Synthetic Biomaterials for Pelvic Floor Reconstruction

*Matthew E. Karlovsky, MD, Leslie Kushner, PhD, and Gopal H. Badlani, MD**

Address
*Department of Urology, Long Island Jewish Medical Center, 270-05 76 Avenue, New Hyde Park, NY 11040, USA.
E-mail: gbadlani@lij.edu

Current Urology Reports 2005, **6:**376–384
Current Science Inc. ISSN 1527-2737

Pelvic organ prolapse and stress urinary incontinence increase with age. The increasing proportion of the aging female population is likely to result in a demand for care of pelvic floor prolapse and incontinence. Experimental evidence of altered connective tissue metabolism may predispose to pelvic floor dysfunction, supporting the use of biomaterials, such as synthetic mesh, to correct pelvic fascial defects. Re-establishing pelvic support and continence calls for a biomaterial to be inert, flexible, and durable and to simultaneously minimize infection and erosion risk. Mesh as a biomaterial has evolved considerably throughout the past half century to the current line that combines ease of use, achieves good outcomes, and minimizes risk. This article explores the biochemical basis for pelvic floor attenuation and reviews various pelvic reconstructive mesh materials, their successes, failures, complications, and management.

Introduction

A biomaterial is any natural or synthetic substance that incorporates or integrates into a patient's tissues during a given treatment [1•]. The purpose of a biomaterial is to perform, supplement, or replace a natural function that is attenuated or lost. The ideal biomaterial has not been established, but the goal is to provide one that is inert, sterile, non-carcinogenic, mechanically durable, causes no inflammatory or immune reaction, must withstand modification by body tissue, inexpensive, convenient, and easy to use. None of the biomaterials available today meet all of these criteria, but many come close. Corrective procedures have incorporated off-the-shelf biomaterials to provide support and minimize morbidity of the procedure. Current biomaterials in use include synthetic and biologic, either derived from the patient's own tissue or from allograft or xenograft donor tissue. There are a multitude of established applications for biomaterials in urology, both removable and implantable, including stents, catheters, and implantable prosthetics. They also have been used recently for female pelvic floor reconstruction and correction of stress urinary incontinence. This article focuses exclusively on synthetic biomaterials in pelvic floor reconstruction and stress urinary incontinence.

Epidemiology

Pelvic organ prolapse (POP), with or without stress urinary incontinence (SUI), is a major health care problem. The lifetime risk for an American woman to undergo a single operation for POP or SUI is 11.1% [2•]. Nearly 200,000 women undergo prolapse surgery in the United States every year [3]. Forty-two percent of women undergoing surgical repair of SUI have simultaneous repairs of pelvic prolapse [3]. Classic repairs rely on weakened tissues damaged from childbirth or have abnormal collagen. Biomaterials are stronger than in situ tissue, can replace that tissue or act as scaffolding for new tissue regeneration, and constitute a modern approach to pelvic reconstructive surgery. These materials can be applied to the correction of uterine/vault prolapse, cystocele, enterocele, rectocele, and SUI.

Biochemical Basis for Pelvic Support Loss

Continence and pelvic organ support rely on the integrity of the muscles and the connective tissue of the pelvic floor. Connective tissue fibroblasts produce primarily collagen types 1 and 3, which are responsible for tensile strength and flexibility. Cross-linking between proline and hydroxyproline amino acids within collagen stabilize the fibers. Elastin, which is in the connective tissue, facilitates compliance and stretching. Alterations in the metabolism of collagen and elastin have been suggested as an underlying etiology of SUI. Collagen degradation is effected by the class of proteases termed matrix metalloproteinases that are regulated by tissue inhibitors of metalloproteinases (TIMP). Recent research indicates that incontinent women have higher matrix metalloproteinases and lower TIMP expression in their periurethral vaginal wall tissue than continent women [4]. Women with SUI have lower collagen content in their endopelvic fascia and skin compared with women without SUI or POP [5].

These reports suggest that alterations in the connective tissue composition of the pelvic floor may lead to hypermobility and pelvic prolapse. Because changes in collagen content are not limited to the endopelvic fascia in women

Table 1. Commonly used synthetic biomaterials

Material	Manufacturer	Structure	Mesh type	Pore size
Marlex	C.R. Bard, Branston, RI	Monofilament	I	> 75 microns [13]
Prolene	Ethicon, Somerville, NJ	Monofilament	I	> 75 microns [13]
Atrium	Atrium Medical, Hudson, NH	Monofilament	I	> 75 microns [13]
Tension-free vaginal tape	Johnson & Johnson, New Brunswick, NJ	Monofilament	I	> 75 microns [59]
SPARC	American Medical Systems, Minnetonka, MN	Monofilament	I	> 75 microns [59]
Gore-Tex	W.L. Gore, Flagstaff, AZ	Multifilament	II	< 10 microns [13]
Teflon	C.R. Bard, Haverhill, RI	Multifilament	III	< 10 microns [13]
Mersilene	Ethicon, Somerville, NJ	Multifilament	III	< 10 microns [13]
ProteGen	Boston Scientific, Natick, MA	Multifilament	III	< 10 microns [13]
Intemesh	American Medical Systems, Minnetonka, MN	Multifilament	IV	< 1 micron [13]
Dexon	Davis & Geck, Danbury, CT	Multifilament, absorbable		
Vicryl	Ethicon, Somerville, NJ	Multifilament, absorbable		

with SUI, biochemical processes responsible for altering endopelvic fascia connective tissue may be a part of a systemic defect in connective tissue processing. Selecting a suitable biomaterial for prolapse or incontinence surgery should take these biochemical processes into consideration. As a result of connective tissue degradation, which is part of a disease process, the long-term integrity of natural biomaterials for repair may be compromised. Autologous rectus fascia has remained the gold standard for fascial slings since its reintroduction as a treatment for SUI, with reported cure rates of 82% to 83% at 3.5 to 7 years [6]. However, in women with SUI or POP, implanted autologous tissue may lose durability in the long term if collagen degradation is systemic. Furthermore, adequate harvesting of autologous fascia for prolapse repair often is not practical and can compromise the abdominal wall. In such cases, the use of synthetic mesh may be more reliable.

Absorbable Mesh

The concept of an absorbable mesh is very attractive, especially when considering the most dreaded complications of erosion/rejection and infection. Absorbable mesh promotes fibroblast activity and resorption and therefore cannot undergo tissue rejection. The most commonly used types are Vicryl (polyglactic acid) and Dexon (polyglycolic acid), which take 30 and 90 days, respectively, to be completely absorbed by the host, resulting in poor mechanical strength. They do not promote infection and are not harmful to adjacent viscera if in contact. However, multiple studies have shown poor scar formation with poor tensile quality, despite deposition of new collagen [7–9]. A recent randomized study by Sand *et al.* [10] yielded dismal results, with a 25% recurrent cystocele rate with absorbable mesh after 1 year, while the women repaired with traditional anterior repair recurred 43% at 1 year. Another similar randomized study [11] found no difference in using absorbable mesh at 2 years. The study by Sand *et al.* [10] underscores the point that pelvic prolapse repair should not be performed unless a reliable biomaterial is used to reinforce weakened tissue, for which traditional repair is unreliable a priori.

Nonabsorbable Mesh

The anatomy of mesh

To minimize erosion and infection and maximize host tissue acceptance and incorporation, a synthetic mesh must be porous, flexible, and durable. Pore size and porosity allow the host tissue to invade and lay down a scaffold of new collagen. Adequate pore size (> 75–100 microns) permits access to fibroblasts, collagen, and immune cells to scavenge for bacteria [12]. Mesh has been classified into four types on the basis of pore size (Table 1). Type-1, or "macroporous," mesh is composed of polypropylene monofilament, with pore sizes greater than 75 microns. Type 2 or "microporous" mesh, with pore sizes smaller than 10 microns, allows passage only to histiocytes and, as a result, adhesion to the host tissue is unstable. Type-3 meshes are polyester multifilaments and are macroporous with microporous components, in which at least one of the three dimensions has a pore size too small to allow macrophages or polymorphonuclear cells (50 microns) to enter. Type-4 "microporous" mesh contains pore sizes smaller than 1 micron.

Filament type and structure are important to mesh function. Polypropylene is a monofilament, whereas the other meshes are multifilament. Multifilaments usually have interstices smaller than 10 microns, preventing access to key immune cells. As pore size increases, so does flexibility of the mesh. Although Prolene and Marlex are polypropylene, Prolene pore size is more than double (1500 vs 600 microns) [2•] that of Marlex and thus is more flexible,

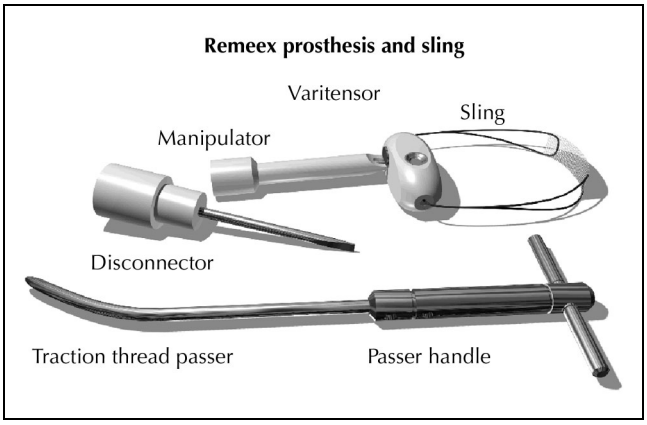

Figure 1. Remeex readjustable sling (Neomedic International, Barcelona, Spain).

contributing to a lower erosion rate. Knitted weave (Prolene) is flexible and has high tissue conformity and is superior to woven mesh (Dacron), which is strong and has good memory, but has poor tissue conformity and frays.

Mersilene and Marlex fell out of favor because of high erosion and fistula rates in the bowel [13]. Silastic is smoother and facilitates the formation of a fibrous sheath; however, it has a high rate of host rejection and sinus tract formation, contributing to its poor long-term results [14]. Dead space between the mesh and host tissue, which contributes to seroma formation, is minimized by large pore type-1 mesh. In addition, type-2 and type-3 mesh need to be removed if infected, whereas type-1 mesh infection can be managed with local drainage, "trimming," and secondary healing [15] if only vaginal erosion is present.

Stress Incontinence

In the past decade, synthetic slings have markedly increased in popularity, owing to the success of tension-free vaginal tape (TVT), a type-1 polypropylene mesh, for SUI. With TVT, mesh erosions in the vagina and urethra are rare, operating and recovery time are short, and tissue harvesting is avoided, all with cure rates equal to open Burch procedures and autologous fascial slings [16]. Erosion rates are between 0% and 2.4% at a mean follow-up of 3 years, with 0% infection [12], which is thought to be due to the plastic sheath covering the tape that is removed only after placement. Tamussino *et al.* [17] reported that in the Austrian database of 800 TVTs, there were no reports of intolerance or rejection. Most complications are procedural, including bladder perforation (3.8% to 11.6%) and hemorrhage (1.9% to 2.7%) [12].

Lo *et al.* [18] performed endovaginal ultrasonography 1 month, 1 year, and 3 years following TVT placement to assess for permanency of the sling. The tape maintained its midurethral location in 85.7%, showed a downward descent of only 1.7 mm, a significant increase in thickness and width over time, and a cure rate of 88.5% at 3 years.

Another midurethral sling, the SPARC (American Medical Systems, Minnetonka, MN), is conceptually similar to TVT and is placed retropubically, but in the antegrade direction. Equal efficacy to TVT has been demonstrated in short-term studies [19,20]. A 12-month European study of 104 patients treated with SPARC for SUI showed objective and subjective cures rate of 90% and 69%, respectively [21]. No vascular, bowel, or nerve injuries were observed, nor were erosions. Another study that included follow-up data on 96 patients who underwent a SPARC revealed a 72.5% dry rate at 24 months, which decreased from 81% at 12 months [22]. Women with a history of incontinence surgery experience a higher incidence of bladder injury than surgically naïve patients (36% vs 7.5%, respectively) [21].

Transobturator sling placement, using the same polypropylene midurethral sling, was introduced to minimize bladder injury during retropubic needle passage. This would be potentially advantageous for women with a history of incontinence surgeries or any intrabdominal surgery that obliterates the retropubic space. In general, curved needles are percutaneously passed through the obturator fossa so as to position the mesh sling under the midurethra. Without passage of the needle and mesh retropubically, the presumption is less resultant bladder injury. The more horizontal line of the mesh tape is thought to recreate the natural position of the pubourethral ligament. Multiple short-term studies from Europe have established the efficacy of the transobturator approach with significantly shorter operating time than TVT (11.5 minutes vs 15.2 minutes, respectively) [23], with cure rates between 80% and 85% at 12 months [24,25] and a de novo urgency rate of 10%. However, early evidence exists that transobturator slings may be better suited for women with hypermobility-predominant SUI, not intrinsic sphincter deficiency. In a small study of 20 patients who underwent transobturator sling placement for SUI, the mean preoperative leak point pressure was 47.4 mL H_2O (range, 18–70 mL H_2O). Nine (45%) were cured, seven (35%) were improved, and four (20%) failed completely at a follow-up of 12 months [26]. One explanation for this finding may be the horizontal line of the mesh sling, as opposed to the vertical positioning of the standard retropubic mesh slings, which may improve urethral coaptation with stress maneuvers.

Readjustable sling

The Remeex adjustable sling (Neomedic International, S.L., Barcelona, Spain) is a novel sling concept, the intention of which is to eliminate sling failures from recurrent SUI or obstruction and retention. It is not currently approved by the US Food and Drug Administration, but it has been available in Europe for the past several years (Fig. 1). A 3.5- by 1.5-cm strip of polypropylene mesh is anchored at each end by two #1 polypropylene monofilament sutures used for adjustment. A short midline suprapubic incision is made down the rectus fascia and the monofilament suture is brought up retropubically with a

trochar. The sutures are placed within a "varitensor" or a tightening device, which is shaped like a small cube and is attached to a narrow screwdriver-like device known as the manipulator. The day after surgery, the patient's catheter is filled with 300 mL of water and then removed and the patient is asked to cough. If it is too loose or too tight, the manipulator, which protrudes from the skin, is twisted to achieve continence while avoiding obstruction or retention. Once satisfied, the manipulator is removed.

A study of 101 women with a mean follow-up of 27.4 months revealed a dry rate of 97%; long-term adjustment was required in nine patients to achieve success [27]. The failures included two patients with mixed urge incontinence and two with de novo urge incontinence. Five patients required cube removal; however, they were the first patients who were not administered perioperative antibiotics. In a study of 60 patients with SUI treated with Remeex, 40 did not initially require any immediate postoperative adjustment [28]. Of the 13 who needed postoperative adjustment, six required tightening and seven required loosening. The other seven patients required remote adjustments, including one at 1 year and one at 3 years. Readjustment was performed using local anesthesia, a small incision to find the cube, and then tightening with the manipulator. In this series, 87% of the patients who had previous incontinence surgeries required a mid- to long-term adjustment, while only 14% of the surgery-naïve patients required adjustment. This may indicate use in patients with intrinsic sphincter deficiency or pipe-stem urethras, or even theoretically in any women in whom SUI recurs over time with age.

Pelvic Organ Prolapse

Transvaginal repair

Only recently has mesh been used for correcting defects of the pelvic floor through the vaginal approach. Mesh is readily obtainable and can be cut down to the appropriate defect size. It was used initially in 1996 by Julian [29], who prospectively compared transvaginal anterior repair alone with the same repair using the Marlex reinforcement. Despite 100% objective success rate at the 24-month follow-up in the mesh group versus 66% in the traditional repair group, the mesh group experienced a 25% erosion rate. Other studies report excellent short-term success with anterior repair using mesh. Flood *et al.* [30] reported on 142 women with no recurrent cystoceles or erosions at 36 months, while Natale *et al.* [31] found a 2.2% recurrent cystocele rate among 138 patients at the 18-month follow-up using a sutureless mesh patch.

A review by Debodinance *et al.* [32] of 287 patients with mesh repair for prolapse or incontinence with patches of various sizes or slings fashioned from Dacron or Gore-Tex revealed an overall "rejection" (erosion) rate of 19.3% and 30.3%, respectively, at 30 months. An explanted Dacron specimen was colonized by giant cells, histiocytes, and lymphoblastocytes and was culture-positive for *Morganella* and *Escherichia coli*. Notably absent were fibroblast colonization and collagen deposition. Bent *et al.* [33] found that all specimens of rejected polytetrafluoroethylene from erosion had inconsistent fibroplasia, with cultures of gram-positive bacteria, and speculated that thin or poorly vascularized vaginal flaps also may affect healing. Dwyer and O'Reilly [34] retrospectively reviewed 97 women with a mean follow-up of 29 months with Atrium (Hudson, NH) polypropylene mesh (pore size, 800 microns) for transvaginal anterior and posterior repair. Six percent of the cystocele repairs had a grade-2 asymptomatic recurrence and 5% required new repair for de novo prolapse. Erosion occurred in nine women. Three erosions healed conservatively with estrogen cream, five after excision of exposed mesh, and one required closure of a rectovaginal fistula with a Martius flap. Most surgical recurrences in either series occurred within the first 6 months.

deTayrac *et al.* [35] reported on 48 women who underwent tension-free cystocele repair with polypropylene mesh and found approximately an 87% success rate at a mean of 20 months. All of the recurrences were stage-2 and asymptomatic; however, 8.3% had erosions wherein excess mesh was excised, which allowed for secondary healing.

Birch and Fynes [36] stated that for posterior compartment repairs, there is less evidence for the role of prosthetic reinforcement. Proximity to the rectum and potential coital problems buoy the concerns for erosion. Case reports of rectal erosions following gynecologic surgery exist [37]; however, formal management recommendations in the literature are lacking, perhaps because of under-reporting.

Transabdominal repair

Mesh repair of vault prolapse by abdominal sacral colpopexy (SC) appears to be a successful operation, with cure rates between 85% and 99% [38•]. Traditional fixation of the vault is to the anterior longitudinal sacral ligaments by a Y-shaped mesh, in which the Y-arms are sutured anteriorly and posteriorly to the vaginal cuff. In a series by Culligan *et al.* [38•] of 245 patients who underwent SC with mesh repair, 15% had objective failure, 80% of which failed within the first year. Graft erosion occurred in 2.4%, with a significant higher proportion occurring in those who had simultaneous hysterectomy. In a comprehensive review by Nygaard *et al.* [39] that supports the effectiveness of mesh SC for treating genital prolapse, the overall erosion rate for 2178 women was 3.4%, of whom only 3% underwent reoperation for erosion. Overall, erosion rates were 0% for autologous or cadaveric fascia, 0.5% for Prolene, 3.1% for Mersilene, 3.4% fore Gore-Tex, 5.5% for Teflon, and 5.0% for Marlex. The authors recommended that decreased mesh erosion (at the vaginal cuff) can be fostered by improved vaginal health with estrogen creams, using perioperative antibiotics, multiple small gauge sutures through the full

Table 2. Commercial kits available for stress urinary incontinence or pelvic organ prolapse

Transobturator sling kits for stress urinary incontinence	Manufacturer
Obtape (TOT)	Mentor Corp., Santa Barbara, CA
Uratape	Mentor Corp., Santa Barbara, CA
TVT-O	Gynecare, Somerville, NJ
Monarc	American Medical Systems, Minnetonka, MN
Pelvic floor kits for prolapse repair	
Perigee	American Medical Systems, Minnetonka, MN
Apogee	American Medical Systems, Minnetonka, MN
Prolift	Gynecare, Somerville, NJ
Posterior intravaginal slingplasty	Tyco Healthcare, Norwalk, CT

thickness of the vaginal wall, and through extra-peritonealizing the suspension strap.

Prolapse "Kits"

Several commercially available "all-inclusive" kits (Table 2) that include trochar needles or mesh passers with predesigned polypropylene mesh patches are intended as minimally invasive alternatives for anterior and posterior compartment and vault prolapse repair. The Perigee system (American Medical Systems, Minnetonka, MN) is placed through the transobturator method using two different helical needle passers to pull four mesh arms out to the skin, which then position the central mesh patch for correction of anterior compartment defects. Standard vaginal dissection and identification of landmarks are necessary to finger-guide the needle tips as they emerge from the obturator and levator muscles. The Apogee system (American Medical Systems, Minnetonka, MN) is intended to correct vault prolapse. Posterior vaginal dissection is performed and a curved needle passer is placed percutaneously perianally, guided up through the ischiorectal fossa, emerging distal to the ischial spine. The needles pull the mesh arm straps out to the skin so as to position the central mesh patch in place, which is then sutured to the apex. A small pilot study of only 11 patents with large cystoceles underwent Perigree repair [40], with no recurrences at 6 months and no visceral perforations; however, there were two erosions.

A total pelvic mesh repair kit, Prolift (Gynecare, Somerville, NJ; Fig. 2), is intended to address all of the site-specific pelvic floor defects. The curved needle guides are placed into a cannula and then passed percutaneously through the transobturator and perianal routes. Once in position, the needle guides are removed and a snare is slipped through the cannula to retrieve the mesh arms that are then pulled out to the skin. No clinical studies exist on Apogee or Prolift.

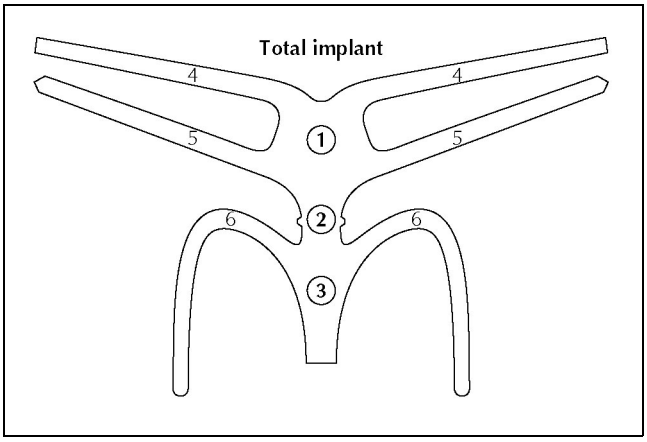

Figure 2. Prolift Total Pelvic Floor Repair System (Gynecare, Somerville, NJ).

Complications

Erosion/infection

Despite the worldwide success of TVT, with more than 600,000 cases performed [41], the literature is replete with examples of erosions from a variety of synthetic sling materials. Most notably, ProteGen (Boston Scientific, Natick, MA), a woven polyester with pressure-injected bovine collagen, was recalled in 1999 for a high erosion rate. Kobashi *et al.* [42] reported on 34 such cases and reviewed the mechanisms of failure. A delayed infection of the sling may lead to vaginal incision separation and discharge, declaring the presence of vaginal erosion. Urethral erosion most likely is caused by undue tension or an unrecognized urethral injury, often presenting as recurrent incontinence. The average time to presentation in their series was 8 months.

Comiter and Colgrove [41] reported on their use of a silicone coated polyester mesh, Intemesh (American Medical Systems, Minnetonka, MN), for sling repair of SUI. Two of their 10 patients had erosions within the first year of follow-up. Reasons for erosions included small pore size, excessive fiber weave, and graft stiffness. A braided polyester suture was used that may have led to bacterial colonization and infection. Silicone coating is smooth, masking exposure of the mesh to host tissues, decreasing tissue ingrowth. Both women with erosions who had their slings removed remained continent at 1 year, owing to the fibrous sheath that forms around silicone.

In a series of 14 sling erosions (urethral, vesicle, vaginal) reported by Clemens *et al.* [43••], 10 were ProteGen, two were autologous fascia, one was cadaveric fascia, and one was Gore-Tex (MycroMesh Plus, W. L. Gore & Associates, Flagstaff, AZ). Urethral erosions commonly resulted in recurrent SUI; however, only one third with isolated vaginal erosions developed persistent SUI. For isolated, small vaginal erosions with polypropylene mesh only, Kobashi and Govier [15] suggest conservative management to allow for delayed epithelialization. They reported on four patients from a series of 90 who underwent TVT or SPARC

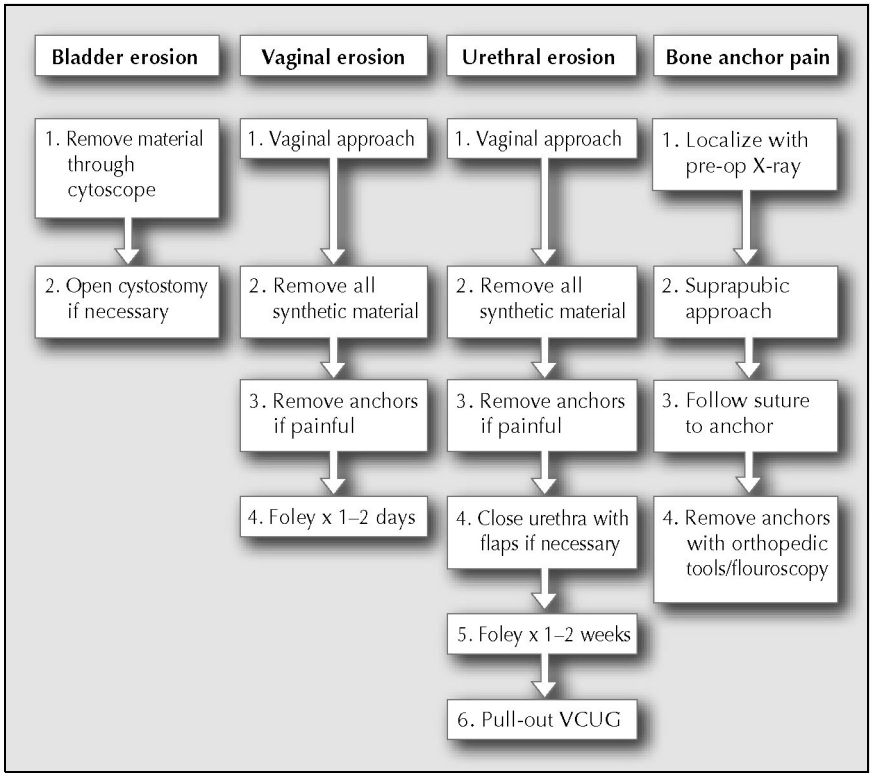

Figure 3. Treatment algorithm for mesh erosion. VCUG—voiding cystourethrogram. *Data adapted from* Clemens *et al.* [43••].

and had vaginal erosions measuring approximately 1 cm. None were excised or treated with local creams. After 6 weeks of sexual abstinence, the slings were completely covered, although they cautioned that defects that do not cover over after 3 months should be considered for removal. In addition, infection and erosion of a modified Gore-Tex mesh sling impregnated with silver carbonate and chlorhexidine diacetate, two well-recognized anti-bacterial agents, have been reported [44]. Gore-Tex is a known inhibitor of fibroblast growth

Vaginal or urethral erosion usually present with persistent pain and tenderness at the vaginal incision, irritative voiding symptoms, recurrent urinary tract infections, dyspareunia, vaginal bleeding, or persistent SUI. A high index of suspicion always should be maintained during every follow-up visit. All mesh adheres to hollow viscous serosa and concern for erosion and migration into hollow organs with no serosal covering, such as bladder, rectum, or denuded bowel, must always be maintained.

Initial management of suspected mesh erosion is simplified in a treatment algorithm in Figure 3. Exposed vaginal mesh or granulation tissue typically presents with pain and discharge, with or without the presence of infection. If uncomplicated by infection, then simple local excision of polypropylene mesh and vaginal wall closure is all that is usually needed. Alternatively, healing by secondary intention with or without estrogen cream can be attempted. Prolonged exposure without healing should prompt surgical closure. All non-polypropylene mesh material should be excised as completely as possible when initially presenting with erosion or infection. Regardless of mesh composition, the presence of urethral and bladder erosion must always be ruled out and, if present, repaired accordingly. Use of a Martius flap is suggested during urethral repair, with or without an autologous fascial sling.

Risk factors for bladder erosion include unrecognized bladder entry or perforation during the procedure or suburothelial placement of the mesh sling that later erodes. Risk factors for urethral erosion are unrecognized intraoperative urethral injury and "over-tensioning" the mesh with resultant prolonged retention. Possible contributing factors to vaginal erosion include buttonholing the vaginal flap with the needle passer, creating very thin flaps, the type of incision used (inverted U-shaped vs single midline), and sling placement by low-volume users.

Voiding dysfunction/obstruction

Persistent voiding dysfunction following mesh slings such as TVT is uncommon, but can include frank urinary retention, obstructive or irritative voiding symptoms, and urge incontinence. Those that are refractory to medical management become evident within weeks to months after surgery. Poor emptying or new-onset detrusor overactivity can be documented on urodynamics and compared with the preoperative study. In one study [45], most of the patients presenting for urethrolysis had irritative complaints (75%), more than half had obstructive complaints (61%), and only 24% had retention. Nitti and Raz [46] proposed that a sustained contraction of any magnitude with reduced flow with fluoroscopic evidence of bladder neck/urethral obstruction constituted outlet obstruction in women. Delayed urethrolysis theoretically can result in

refractory voiding dysfunction; however, most usually are performed between 4 weeks and 3 months after surgery [47]. Treatment typically consists of simple tape transection at the midurethra through a small vaginal incision. Among 1175 women who underwent TVT for SUI, 23 (1.9%) had persistent voiding dysfunction refractory to conservative treatment [48]. Median time to TVT transection was 8.6 weeks. All of the patients with incomplete emptying resolved, while irritative symptoms were resolved or improved in 30% and 70%, respectively. At 6 weeks, 61% and 26% were continent or improved over baseline, while 13% had recurrent SUI. A repeat procedure for SUI is not advised at the time of mesh transection because usually 50% to two thirds remain continent.

Dyspareunia

Postoperative dyspareunia unrelated to erosion can result from decreased vaginal caliber or length, scarring, or levator spasm. Dyspareunia is known to occur after standard posterior colporrhaphy in 15% to 25% [49]. Does the presence of mesh beneath the vaginal epithelium (whether for SUI or POP repair) impact postoperative sexual dysfunction, contribute to painful intercourse, or increase erosion risk? Few reports in the literature have addressed these matters. Post-TVT dyspareunia is reported to occur in 1% to 14.5% of patients [50,51]. Most of the patients (72%) reported no change in sexual function, improvement in 3% [52], and loss of libido in 5.4% [51]. Erosion rates were not reported in these studies. With regard to dyspareunia after mesh pelvic floor repair, little reporting exists. Sixty-seven patients answered a questionnaire retrospectively assessing the effect of TVT or intravaginal slingplasty on their sexuality [53]. Among the 79% who were sexually active before the surgery, 50% of whom experienced incontinence during intercourse, 50% of the cured patients experienced a better sexual life after the operation. Only two (4%) reported loss of libido, attributing it to the procedure. A study of 63 women who underwent prolene mesh repair of POP were evaluated for postoperative sexual function at a mean follow-up of 17 months [54]. The objective success rate was 94% for anterior and posterior repairs. Of the 32 women who underwent anterior repair, the sexual activity rate did not change, but dyspareunia increased by 20%; 13% had vaginal mesh erosion. Of 32 women who had posterior repair, sexual activity decreased in 12%, dyspareunia increased in 63%, and vaginal erosion occurred in 6.5%, with one woman requiring removal because of a pelvic abscess. Another study assessing short-term (6 months) outcomes following mesh for cystocele repair reported a 96% cure rate (grade 0 or 1) [55]. Of the 47% of patients who were sexually active before surgery, two (14%) complained of anterior dyspareunia, with an overall erosion rate of 7% (2/30). These concerning reports highlight the need for full pre- and postoperative sexual function assessment in addition to close follow-up. Time to resumption of postoperative sexual activity is not uniformly reported and may lead to early erosion. In addition, we think that raising thick vaginal epithelial flaps for better coverage can minimize mesh erosion. If erosion is going to occur, it usually presents within the first 12 postoperative months. Infrequent late erosions after abdominal SC have been reported beyond 1 year. In addition, we think that mesh repair of rectocele should be discouraged to avoid the uncommon complications of pelvic abscess or even diverting colostomy [56], which may lead to lifelong morbidity.

Our Experience

Our basis for choosing a polypropylene sling or mesh is that it is readily available, of consistent quality, low cost, and disease-free. In addition, polypropylene promotes tissue ingrowth and is non-degradable; therefore, its tensile strength does not decrease over time. Of 58 patients with SUI who were treated with polypropylene slings [57], the 49 available at the 5-year follow-up had a cure rate of 81%, with no infections or erosions. A retrospective analysis [58] of 29 of our patients who underwent transvaginal sacrospinous ligament fixation for prolapse repair with polypropylene mesh revealed that only two (6.8%) had prolapse recurrence with no erosions at the 2-year follow-up.

Conclusions

Although long-term outcomes of prospective, randomized trials for use of biomaterials for pelvic floor prolapse or SUI correction are needed, several short- and long-term studies demonstrate that polypropylene for pelvic floor reconstruction and SUI treatment is promising. Polypropylene mesh carries the clear advantage over previous synthetic mesh compositions with regard to infection and erosion, whereas antibacterial mesh may not necessarily confer resistance to infection. An imbalance in collagen degradation underscores the theoretical foundation for preferentially using mesh in pelvic floor repair for long-term durability. Polypropylene or absorbable monofilament suture should be used to minimize delayed infection. There is no clear consensus in the literature about which biomaterial is best suited for any given pelvic floor defect. Midurethral mesh slings have become a new standard of care for correction of uncomplicated SUI. Mesh repair for pelvic floor defects is feasible and efficacious, with mixed outcomes for dyspareunia. Thicker vaginal wall flaps and delayed resumption of sexual activity may minimize painful intercourse or erosion. When erosions or surgical failures occur, they do so most frequently within the first year of surgery. An attempt at initial conservative management of vaginal-only erosions is acceptable. Erosions usually are heralded by persistent pain, discharge, irritative voiding symptoms, or incontinence and clinicians must be vigilant in follow-up.

References and Recommended Reading

Papers of particular interest, published recently, have been highlighted as:

- • Of importance
- •• Of major importance

1.• Beiko D, Knudsen BE, Watterson JD, *et al.*: **Biomaterials in Urology.** *Curr Urol Rep* 2003, **4:**51–55.

An excellent review of general information that is pertinent to all biomaterials.

2.• Olsen AL, Smith VJ, Bergstrom JO, *et al.*: **Epidemiology of surgically managed pelvic organ prolapse and urinary incontinence.** *Obstet Gynecol* 1997, **89:**501–506.

Specific types of different synthetic materials are discussed in detail.

3. Boyles SH, Weber AM, Meyn L: **Procedures for pelvic organ prolapse in the United States, 1979–1997.** *Am J Obstet Gynecol* 2003, **188:**108–115.
4. Chen B, Wen Y, Wang H, *et al.*: **Differences in estrogen modulation of tissue inhibitor of matrix metalloproteinase-1 and matrix metalloproteinase-1 expression in cultured fibroblasts from continent and incontinent women.** *Am J Obstet Gynecol* 2003, **189:**59–65.
5. Chen Y, DeSautel M, Anderson A, *et al.*: **Collagen synthesis is not altered in women with stress urinary incontinence.** *Neurourol Urodyn* 2004, **23:**367–373.
6. Haab F, Zimmern P, Leach G: **Female stress urinary incontinence due to intrinsic sphincter deficiency: recognition and management.** *J Urol* 1996, **156:**3–17.
7. Lamb JP, Vitale T, Kamenski DL: **Comparative evaluation of synthetic meshes used for abdominal replacement.** *Surgery* 1983, **93:**643–648.
8. Tyrell J, Silberman H, Chandrasoma P, *et al.*: **Absorbable versus permanent mesh in abdominal operations.** *Surg Gynecol Obstet* 1989, **168:**277–233.
9. Brenner J: **Mesh materials in hernia repair.** In *Inguinal Hernia Repair: Expert Meeting on Hernia Surgery.* Edited by Schumpelick V, Wantz GE. Basel, Switzerland: Karger; 1995:172–179.
10. Sand PK, Koduri S, Lobel RW, *et al.*: **Prospective, randomized trial of polyglactin 910 mesh to prevent recurrences of cystoceles and rectoceles.** *Am J Obstet Gynecol* 2001, **184:**1357–1364.
11. Weber AM, Walters MD, Piedmonte MR, *et al.*: **Anterior colporrhaphy: a randomized trial of three surgical techniques.** *Am J Obstet Gynecol* 2001, **185:**1299–1306.
12. Boublil V, Ciofu C, Traxer O, *et al.*: **Complications of urethral sling procedures.** *Curr Opin Obstet Gynecol* 2002, **14:**515–520.
13. Cosson M, Debodinance P, Boukerrou M, *et al.*: **Mechanical properties of synthetic implants used in the repair of prolapse and urinary incontinence in women: Which is the ideal material?** *Int Urogynecol J* 2003, **14:**169–178.
14. Duckett JR, Constantine G: **Complications of silicone sling insertion for stress urinary incontinence.** *J Urol* 2000, **163:**1835–1837.
15. Kobashi KC, Govier FE: **Management of vaginal erosion of polypropylene slings.** *J Urol* 2003, **169:**2242–2243.
16. Walters MD: **The use and misuse of prosthetic materials in reconstructive pelvic surgery: Does the evidence support our surgical practice?** *Int Urogynecol J* 2003, **14:**365–366.
17. Tamussino K, Hanzal E, Kolle D, *et al.*: **The Austrian Tension-Free Vaginal Tape registry: an update.** *Int Urogynecol J* 2001, **12(suppl 3):**S22.
18. Lo TS, Horng SG, Liang CC, *et al.*: **Ultrasound assessment of mid-urethra tape at 3-year follow-up after tension-free vaginal tape procedure.** *Urology* 2004, **63:**671–675.
19. Dietz HP, Foote AJ, Mak HL, *et al.*: **TVT and Sparc suburethral slings: a case-control series.** *Int Urogynecol J Pelvic Floor Dysfunct* 2004, **15:**129–131.
20. Tseng LH, Wang AC, Lin YH, *et al.*: **Randomized comparison of the suprapubic arc sling procedure vs tension-free vaginal taping for stress incontinent women.** *Int Urogynecol J Pelvic Floor Dysfunct* 2005, **16:**230–235.
21. Deval B, Levardon M, Samain E, *et al.*: **A French multicenter clinical trial of SPARC for stress urinary incontinence.** *Eur Urol* 2003, **44:**254–258.
22. Primus G: **SPARC-sling system for the treatment of female urodynamic stress: a prospective study with two years follow up [Abstract #63].** *Abstract presented at the European Urological Association Annual Meeting.* Istanbul, Turkey: March 17–19, 2005.
23. Ryu KH, Shin JS, Du JK, *et al.*: **Randomized trial of tension-free vaginal tape (TVT) vs. tension-free vaginal tape obturator (TVT-O) in the surgical treatment of stress urinary incontinence: comparison of operation related morbidity [Abstract #50].** *Abstract presented at the European Urological Association Annual Meeting.* Istanbul, Turkey: March 17–19, 2005.
24. Waltregny D, Reul O, Keppenne V, *et al.*: **Inside-out transobturator vaginal tape (TVT-O): one year results of a prospective study [Abstract #53].** *Abstract presented at the European Urological Association Annual Meeting.* Istanbul, Turkey: March 17–19, 2005.
25. Roumeguere T, Quackels T, Bollens R, *et al.*: **Transobturator vaginal tape (TOT) for the treatment of female stress incontinence: one year follow up in 100 patients [Abstract #56].** *Abstract presented at the European Urological Association Annual Meeting.* Istanbul, Turkey: March 17–19, 2005.
26. Katz E, Khater U, Ghoniem G: **Is transobturator tape (TOT) effective in treatment of female stress urinary incontinence (SUI) with intrinsic sphincter deficiency (ISD) [Poster #13]?** *Presented at the Society of Urodynamics and Female Urology Winter Meeting.* Orlando: February 2005.
27. Cerezuela JF, Luelmo E, Medina N, *et al.*: **Readjustable sling: Remeex long term results [Abstract #709].** *Presented at the International Continence Society/International Urogynecologic Association Joint Meeting.* Paris: August 23–27, 2004.
28. Maroum B, Mattos I, Munoz F, *et al.*: **Analyze and review of the percentage of readjustment in the surgical treatment of stress urinary incontinence using a readjustable sling Remeex system [Abstract #685].** *Presented at the International Continence Society/International Urogynecologic Association Joint Meeting.* Paris: August 23–27, 2004.
29. Julian TM: **The efficacy of marlex mesh in the repair of severe recurrent vaginal prolapse of the anterior mid vaginal wall.** *Am J Obstet Gynecol* 1996, **175:**1472–1475.
30. Flood CG, Drutz HP, Waja L: **Anterior colporrhaphy reinforced with marlex mesh for the treatment of cystoceles.** *Int Urogynecol J* 1998, **9:**200–204.
31. Natale F, Marziali S, Cervigni M: **Tension-free cystocele repair (TRC): long-term follow-up.** *Proceedings of the 25th Annual Meeting of the International Urogynecological Association.* Rome: October 22–25, 2000.
32. Debodinance P, Cosson M, Burlet G: **Tolerance of synthetic tissues in touch with vaginal scare: review to the point of 287 cases.** *Euro J Obstet Gynecol Rep Biol* 1999, **87:**23–30.
33. Bent AE, Ostergard DR, Zwick-Zaffuto M: **Tissue reaction to expanded polytetrafluoroethylene suburethral sling for urinary incontinence: clinical and histologic study.** *Am J Obstet Gynecol* 1993, **169:**1198–1204.
34. Dwyer PL, O'Reilly BA: **Transvaginal repair of anterior and posterior compartment prolapse with Atrium polypropylene mesh.** *BJOG* 2004, **111:**831–836.
35. deTayrac R, Gervaise A, Chauveaud-Lambling A, *et al.*: **Combined genital prolapse repair reinforced with a polypropylene mesh and tension-free vaginal tape in women with genital prolapse and stress urinary incontinence: a retrospective case-control study with short-term follow-up.** *Acta Obstet Gynecol Scand* 2004, **83:**950–954.
36. Birch C, Fynes MM: **The role of synthetic and biological prostheses in reconstructive pelvic floor surgery.** *Curr Opin Obstet Gynecol* 2002, **14:**527–535.
37. Kenton KS, Woods MP, Brubaker L: **Uncomplicated erosion of polytetrafluoroethylene grafts into the rectum.** *Am J Obstet Gynecol* 2002, **187:**233–234.

38.• Culligan PJ, Murphy M, Blackwell L, *et al.*: **Long-term success of abdominal sacral colpopexy using synthetic mesh.** *Am J Obstet Gynecol* 2002, **187:**1473–1482.

Comprehensive review of a variety of mesh material for sacrocolpopexy.

39. Nygaard IE, McCreery R, Brubaker L, *et al.*: **Abdominal sacrocolpopexy: a comprehensive review.** *Obstet Gynecol* 2004, **104:**805–823.

40. Rane AM, Naidu AK, Barry CL, *et al.*: **Total anterior vaginal wall repair via a transobturator system: a pilot study [Abstract #5].** *Presented at the 31st Annual Meeting of the Society of Gynecologic Surgeons.* Rancho Mirage, CA: April 4–6, 2005.

41. Comiter CV, Colgrove PM: **High rate of vaginal extrusion of silicone-coated polyester sling.** *Urology* 2004, **63:**1066–1070.

42. Kobashi KC, Dmochowski R, Lee SL, *et al.*: **Erosion of woven polyester pubovaginal sling.** *J Urol* 1999, **162:**2070–2072.

43.•• Clemens JQ, DeLancy JO, Faerber GJ, *et al.*: **Urinary tract erosions after synthetic pubovaginal slings: diagnosis and management strategy.** *Urology* 2000, **56:**589–595.

Excellent management points.

44. Choe JC: **Vaginal erosion caused by antibacterial mesh sling.** *J Urol* 2002, **168:**1504.

45. Carr LK, Webster GD: **Voiding dysfunction following incontinence surgery: diagnosis and treatment with retropubic or vaginal urethrolysis.** *J Urol* 1997, **157:**821–823.

46. Nitti VW, Raz S: **Obstruction following anti-incontinence procedures: diagnosis and treatment with transvaginal urethrolysis.** *J Urol* 1994, **152:**93–98.

47. Leng WW, Chancellor MB: **Recognition and treatment of bladder outlet obstruction after sling surgery.** *Rev Urol* 2004, **6:**29–33.

48. Rardin CR, Rosenblatt PL, Kohli N, *et al.*: **Release of tension-free vaginal tape for the treatment of refractory postoperative voiding dysfunction.** *Obstet Gynecol* 2002, **100:**898–902.

49. Cundiff GW, Fenner D: **Evaluation and treatment of women with rectocele: focus on associated defecatory and sexual dysfunction.** *Obstet Gynecol* 2004, **104:**1403–1421.

50. Elzevier H, Lycklama A, Nijeholt G: **Sexual function after tension-free vaginal tape (TVT) for stress urinary incontinence: results of a mailed questionnaire [Abstract #732].** *Presented at the International Continence Society/International Urogynecologic Association Joint Meeting.* Paris: August 23–27, 2004.

51. Mazouni C, Karsenty G, Bretelle F, *et al.*: **Urinary complications and sexual function after the tension-free vaginal tape procedure.** *Acta Obstet Gynecol Scand* 2004, **83:**955–961.

52. Maaita M, Bhaumik J, Davies AE: **Sexual function after using tension-free vaginal tape for the surgical treatment of genuine stress incontinence.** *BJU Int* 2002, **90:**540–543.

53. Glavind K, Tetsche MS: **Sexual function in women before and after suburethral sling operation for stress urinary incontinence: a retrospective questionnaire study.** *Acta Obstet Gynecol Scand* 2004, **83:**965–968.

54. Milani R, Salvatore S, Soligo M, *et al.*: **Functional and anatomical outcome of anterior and posterior vaginal prolapse repair with prolene mesh.** *BJOG* 2005, **112:**107–111.

55. Yan A, Anne M, Karine A, *et al.*: **Cystocele repair by a synthetic vaginal mesh secured anteriorly through the obturator foramen.** *Eur J Obstet Gynecol Reprod Biol* 2004, **115:**90–94.

56. Goh TW, Dwyer PL: **Effectiveness and safety of polypropylene mesh in vaginal prolapse surgery.** *Int Urogynecol J* 2001, **12:**S90.

57. Shah DK, Paul EM, Amukele S, *et al.*: **Broad-based tension-free synthetic sling for stress urinary incontinence: 5-year outcome.** *J Urol* 2003, **170:**849–51.

58. Shah DK, Paul EM, Rastinehad AR, *et al.*: **Short-term outcome analysis of total reconstruction with mesh: the vaginal approach.** *J Urol* 2004, **171:**261–263.

59. Bukkapatnam R, Rodriguez LV: **Synthetic sling options for stress urinary incontinence.** *Curr Urol Rep* 2004, **5:**374–380.