recurrent POP showed a significantly higher posterior cure rate in the mesh arm (76.5% vs. 95.9%, $P = 0.003$) [33]. The other noted significantly different POP-Q values in both the posterior and apical compartments at 1-year follow-up [37].

Only three of the six trials looked at subjective cure. In one trial this outcome was comparable between arms [33], and in the smallest study, a difference of 11% was noted [35], but again this was not statistically significant. In the largest trial,

Table 14.1 Anatomic cure with Prolift® vs. native tissue repair

Study	Patients (*N*)	Length (mo)	Compartment studied	Mesh cure anatomic (%)	Native cure anatomic (%)	*P* value
Withagen et al. [33]	194	12	All	92.2	44.9	< 0.001
Altman et al. [34]	389	12	Anterior	82	48	< 0.001
Gutman et al. [35]	65	36	All	85	71	**0.45**
Halaska et al. [36]	168	12	All	83	61	0.003
Svabik et al. [37]	72	12	All	97	35	< 0.001
Dos Reis Brandão da Silveira et al. [38]	184	12	Anterior posterior	86.4 97.7	70.4 91.4	0.019 0.089

subjective cure was higher in the mesh arm (62% vs. 75%, $P = 0.008$) [34]. All trials reported on either de novo dyspareunia rates or Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ) scores. There were no significant differences noted between arms on these outcomes in any of the studies. De novo dyspareunia rates ranged from 3.7% to 10.3% in the native tissue arm and from 3.4% to 8.1% in the mesh arm. Four studies looked at pelvic pain beyond the immediate postoperative period, and no differences were noted between groups. Pain rates ranged from 0.0% to 11.7% in the native tissue arm and from 0.5% to 10.1% in the mesh arm. De novo SUI rates were noted in five studies, these rates were comparable between study arms in all but one study that noted a significantly higher rate in the mesh arm ($P = 0.02$) [37]. Mesh exposure rates varied from 3.0% to 20.8%. Three of the studies reported the percentage of patients that needed to undergo mesh revision under anesthesia; these rates ranged from 3.0% to 7.6% [34, 36, 37].

Most of these RCTs followed patients for 12 months, but there are quite a few studies with longer-term follow-up that show comparable longer-term success rates (Table 14.2) [39–47].

Table 14.2 Studies of Prolift® with 40 or more patients with >1 year follow-up

Study	Patients (*N*)	Length of follow-up (mo)	Graft type (other surgical criteria)	Visceral injury and/or erosion	Vaginal mesh exposure (%)	Success rate (%)
Wang et al. [39]	80	36	Prolift® (severe POP, w/ hysterectomy)	1 Rectal injury	6.3	93.3
Khandwala [40]	157	13	Anterior, posterior, and total Prolift® + M	None	2.2	94
Alperin [41]	85	24	Anterior, posterior, and total Prolift®	2 Bladder and 1 rectal injury	13	91.5
Gad [42]	40	7–39	Anterior, posterior, and total Prolift®	N/A	N/A	97.5
Benbouzid et al. [43]	75	54	Anterior, posterior, and total Prolift®	N/A	5.3	85.3
de Landsheere et al. [44]	524	38	Anterior, posterior, and total Prolift®	33 Bladder and 1 rectal injury; 0 visceral erosion	2.5	97
Huang et al. [45]	65	25	Total Prolift®	1 Bladder and 1 rectal injury	2	94
Lo [46]	43	16	Anterior and posterior Prolift® (severe POP only)	None	2.3	95
Wetta et al. [47]	68	14	Anterior, posterior, and total Prolift®	2 Bladder injuries	4.4	97.8

POP pelvic organ prolapse

Single-Incision Kits

Single-incision kits include procedures whereby the mesh is implanted through a vaginal incision without the use of trocars. A number of different systems have been marketed, but this chapter will focus on the two most popularly used systems in the United States: Elevate (American Medical Systems) and Uphold™ (Boston Scientific); as of this writing only, the latter is still on the market.

The Elevate system was available in both an anterior/apical and a posterior/apical kit. In both kits, self-fixating tips (shaped like arrow heads) swedged onto mesh arms are placed into the sacrospinous ligament, which are then articulated to bodies of mesh placed into the anterior or posterior compartments through a single vertical vaginal incision. In the case of the anterior system, there are two additional self-fixating tips swedged onto the distal aspect of the body of the mesh that are inserted into the distal aspect of the arcus tendineus.

There are substantially less prospective and comparative data on the Elevate system than the Prolift®. However, there are two high-quality, multicenter prospective series looking at the Elevate. The first investigates outcomes with the posterior system [48] and the second with the anterior system [49]. The study of the posterior system followed 139 women for 12 months after surgery. This showed objective posterior wall and apical cure rates of 92.5% and 89.2%, respectively. The mesh exposure rate was 6.5% [48]. The study design of the anterior system was similar with a sample size of 128 women. This showed objective anterior wall and apical cure rates of 87.5% and 88.5%, respectively. The mesh exposure rate was similar to the posterior series at 6.3% [49]. Both studies noted significant improvement in domain-specific quality of life and sexual function questionnaires and other adverse rates of de novo SUI, dyspareunia, and hematoma formation at <5%.

While there are no RCTs involving Elevate, there are at least four retrospective cohort studies comparing Elevate to other transvaginal mesh systems. Three of these compare anterior Elevate to the Perigee™ system [50–52], and the other is a comparison to anterior Prolift® [53]. Most of the studies had sample sizes between 50 and 100 in each arm and follow-up of at least 1 year. All studies showed comparable anatomic success between the two systems studied. However, all but one, Wong et al. [50] showed lower mesh exposure rates in the Elevate group.

The second nontrocar/single-incision kit, Uphold™, is the only kit currently being marketed for prolapse in the United States. Unlike many of the other systems, Uphold™ has only one kit, and it is designed to treat anterior/apical defects. There is no posterior compartment equivalent. The mesh used in the original iteration of the Uphold™ had a weight of 45 g/m^2; the mesh used in the current kit (Uphold™ LITE) is 25 g/m^2. The mesh delivery system includes a body with two extending arms of mesh that are fixated in a tension-free manner to the sacrospinous ligaments using a push-and-catch suturing device (Capio®, Boston Scientific) that is included in the kit.

There have been five large published series of this procedure (only one of these was a comparative trial). A summary of the findings of these studies is displayed in Table 14.3 [54–58]. All followed the study population for at least 12 months, three were prospective, and three limited their population to *utero*vaginal prolapse

Table 14.3 Anatomic cure and mesh exposure rates with uphold system

Study	Study design	Length (mo)	Patients (*N*)	Population	Anatomic success (%)	Rate of mesh exposure (&)
Vu et al. [54]	Single-site retrospective	12	115	Uterovaginal and vaginal vault prolapse	93	2.6
Jirschele et al. [55]	Multicenter prospective	12	99	Uterovaginal prolapse	96.6	6.5
Letouzey et al. [56]	Retrospective	23	115	Uterovaginal prolapse	92	2.7
Altman et al. [57]	Multicenter prospective	12	207	Uterovaginal and vaginal vault prolapse	94	1.4[a]
Gutman et al. [58]	Multicenter prospective	12	76	Uterovaginal prolapse	80	6.6

[a]This was the percentage of patients who underwent surgery for mesh exposure. Total percentage of exposure not listed. Two additional patients had mesh removed for other complications

patients. All but one demonstrated an anatomic success rate of greater than 90%. The rate of mesh exposure ranged from 2.6% to 6.6%.

The first study comes from the center that helped develop the technique and product [54]. In it the authors demonstrate the efficacy of the device in both uterovaginal and posthysterectomy POP. In some of the cases of uterovaginal prolapse, the uterus was preserved, and in others a concomitant hysterectomy was performed. As with other mesh-based prolapse repairs [59], a higher rate of mesh erosion appeared to be associated with concomitant hysterectomy at the time of the Uphold™ procedure. Notably, all but one of the remaining studies limited their populations to patients with uterovaginal prolapse, with the vast majority of the subjects undergoing hysteropexy.

The first of these studies investigating Uphold™ for the treatment of uterovaginal prolapse is a multicenter, prospective trial in which all of the 99 subjects underwent hysteropexy [56]. The anatomic success rate at 12 months was 96.6%, with an exposure rate of 6.5%, and a reoperation rate of 7.5%. All of the domain-specific quality of life questionnaires showed significant pre- to postoperative improvement. In the second study, 17 (14.8%) of the 115 subjects underwent concomitant hysterectomy, and the remaining subjects underwent hysteropexy [57]. There were three patients (2.7%) who required surgery for vaginal mesh exposure in this study; one of the three patients had undergone concomitant hysterectomy. The anatomic success rate was 93% at a mean follow-up of 23 months, and no patients required surgery for recurrent prolapse. In addition to the three abovementioned patients, one other patient underwent partial mesh removal for subsequent pain attributed to pudendal neuralgia, for a total reoperation rate of 3.4% for mesh-related complications. The last study limited to patients with uterovaginal prolapse is a multicenter, prospective parallel cohort study comparing laparoscopic hysteropexy ($n = 74$) to vaginal mesh (Uphold™) hysteropexy ($n = 76$) [58]. In this study, the operative time for the laparoscopic approach was almost three times that of the vaginal ($P < 0.001$). There were no differences in blood loss, complications, and hospital stay. Anatomic

and symptomatic cure rates were comparable between the laparoscopic and vaginal groups (83% vs. 80%, $P = 0.20$ and 90% vs. 95%, $P = 0.40$, respectively). The rate of mesh exposure was also similar between groups (2.7% vs. 6.6%, $P = 0.44$).

The remaining Uphold™ study is a prospective, multicenter single cohort study of 207 women with either uterovaginal or posthysterectomy POP [59]. Objective and subjective cure rates were similar to those of the previous studies: 94% and 91%, respectively. The overall rate of serious complications was 4.3%. Within 1 year of follow-up, seven (3.4%) patients underwent reoperation for prolapse recurrence, and three (1.4%) underwent surgical revision of mesh due to exposure.

Multiple prospective studies comparing Uphold™ to other types of surgical repair of POP are currently underway. These include the FDA-mandated 522 cohort study comparing 3-year outcomes between Uphold™ and vaginal native tissue repair and two randomized trials conducted by the Pelvic Floor Disorders Network: one comparing hysteropexy with Uphold™ to vaginal hysterectomy with uterosacral ligament vault suspension and, the other, a three-arm study comparing transvaginal native tissue repair, TVM with Uphold™, and sacral colpopexy. Thus, robust comparative outcome data regarding the Uphold™ procedure should be available within the next few years.

Overall Outcomes of Transvaginal Mesh for Prolapse

Many individual studies and systematic reviews exist to give us an overall appreciation regarding the various outcomes associated with vaginal mesh procedures for POP as a whole. The goal of augmenting a prolapse repair with synthetic mesh is to increase the longevity and durability of the repair. Obviously, however, anatomic cure is far from the only important outcome for prolapse surgery. Equally important are complications and subjective outcomes.

Erosion

Erosion of mesh into the vaginal lumen (exposure) or into visceral organs is a unique complication of mesh-based prolapse repairs. Fortunately, erosion into visceral organs is a rare complication [60]. But vaginal exposure is noted in most published studies of vaginal mesh.

The rate of mesh exposure has been examined in a number of systematic reviews. One such review that includes 91 (total $N = 10{,}440$) comparative and single-arm studies that have an $n \geq 30$ noted an average rate of 10.3% (95% CI 9.7–11.0) [61]. A systematic review limited to randomized trials shows an average rate of 8% of patients requiring reoperation for mesh exposure [62]. Another systematic review limited to comparative studies showed a mesh exposure rate ranging from 1.4% to 19% in the anterior compartment and 3–36% when mesh was placed in multiple compartments [5].

Risk factors that have been associated with the risk of exposure include smoking, mesh placed in multiple compartments, surgeon experience [63], multiple child-

birth, somatic inflammatory disease (i.e., rheumatoid arthritis) [64], older age [65], concurrent hysterectomy, and inverted "T" colpotomy [66]. Surgical technique almost certainly plays a role in the risk of mesh exposure, given the wide range of the incidence of this outcome. In fact, one multicenter RCT demonstrated a range of mesh exposure rates from 0% to 100% at the different clinical centers, despite the use of the same mesh and mesh delivery system [63].

Other Complications

While complications such as chronic pain, dyspareunia, de novo SUI, and visceral injury are often attributed to the use of mesh in vaginal prolapse repair, these complications are certainly not unique to mesh-augmented repairs.

Pain and dyspareunia have been shown to occur postoperatively in up to 13% and 45% of mesh patients, respectively. As would be expected, pre-existing pain and dyspareunia are associated with higher rates of these conditions postoperatively [63]. However, systematic review suggests that the use of vaginal mesh in prolapse repair is not associated with a higher risk of de novo dyspareunia when compared to native tissue repairs (RR = 0.92, 95% CI 0.58–1.47) [62]. And there is no evidence from systematic review to suggest that the rate of de novo pain is any higher in mesh patients either [5].

In regard to intraoperative complications, the rates appear to be comparable between mesh and native tissue vaginal repair [5]. However, the rate of bladder injury may be higher in mesh-based repairs (RR = 3.92, 95% CI 1.62–9.5) [62].

Unmasking of occult SUI is a well-known phenomenon that occurs after surgical repair of POP. Just as correcting prolapse can lead to a resolution of incomplete bladder emptying, it can also lead to de novo SUI. It could be argued that de novo SUI is actually a marker of effective correction of prolapse. Nonetheless, de novo SUI is an unwelcome outcome of prolapse repair. The data on de novo SUI as it relates to mesh and native tissue repairs are mixed. The risk of de novo SUI is not statistically higher (RR = 0.67, 95% CI 0.44–1.01) in mesh-augmented repairs of the anterior compartment [67], but it does appear to be when all mesh procedures are combined (RR = 1.39, 95% CI 1.06–1.82) in the meta-analysis [62]. However, the risk of undergoing repeat surgery for de novo SUI is not higher in either population.

The need to undergo surgery for recurrent POP is perhaps one of the best indicators of prolapse repair failure. A meta-analysis involving outcomes from 12 RCTs suggests that the rate of repeat surgery for prolapse is lower in transvaginal mesh surgery as compared to native tissue repair (RR = 0.53, 95% CI 0.31–0.88) [62]. A similar analysis limited to anterior compartment repair suggests that the rate of need for repeat surgery for prolapse is approximately twice as high (RR = 2.03, 95% CI 1.15–3.58) following native tissue repair as compared to mesh [67]. Risk factors for recurrent prolapse include age <60 years, obesity, and preoperative stage III or IV prolapse [17, 68]; furthermore, the anterior compartment is the site most prone to recurrence [69]. It therefore follows that patients with these characteristics may be the most likely to benefit from a mesh-augmented repair.

There are no randomized studies comparing mesh-based repairs that are done abdominally with robotic assistance to those done transvaginally. However, there are

two retrospective cohort studies that compare outcomes between these procedures. One looked specifically at the risk of reoperation after these two types of surgeries [70]. The median length of follow-up in the 181 women who underwent robotic surgery was 3 months, and it was 11.5 months in the 64 women who had vaginal mesh surgery. The authors found no difference in overall rate of reoperation for apical prolapse (10.3% vs. 7.8%, respectively, $P = 0.63$). They specifically found no differences in the rates of reoperation for prolapse (3.0% vs. 0%, $P = 0.33$) or mesh exposure (1.2% vs. 3.1%, $P = 0.58$). Similarly, the authors of the other study found equivalent rates (2.6% in both arms) of mesh exposure in the robotic and vaginal groups [71]. No difference was noted in blood loss, hospital stay, or time of return to normal voiding.

Anatomic Outcomes

Anatomic cure is the primary outcome that is used to calculate sample size (and thus power) for most RCTs comparing mesh to native tissue repair. As such, the data for this outcome are the most robust data we have regarding vaginal mesh outcomes. When anatomic cure is assessed in meta-analysis, it is consistently noted to be higher in mesh-based vaginal repair, particularly in regard to the anterior compartment. One review from Brazil noted an odds ratio of 1.28 (95% CI 1.07–1.53) significantly favoring mesh over native tissue [72]. The difference noted by the most recent Cochrane review was more distinct with a relative risk of 0.45 (95% CI 0.36–0.55). When the analysis was limited to studies of anterior compartment repair, the benefit in the mesh group was more pronounced (RR = 0.36, 95% CI 0.28–0.47) [62]. A similar analysis by the same group suggests that if recurrent anterior compartment prolapse occurs in 13% of women after mesh repair, 32–45% would have recurrence after native tissue repair [67].

Subjective Outcomes

While early systematic reviews noted some benefit of mesh augmentation in regard to anatomic outcomes following vaginal POP repair, there were not enough data to comment on differences in subjective outcomes [60]. However, in the last 10 years, a large increase in the number of higher-quality comparative studies of transvaginal mesh vs. native tissue surgeries has made such an analysis possible.

Two independent meta-analyses have addressed this topic and have drawn the same conclusion. The first looks at "awareness of prolapse" after surgery as the variable of interest in randomized trials [62]. The authors conclude that this outcome at one to 3 years was less likely after mesh repair (RR = 0.66, 95% CI 0.54–0.81). The second [5] used two variables to measure subjective outcomes in all comparative studies: "symptoms of bulge" (Fig. 14.1) [23, 34, 73–79] and the net change from pre- to postoperative scores on the Pelvic Organ Prolapse Distress Inventory (POPDI) subscale (Fig. 14.2) [25, 77, 79–81]. Both analyses favored mesh, with a

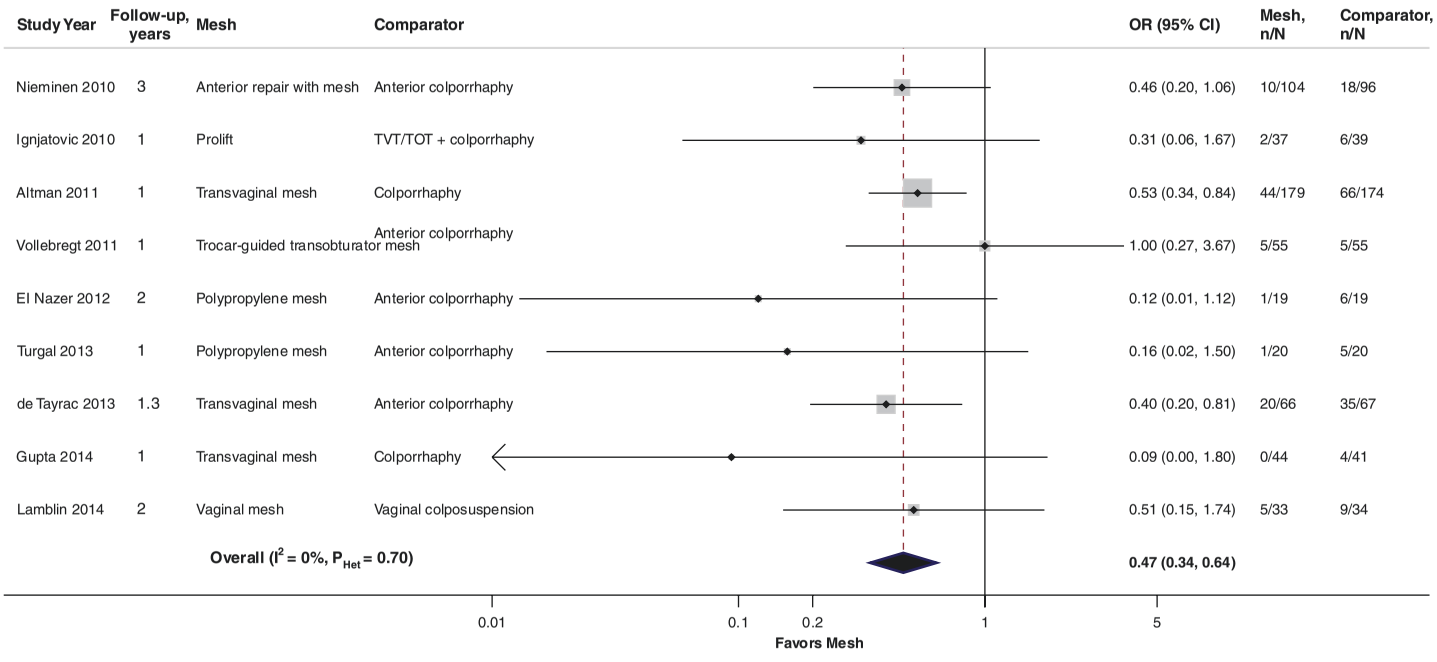

Fig. 14.1 Meta-analysis of anterior vaginal wall repair, synthetic nonabsorbable mesh vs. no mesh, subjective symptoms of a bulge postoperatively [23, 34, 73–79]. OR odds ratio, CI confidence interval, TVT/TOT tension-free vaginal tape and transobturator tape midurethral sling surgery. (From Schimpf et al. [5], with permission)

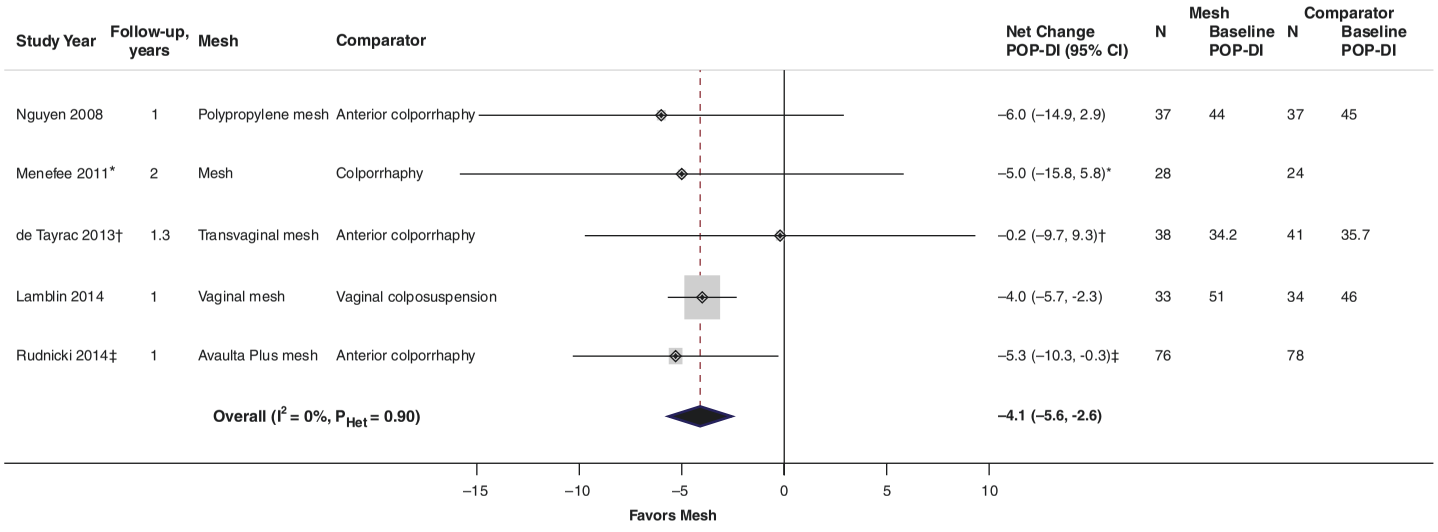

Fig. 14.2 Meta-analysis of anterior vaginal wall repair, synthetic nonabsorbable mesh vs. no mesh, total score on Pelvic Organ Prolapse Distress Inventory (POPDI) subscale score [25, 77, 79–81] (*Difference in median values; standard error derived from the median standard deviation across other studies; † Reported POP-DI divided by 3; ‡ Difference of final values; *CI* confidence interval; (From Schimpf et al. [5], with permission)

lower rate of symptoms of bulge as compared to native tissue (OR = 0.47, 95% CI 0.34–0.64) and greater improvement in POPDI score (net change = −4.1, CI −5.6 – −2.6). Sensitivity analysis of this second meta-analysis yielded similar results when limited to randomized trials. Both reviews failed to find a difference in overall quality of life and sexual function outcomes as assessed by pre- and postoperative validated questionnaires.

Conclusion

While a common criticism of vaginal mesh surgeries is a lack of data on these procedures, as this chapter demonstrates, there is actually a very large body of evidence regarding the outcomes of many of these procedures. This literature suggests that mesh use may decrease the risk of both objective and subjective prolapse recurrence, without significantly compromising the risk of sexual dysfunction or pain. However, mesh exposure is clearly a unique risk of mesh use whether it is placed vaginally or abdominally.

As such, we must continue to strive to discern in which patients this risk is outweighed by the potential benefits of vaginal mesh surgery. We know from the current data that the benefit of mesh in most patients appears to be greatest in repair of anterior compartment defects. Furthermore, the risk of recurrence is greatest in patients with more advanced (stage III and IV) defects.

When is hysterectomy indicated? And are there times when a native tissue or an abdominally placed mesh may be of greater benefit to a particular type of patient? These questions need to be addressed. Fortunately, there are number of well-designed experimental trials currently enrolling patients that should help to answer such questions. It is critical to realize, however, that while research trials give us valuable information, it is unlikely that we will ever find one single procedure that works best for every patient with POP. It is important that we continue to have a number of different surgical techniques at our disposal and that, through careful counseling with our patients, we continue to be able to tailor our surgery to best fit each individual woman suffering from pelvic floor dysfunction.

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