The Use of Prostheses in Pelvic Reconstructive Surgery: Joy or Toy?

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SUMMARY

The high recurrence rate of pelvic organ prolapse (POP) of up to 30% after pelvic reconstructive surgery makes a more refined surgery imperative, as well as the need for either biological or synthetic prostheses as adjuvant treatment. Patients with recurrence risks may benefit from the adjuvant treatment: (1) to substitute for the lack of supportive tissue; (2) to reinforce inadequate tissue; (3) to induce new supportive tissue; and (4) to consolidate and complement the insufficient surgical techniques. However, some debatable issues in use of the prosthetics remain. The use of prosthetics enables the simultaneous repair of all vaginal defects of POP and concomitant anti-incontinence surgery to be faster, easier and more precise. Nevertheless, great care should be devoted to the actual and theoretical short- and long-term risks, many of which have not been fully elucidated. Despite the lack of various ideal characteristics, the type I monofilament, macroporous polypropylene, has been suggested to have the lowest incidence of infection and erosion among the nonabsorbable prostheses. There is good evidence to support the use of nonabsorbable synthetic mesh for abdominal sacrocolpopexy, while the use of prostheses for repairing isolated anterior and posterior compartment defects remains controversial. There have been no long-term studies with sufficient patient numbers to prove whether synthetic or biological prostheses are superior during vaginal surgery. Tension-free vaginal mesh techniques with procedural kits are being adopted increasingly, despite the paucity of data. Although short-term follow-up studies have shown tension-free vaginal mesh to be a safe and effective technique to correct POP, anatomic and functional results of long-term follow-up studies, however, have not yet confirmed the effectiveness and safety. Mesh erosion remains a concern, with variable rates according to different materials and approaches. Newly developed prostheses offer an alternative option to pelvic reconstructive surgery. However, some questions remain: (1) Should prostheses be considered for primary repairs, secondary repairs, or solely in patients with risk factors for recurrence? (2) Which prosthetic material is better: synthetic or biological ones; absorbable or nonabsorbable ones? (3) Do the benefits of prosthetics in pelvic reconstructive surgery outweigh the risks of complications? These questions are explored and reports in the literature reviewed. [*Taiwan J Obstet Gynecol* 2008;47(2):151–156]

Key Words: pelvic organ prolapse, pelvic reconstructive surgery, prosthesis, tension-free vaginal mesh

Introduction

The high recurrence rate (30%) after surgery for pelvic organ prolapse (POP) makes a more refined reconstructive surgery imperative [1]. There are some risk factors for POP recurrence, e.g. poor tissue quality before and during surgery, impaired healing, chronic diseases causing increased intra-abdominal pressure (due to obstructive pulmonary disease, asthma or constipation), high-grade cystocele, and age 60 years or older [2,3]. Patients with risk factors may benefit from adjuvant prosthetic materials during pelvic reconstructive surgery. Therefore, biological and synthetic prostheses have emerged as adjuvant prosthetic materials [4]. Through the evolution of pelvic reconstructive surgery, prostheses have played important roles as reinforcement

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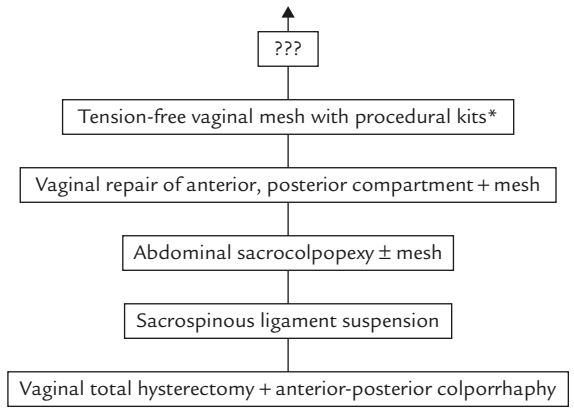

Figure. The evolution of pelvic reconstructive surgeries. *Include Prolift (Gynecare, Ethicon, Somerville, NJ, USA); Perigee and Apogee (American Medical Systems, Minnetonka, MN, USA); posterior intravaginal slingplasty (United States Surgical, Tyco Healthcare, Norwalk, CT, USA); Nazca (Promedon, Cordoba, Argentina).

adjuvant (Figure). Once a successful material is identified or developed, it may decrease operating time and morbidity during vaginal surgeries. However, some debatable issues in the use of prostheses for pelvic floor reconstructive surgery remain.

Prostheses can serve as a scaffold for tissue in growth after pelvic reconstructive surgery with the purpose to: (1) substitute for the lack of supportive tissue; (2) reinforce inadequate tissue; (3) induce new supportive tissue growth; and (4) consolidate and complement insufficient surgical techniques [5]. With the use of prostheses, the surgeon can repair all vaginal defects faster, easier and more accurately. In the anterior compartment, a graft can be anchored bilaterally to the arcus tendineus fasciae pelvis, re-creating a level II attachment. In the apical and posterior compartment, it is located apical and posterior to the level of the ischial spine, re-creating a level I support [6]. Prostheses can also be potentially used to treat stress urinary incontinence concomitantly using different shaped materials [7]. The ideal pelvic reconstructive surgery of severe cystocele should include repair of bladder herniation, correction of coincident stress urinary incontinence without causing obstruction, and retention or improvement of vaginal depth and axis [8].

Historically, the use of synthetic nonabsorbable prostheses, recently reviewed by Birch [9], dates to the beginning of the 20th century with the use of metallic silver mesh as early as 1903, which was followed by the use of nylon mesh in 1938, and Dacron (Mersilene) in 1956. Mersilene was a popular prosthetic material for many decades, but its use is rapidly declining in favor of polypropylene, which is now the most commonly used synthetic product and was introduced as Marlex in 1958 [9].

With the accumulating experience in general surgery, more recent reports in the surgical literature has suggested the routine use of synthetic prosthesis for all primary hernia repairs. Luijendijk et al [10] reported on the recurrence rates of inguinal hernias following primary suture repair compared with augmented repair employing a synthetic graft, with a 43% recurrence in the suture repair group versus 24% in the mesh augmented repairs after 3 years of follow-up. Surgical principles for the correction of POP are similar to those employed for abdominal wall hernias. Gynecologists performing reconstructive pelvic floor surgery have begun to adopt these surgical principles and are using a variety of synthetic and biological products for both primary and secondary prolapse surgeries. Nevertheless, great care should be devoted to actual and theoretical short- and long-term risks, many of which have not been fully elucidated. In this review article, the characteristics of the different prostheses, the use synthetic prostheses for pelvic reconstructive surgery, and the associated complications of prostheses are included.

Characteristics of Different Prostheses

The ideal prosthesis should be sterile, durable, noncarcinogenic, inexpensive, easily applied, and causes no antigenic response but withstands remodeling by body tissues [11]. Current prostheses are either synthetic (absorbable, nonabsorbable or mixed) or biological (autologous, allograft or xenograft donor tissue) for the purpose of integrating with the host tissue and supporting the attenuated areas.

Synthetic absorbable and nonabsorbable materials

These implants differ not only with respect to the material (polyethylene, polypropylene, polypropylene terephthalate, Gore-Tex) but also in terms of structure (woven, knitted), fiber type (monofilament, multifilament, monofilament/multifilament), pore size, mechanical properties, shape, and surface characteristics [12]. Most commercially available synthetic prostheses in surgical fields are listed in the Table according to the Amid classification [13].

- Nonabsorbable materials: e.g. Prolene (Ethicon, Somerville, NJ, USA), Marlex (Bard, Cranston, RI, USA), Atrium (Atrium, Hudson, NH, USA), Gore-Tex (Gore, Flagstaff, AZ, USA), Mersilene (Ethicon, Somerville, NJ, USA), and Teflon (DuPont, Wilmington, DE, USA), Cellgard (Hoechst-Celanese, Charlotte, NC, USA).

Table. Classification of synthetic prostheses

Type	Fiber type	Pore size	Component	Brand names
Type I	Monofilament macroporous	>75 μm	Polypropylene	Prolene (Ethicon, Somerville, NJ, USA) Marlex (Bard, Billerica, MA, USA) Atrium (Atrium, Hudson, NH, USA)
Type II	Monofilament microporous	<10 μm	ePTFE	Gore-Tex (Gore, Flagstaff, AZ, USA)
Type III	Multifilament microporous/ macroporous		Polyethylene	Dacron (Mersilene; Ethicone, Somerville, NJ, USA) Teflon (DuPont, Wilmington, DE, USA) SurgiPro (Autosuture, Tyco Healthcare, Norwalk, CT, USA)
Type IV	Submicronic	<1 μm	Polypropylene sheet	Silastic (Dow Corning, Midland, MI, USA) Cellgard (Hoechst-Celanese, Charlotte, NC, USA)
Absorbable	Monofilament/ multifilament		Polypropylene/ polyglactin 910	Vypro (Ethicon, Somerville, NJ, USA)
	Multifilament		Polyglactin 910	Vicyl (Ethicon, Somerville, NJ, USA)

ePTFE = expanded polytetrafluoroethylene.

- Absorbable materials: e.g. Vypro, Vicryl (Ethicon, Somerville, NJ, USA).

Biological materials

Biological materials are categorized as follows:

- Xenograft: porcine small intestine submucosa (SIS; Cook, Letchworth, UK), bovine pericardium, and Pelvicol (Bard, Billerica, MA).
- Allograft: dura mater, fascia lata.
- Autologous material: rectus sheath, fascia lata, and vaginal mucosa.

The newly developed absorbable material called SIS (Cook, Lafayette, IN, USA) is also worth our attention [14]. SIS is a natural biomaterial harvested from the porcine small intestine and made into a biocompatible medical product. The emergence of absorbable material may bring a new era; however, owing to limited number of reports in the literature, the long-term effect remains unknown.

Since no ideal prosthesis with the various characteristics is available, the search for the optimal prosthesis remains uncertain.

Synthetic Prostheses for Pelvic Reconstructive Surgery

Abdominal sacrocolpopexy

The efficacy of nonabsorbable synthetic prostheses for abdominal sacrocolpopexy is assured by supportive evidence [15]. There have been many reports in the literature on the support of the middle compartment. First described by Lane in 1962 [16], sacrocolpopexy has undergone numerous modifications, including the type of prosthesis used and placement onto the anterior and posterior walls of the vagina. In a recent comprehensive review of 98 articles on abdominal sacrocolpopexy, the success rate, when defined as lack of apical prolapse postoperatively, was 78–100% and when defined as no postoperative prolapse, was 58–100%; the follow-up duration for most studies ranged from 6 months to 3 years. The median rate for a second operation for POP and/or stress urinary incontinence after abdominal sacrocolpopexy was 4.4% (range, 0–18.2%) [17]. Synthetic rather than biological prostheses for bridging the vagina to the sacrum was supported by a recent randomized trial by Culligan et al [18], who asserted that polypropylene mesh (91% cure) was better than cadaveric fascia lata (68% cure) for abdominal sacrocolpopexy ($p = 0.007$) at 1 year of follow-up. There were significant differences in favor of the polypropylene mesh group at points Aa and C of the POP quantification system, as well as overall prolapse stages [18]. Fitzgerald et al [19] also noted poor anatomic outcomes (the failure rate of 83% by 17 months) when freeze-dried, irradiated donor fascia lata was used for abdominal sacrocolpopexy.

Vaginal repair of the anterior and posterior compartments

The data available on synthetic nonabsorbable prostheses are sparse and largely consist of small retrospective series with short-term follow-up. Julian [20] first described anterior vaginal colporrhaphy with prosthetic

reinforcement in 1996. The prospective study used Marlex (Bard, Billerica, MA, USA), a type I monofilament polypropylene prosthesis, which was randomly allocated to 24 patients with anterior colporrhaphy with or without prosthetic reinforcement, and showed success rates of 100% and 66%, respectively, at 24 months' follow-up; however, there was a high erosion rate of 25% (4/12) [20]. A retrospective analysis by Flood et al [21] of 142 women using Marlex revealed a success rate (prolapse less than grade 1) of 100% at a mean follow-up of 36 months, with no prosthetic-related complications. Dwyer and O'Reilly [22] used a polypropylene prosthesis (Atrium) in the anterior and posterior compartments and showed a recurrence rate of 6%. de Tayrac et al [23] reported a recurrence rate of 8% and seven erosions (8.3%) using the polypropylene prosthesis Gynemesh (Gynecare, Ethicon, Somerville, NJ, USA) on 87 women with a mean follow-up of 24 months. The studies using polypropylene meshes to augment the surgically corrected anterior vaginal prolapse showed success rates of 87% [24], 91.6% [23], and 100% [25]. The researchers concluded that the use of nonabsorbable prosthetic reinforcement appeared to be an effective method of preventing prolapse recurrences; however, the concerns included the short-term follow-up periods and material erosion rates.

Owing to the limited number of reports on graft augmentation in the posterior vaginal wall, the data on the effects of graft augmentation on the bowel, bladder and sexual function are limited. Milani et al [25] reported a prospective observational cohort of 63 women who had conventional anterior ($n=32$) or posterior ($n=31$) colporrhaphies augmented with polypropylene mesh. Both groups had excellent anatomic outcomes at 12 months after surgery (94% with stage 0) but had significant increases in the rates of dyspareunia. Of those who had anterior mesh repairs, 20% had worsening dyspareunia after their repairs, while 63% of those who had posterior mesh repairs developed worsening dyspareunia [25]. The authors concluded that while the studies showed good anatomic results with the use of Prolene mesh for vaginal prolapse repairs, the morbidity rates, however, were high [25]. In addition, Deffieux et al [26] reported a comparable incidence of *de novo* dyspareunia in patients with vaginal erosion and those without it (9% *vs.* 11%; $p=0.85$).

The use of synthetic absorbable prostheses is a response to the morbidity arising from the erosion rates with the use of synthetic nonabsorbable prostheses. Two prospective randomized controlled trials compared synthetic absorbable prostheses, polyglactin 910 (Vicryl; Ethicon, Somerville, NJ), with traditional transvaginal repairs. Sand et al [27] studied 161 women (21 recurrent and 140 primary), with significantly lower recurrence rates found in the prosthetic-reinforced repair group compared with the non-reinforced group (25% *vs.* 43%; $p=0.002$) at 12 months of follow-up. Weber et al [28] undertook a prospective three-armed randomized controlled trial on 114 patients and found that absorbable augmented meshes (polyglactin 910 mesh) did not improve anatomic results at a mean follow-up of 23 months (range, 4.5–44 months).

Tension-free vaginal mesh (TVM) techniques with procedural kits

The TVM techniques with procedural kits, which include disposable insertion needles, retrieval devices and pieces of polypropylene mesh, are increasingly being adopted, e.g. anterior, posterior and total Prolift (Gynecare, Ethicon, Somerville, NJ, USA), Apogee and Perigee (American Medical Systems, Minnetonka, MN, USA), and Nazca (Promedon, Cordoba, Argentina). These TVM techniques with procedure kits were designed to offer a simple and efficient surgical technique, reduce the surgery time, shorten the learning curve, transfer the anchoring arms simply and precisely, and simplify the tension-free system. Also, the use of monofilament macroporous polypropylene mesh improves tissue integration, promotes tissue ingrowth, and minimizes erosion and exposition risk. Therefore, they potentially offer a minimally invasive approach by the ergonomically designed handle system. Based on a retrospective multicentric study, the perioperative and immediate postoperative results demonstrated a failure rate (recurrent prolapse even asymptomatic or low grade symptomatic prolapse) of 4.7% (5/110) [29]. The authors concluded that the Prolift repair seems to be a safe technique to correct POP. However, anatomic and functional results of a long-term follow-up study has not confirmed the effectiveness or safety of the procedure [29].

In summary, the synthetic prostheses for sacrocolpopexy are well established yet remain controversial for repairing isolated anterior and posterior compartment defects. No long-term studies with sufficient patient numbers have been conducted to conclude whether synthetic or biological prostheses are superior for use in vaginal surgery.

Complications of Use of Prostheses in Pelvic Reconstructive Surgery

Mesh erosion remains a major concern in the use of prostheses in pelvic reconstructive surgery. In the study by Nygaard et al [17], the complications attributable to erosion occurred in 3% of patients in 20 studies of

abdominal sacrocolpopexy. The posterior placement of prosthesis to the perineal body using a combined abdominal and vaginal approach was associated with a high sepsis and erosion rate (40%) [30].

Based on a retrospective study of 138 transvaginal repairs of cystocele using Gynemesh or Gynemesh Soft mesh, age was an independent predictive factor of vaginal erosion (age, > 70 years; odds ratio, 3.6; $p = 0.010$). On the contrary, cystocele stage of more than 2 (Baden and Walker classification) was a protective factor against vaginal erosion (odds ratio, 0.3; $p = 0.016$) [26].

Mesh erosion differs in different types of prostheses

Erosion rates vary according to the different types of prostheses. Early experience with type II and type III synthetic prostheses for pelvic reconstructive surgery was associated with a significantly high postoperative mesh erosion rate of 20–30% after Dacron or Gore-Tex use [15,31]. The woven, multifilament nature of these mesh materials might cause limited host tissue ingrowths, leading to erosions, draining sinuses and fistulae. More recently, some concern has arisen about a relatively high erosion rate (17%) seen with the intravaginal slingplasty (United States Surgical, Tyco Healthcare, Norwalk, CT, USA) sling material [32]. The erosion rate decreased to 0.5–5% by using type I synthetic prosthesis [29]. The erosion rate of the currently available synthetic prosthesis has been reported to be 0.5% for polypropylene, 3.1% for polyethylene terephthalate (Mersilene; Ethicon, Somerville, NJ, USA), 3.4% for Gore-Tex (Gore, Flagstaff, AZ, USA), 5.0% for polyethylene (Marlex; Bard, Billerica, MA, USA), and 5.6% for Teflon (DuPont, Wilmington, DE, USA) [17].

Mesh erosion differs in different approaches

Erosion rates also vary according to the different types of approaches. Visco et al [30] retrospectively analyzed Mersilene mesh erosion rates in 273 women who had undergone sacrocolpopexy or sacral colpoperineopexy; the overall risk of erosion was 3.2% for abdominal sacrocolpopexy (median time to erosion, 15.6 months) and 4.5% for abdominal sacral colpoperineopexy (median time to erosion, 12.4 months), by introducing the prostheses and sutures abdominally. Erosion rate increased to 16% when sutures were placed vaginally and attached to an abdominally introduced mesh during sacral colpoperineopexy (median time to erosion, 9.0 months). When the mesh was introduced vaginally, the erosion rate peaked at 40% (median time to erosion, 4.1 months). The three most recent studies of polypropylene mesh augmenting the surgical correction of anterior vaginal prolapse reported an erosion rate of 8.3–13% [23–25]. Deffieux et al [26] recommended that vaginal mesh placement should be avoided for women with moderate cystocele, and those with total hysterectomy and vertical incision, if possible. Managing vaginal erosion is simple and associated with a low rate of morbidity. However, patients should be informed of the risk of postoperative mesh erosion.

TVM techniques with procedural kits

Analyzing the first 100 TVM procedures with procedural kits revealed a 17.5% erosion rate, which fell to 2.7% when T-shaped colpotomies, concomitant hysterectomy and perineal incisions were avoided [33]. In a retrospective multicentric study of 110 patients, perioperative and immediate postoperative results showed mesh exposure in five cases (4.7%), two of which required surgical management [29]. Granuloma without exposure was found in three cases (2.8%) [29].

The choice for better prosthetic materials

The choices for better materials are of prime importance. Synthetic prostheses types II and III have resulted in unacceptably high rates of postoperative erosion and should be abandoned. One of the potential advantages of absorbable or biological prostheses is the low erosion rate. If erosion occurs, conservative management should be used and surgery is seldom required [9]. Although the reports in the literature are difficult to interpret because of the diversity of studies and other factors, synthetic grafts generally may have slightly higher success rates but higher erosion rates, whereas biological materials appear to be better tolerated with lower erosion rates [9]. Current evidence suggests that the use of monofilament, macroporous polypropylene has the lowest incidence of infection and erosion when compared among the nonabsorbable meshes [4].

Unanswered Questions and Discussion

The evolution of newly developed prostheses offers a new era in pelvic reconstructive surgery. However, some unanswered questions remain: (1) Should prostheses be considered for primary repairs, secondary repairs or solely in patients with risk factors for recurrence (diabetics, obesity, steroid use, chronic respiratory disease)? (2) No ideal prostheses with the various characteristics are available now. Which prosthesis is optimal: synthetic nonabsorbable, synthetic absorbable, mixed synthetic or biological prostheses? (3) Do the benefits of prostheses for pelvic reconstructive surgery outweigh their risk of complications? Therefore, further well-designed randomized control trials as well as basic studies are needed to answer these questions.

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