

Meshes in Pelvic Floor Repair

**Findings from literature review and
conversations/interviews with surgeons**

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Meshes in Pelvic Floor Repair

Findings from literature review and conversations/interviews with surgeons

1. Summary and Conclusions

This report is based on findings from in-house data, from 62 publications on pelvic floor repair, including studies on the use of mesh implants, and from conversations and interviews with 23 surgeons from US, UK, Sweden, Finland, France, Italy, The Netherlands and Germany.

It appears that there is no internationally recognized gold standard procedure for treatment of pelvic floor defects. Abdominal, laparoscopic and vaginal approaches are all common, the latter being predominant and also the most attractive one for a mesh repair concept for its procedural simplicity.

Pelvic floor prolapse has different clinical manifestations:

- Anterior vaginal wall prolapse
- Posterior vaginal wall prolapse
- Prolapse of the vaginal vault
- Stress urinary incontinence

These clinical manifestations often appear combined and may then be treated in one operation, through multiple procedures. The National Center for Health Statistics, figures for 1987, report that nearly 400,000 operations are performed annually for pelvic organ prolapse and stress urinary incontinence (24457). About 90% of all pelvic floor prolapse repairs are repairs of the anterior vaginal wall prolapse.

1.1 Rationale of using mesh implant :

It was observed that even with extending the procedure from traditional anterior and posterior colporrhaphy to include additional procedures such as needle urethropexy, bilateral transvaginal paravaginal defects repairs, sacrospinous ligament fixation or prespinous repair, enterocele repair or prophylaxis, the recurrence rate still was 20% (20827). This clearly demonstrates that there is a clinical need for improvement of current techniques.

Using a mesh implant therefore targets at reducing the recurrence rate, but there are also additional aims, namely to (24589)

Create a tension-free repair
Minimize postoperative pain
Minimize difficulty in defecation (rectocele repair)
Avoid stenosis and dyspareunia

The rationale of colporrhaphy technique is to repair the defect by creating a thin scar which will then restore the original function of the tissue. To buttress the repair additionally mesh implants – non-absorbable, composite and absorbable - have been used for repair of prolapse stage III or IV for second or more recurrence, but are generally not recommended for primary repairs, because there is concern to use mesh implants in view of the observed mesh-related complications (22210):

- Erosions in abt. 10% (more when ePTFE was used)
- After sling procedures up to 35% removal rate (Gore-Tex)
- 10% sinus tract formation (Gore-Tex)
- Urethral erosion 4% (Marlex)
- Fistula (1.4%)
- Mesh removal 6%
- Overall revision and removal rate among 961 synthetic suburethral slings of 7,3% (22210).
- Overall revision and removal rate among 592 sacrocolpopexie of 2,7%.

Out of the 23 surgeons interviewed, 11 already had used meshes for pelvic floor repair , 8 of them for anterior vaginal wall (cystocele) repair, another 3 for colposacropexy or posterior vaginal wall repair, but not for cystocele repair. All of them had experience with Prolene Mesh or Gynemesh and 3 reported on the successful use of Vypro.

Another 9 surgeons stated that they had little experience with synthetic mesh implants and that they would use meshes for pelvic floor repair, provided a suitable mesh was available.

Only 3 surgeons could not see an added benefit to their technique by using mesh implants.

Those who had used Prolene mesh or Gynemesh mentioned the following advantages and disadvantages:

1.2 Experience with Prolene/Gynemesh

Advantages:

- Well tolerated, inert
- No late infection encountered
- Good tissue incorporation
- No need to explant mesh in case of exposure
- If mesh exposed, treatment by excision of exposed mesh area and re-suturing mucosa over it, has proven adequate and successful therapy.

Disadvantages:

- Too thick and bulky

Too stiff
Releases particles when cut
Erosion rate similar to other synthetic meshes (10% observed with Gynemesh by P. Hardiman , confidential unpublished data)

1.3 Conclusions

The repair concept using a mesh implant is plausible. However, considering the surgeons' concern with synthetic materials and also taking into account their conservative behaviour it may take some time until a wide adoption of a novel mesh can be achieved.

A mesh thinner than the current Prolene mesh and with some elasticity would be well accepted. Vypro would meet these requirements. A totally nonabsorbable mesh with similar mechanical properties as Vypro would also be well accepted.

1.3.1 Desirable mesh product features

Anterior and posterior vaginal wall repair:

- Multidirectionally stretchable to conform to bladder filling after surgery to reduce tension on the fixation sutures.
- Cuttable without releasing fibres after cutting
- No sharp edges after cutting
- Able to be sutured
- Relatively large pore size (similar to Vypro or Vypro II)
- Minimum amount of foreign body mass
- Minimum foreign body reaction
- Tissue incorporation with little retraction (ideally, the mesh would induce formation of neofascia and then absorb)
- Mechanical strength: The in vivo forces and exerted strains on pelvic floor repair during the postoperative period are not known. No studies on this subject were identified through literature search or interviews with experts. However, experimental and clinical data are available on Vypro mesh for incisional hernia repair. First confidential verbal reports of surgeons using Vypro for cystocele repair suggest that its mechanical characteristics comply with requirements of anterior and posterior vaginal wall reconstruction.
- Handling: easily conforming to implant area . Edges should be smooth. Mesh should not roll at the edges.

Vaginal vault prolapse:

For sacrospinous fixation or sacrocolpopexy a mesh with the similar characteristics, but with less flexibility, such as Soft Prolene Mesh , would be preferred. There may be a great variety of tissue

incorporation in the individual patients, so some surgeons are concerned that too much elasticity of the mesh could lead to recurrence of the prolapse. On the other hand, good long-term results with PDS sutures for this procedure have been reported.

1.3.2 Success factors of the ideal treatment in pelvic floor repair:

Less than 20% recurrence
Less than 10% erosions
Access allowing simultaneous or later correction of associated stress incontinence
Minimally invasive- reduced trauma
Simple to perform
Minimal dissection
Scarce resection of healthy tissue
Repositioning normal anatomy
Painfree postoperatively
Tension-free
No obstruction (no dyspareunia)
No overcorrection (could cause voiding problems or fecal obstruction)
Short operation time
Fast patient recovery
Ambulatory procedure

1.3.3 Multi-Generation Product Portfolio:

To address both, stress incontinence and cystocele, the tape (TVT) could theoretically be modified to include a broader central mesh area.

However, we must be cautious not to risk the excellent results we have with TVT as it is now, with very rare verbal reports on mesh erosion.

I would therefore recommend not to offer a combined product at this stage, but to launch a separate mesh product for prolapse repair (cystocele, rectocele, vaginal vault), as a second generation Gynemesh. The vaginal approach would allow to perform both, TVT and cystocele repair in one operation, however, with a different anesthesia protocol.

Next generation products:

- A product concept for combined incontinence and prolapse treatment using the vaginal approach.
- A totally absorbable implant that will restore the fascial connective tissue integrity, not just repair it.

2. Findings from the literature review

This review is based on 62 international publications. It includes results from a literature search on meshes in hernia repair carried out by Teltech for NBD (Dale Peterson, Project Matrix). That broad search revealed 95 publications out of which only 16 dealt with pelvic floor repair (cystocele, rectocele, vaginal vault prolapse).

Pelvic floor prolapse is the general term used to describe various clinical conditions associated with pelvic floor relaxation in female patients (24784). These conditions are considered most difficult to diagnose and treat (24191). Their clinical manifestations are:

- Stress urinary incontinence
- Anterior vaginal wall prolapse (medial and / or lateral cystocele)
- Posterior vaginal wall prolapse (rectocele)
- Vault prolapse (Enterocoele, uterine prolapse, vaginal vault prolapse)

In a high percentage, these clinical manifestations are combined. Therefore, combined approaches such as colposacropexy plus anterior and posterior colporrhaphy are common.

2.1 Epidemiology

National Center for Health Statistics, figures for 1987, report that nearly 400,000 operations are performed annually for pelvic organ prolapse and stress urinary incontinence (24457). Since there is no distinction between these clinical manifestations, it is not clear what percentage of the 400,000 refers to the cure of anterior or posterior vaginal wall prolapse. The estimated frequency of vaginal vault prolapse is 5% of all hysterectomies (= 60,000 cases worldwide).

Estimates suggest that 50% of parous women have some degree of genital prolapse, but that only 10-20% of the cases are significant enough to cause symptoms. (24625)

In a British region, the annual incidence of hospital admission with prolapse before 60 years of age was 2 % per 1000 person-years (24197 Ref. 2)

Samuelsson et al.(24197) who studied the prevalence of genital prolapse in a general population of Swedish women 20 to 59 years of age , with 487 women recruited for the study, found the highest prevalence (abt. 55 %) in the age group 50 to 59 years. 44% of parous women of the studied ages had some form of prolapse, but only 1.6% had a prolapse that reached the introitus when straining. No woman from this population had a prolapse which would correspond to stage III or IV of the terminology proposed by Bump et al (24314).

2.2 Classification

Pelvic floor prolapse is classified in the following stages (24314):

Stage

- | | |
|-----|---|
| 0 | No prolapse demonstrated |
| I | Most distal portion of the prolapse is more than 1 cm above the level of the hymen |
| II | Most distal portion of prolapse is less or equal to 1 cm proximal to or distal to the plane of the hymen |
| III | Most distal portion of the prolapse is more than 1 cm below the plane of the hymen but protrudes no further than 2 cm less than the total vaginal length in centimeters |
| IV | Complete eversion of the total length of the lower genital tract.
In most instances, the leading is the cervix or vaginal cuff scar |

2.3 Normal pelvic floor physiology:

The levator muscle plate is nearly horizontal

There is a double muscular layer in the area of most stress

When the abdominal pressure rises, the muscles of the pelvic floor contract to increase the closure pressure of the urethral and anal sphincters.

This supportive function of the muscles relieves the stress on the ligaments / connective tissue layers / fascial structures

In the normal strong and well supported pelvic floor, changes in intra-abdominal pressure are properly and equally transmitted to the intra-abdominal viscera, including urethra and bladder. Pelvic floor relaxation, however, will not allow proper transmission of intra-abdominal pressures to the bladder and urethra because of dampening effect of the convex, lax pelvic floor (24785).

2.4 Pathophysiology / etiology of pelvic prolapse

Prolapse occurs when the musculofascial support system of the pelvic organs becomes weakened or damaged. When the muscles are weakened, the stress on the ligamentous structures becomes more intense, thus leading to their over-extension and finally to their deterioration.

Due to the hydrostatic pressure when standing upright, the pressure is highest on the lowest pole = on the pelvic floor, but its surface is small and thus does not bear the whole pressure exerted by the section of the intestinal cylinder.

The essential forces that hold the intestinal cylinder and that relieve the pressure from the pelvic floor are the suction effect of the lungs and the tension of the abdominal wall muscles. Consequently, the pelvic floor faces most unfavourable conditions with a small thorax and atrophied abdominal wall muscles. With diastasis of the levator ani muscles and connective tissue that connects them to the lateral walls of the vagina (24802), the hiatus genitalis becomes the hernial orifice for the inner genitals.

Underlying causes of pelvic floor defects : (24191, 24732)

- intrinsic defects, mainly weakness of tissue collagen
- mechanical trauma / damage to the pelvic floor and its nerve supply during childbirth (above all, vaginal delivery of big children is considered a risk factor)
- Injury of nerval structures
- Hysterectomy
- Estrogen insufficiency (receptors expressed in the squamous epithelium of the proximal and distal urethra, vagina, trigone of the bladder, pubococcygeus muscles)
 - Cascade of events in oestrogen deficiency:
 - Reduced tissue vascularity
 - Decreased glycogen content of epithelial cells
 - Fall in lactobacilli content
 - Increase of pH
 - Other bacterial including coliforms grow
 - Irritation, discharge
 - Atrophy of vaginal epithelium
 - Presenting symptoms: Vaginal dryness, soreness, dyspareunia
- Influence of aging:
 - Connective tissue becomes more elastic .
 - Abdominal wall and pelvic floor muscles undergo atrophic changes
 - Less energy is required to produce irreversible damage .
- Chronic increases in intraabdominal pressure (obesity, chronic lung disease, occupational straining, constipation (24625)

The usual symptoms associated with genital prolapse are the following (24457)

Protrusion of tissue	>90
Pressure	>90
Impaired coitus	37
Voiding difficulty	33
Urinary incontinence	33
Walking difficulty	25
Difficulty in defecating	25
Pelvic pain	17

2.5 Anterior vaginal wall prolapse (cystocele)

Anterior vaginal wall prolapse is defined as pathologic descent of the anterior vaginal wall and overlying bladder base.

As Weber points out (G-28, p. 211) there has never been a systematic or comprehensive description of anterior vaginal prolapse based on physical findings and correlated with findings at surgery to provide objective evidence for any of the theories on pathologic anatomy. Improvements in diagnostics such as MRI may lead to a greater understanding of normal pelvic anatomy and the abnormalities associated with prolapse.

Asymptomatic patients with grade 1 or 2 cystoceles isolated do not usually require treatment. The surgical approach is perceived as necessary in grade III and IV cystocele (grading according to classification mentioned above). These large cystoceles may result from weakness of the levator hiatus with resulting laxity of the pubocervical fasciae and separation of the cardinal ligaments (24785). They are considered a significant clinical problem and difficult to manage (24787). About 1/3 of patients with large cystocele typically have masked concomitant urinary incontinence that can be detected by urodynamic evaluation and by inserting a vaginal pack or a temporary pessary device simulating the reduced cystocele. Of the other two thirds, abt 50% will most likely develop stress incontinence later on.

This is the reason why surgeons recommend to choose combinations of pubovaginal slings with anterior colporrhaphy as treatment of choice (24785, 24787).

2.5.1 Vaginal approach

The anterior colporrhaphy (including Kelly plication) using the vaginal approach is considered the standard for cystocele repair (24785) by many gynecologic surgeons.

Surgical technique : multiple interrupted absorbable sutures (e.g. Vicryl) from the vaginal cuff to approximately the level of the bladder neck (2 cms away from the bladder neck, if a pubovaginal sling is performed additionally (24191). The sutures should not be placed too far laterally, as this would place undue tension on the fascia, which is relatively fixed at the arcus tendineus and not too deeply since inadvertent intrusion into the bladder or obstruction of the ureters can occur .

The vaginal repair is also the approach of choice when there is a need to address both, anterior and posterior vaginal wall prolapse, additionally accompanied by incontinence. Surgery may then be performed by a combined bladder suspension technique, anterior and posterior colporrhaphy.

Few studies have addressed the long-term success of surgical treatment of anterior vaginal wall prolapse. No controlled studies have compared different procedures performed primarily for anterior vaginal wall prolapse (G-28, p.219). Long term results are also difficult to compare because of significant differences in technique, different definitions of failure and different indications for the procedure, many anterior colporrhaphy procedures being performed for urinary incontinence and not cystocele (24191, 24457).

According to Dr. Petri (personal communication, March 15, 2000), a recent survey carried out in Germany demonstrated that more than 60 % of the gynecologists still perform a hysterectomy combined with anterior and posterior colporrhaphy to treat stress urinary incontinence, though several authors have pointed out that this procedure should be abandoned as treatment of stress urinary incontinence, for unsatisfactory long-term results.

The anterior vaginal segment is considered the most common site for recurrent pelvic support defects, failure rates amounting to 20-40% (20827, 9087) are a disappointing result. Apart from recurrence, these are the complications of anterior vaginal wall repair reported: Erosion, draining sinuses, chronic areas of vaginal granulation tissue if permanent sutures or mesh materials are used, voiding difficulty. Also, repair of one vaginal compartment may predispose another compartment to the development of prolapse, e.g. anterior wall repair may cause rectocele to develop (24457).

Although the vaginal approach to cystocele is common, vaginal anterior colporrhaphy addressing only the medial defect may be insufficient if also lateral defects are present as this will lead to recurrence (24780). Some surgeons therefore claim the importance of correctly diagnosing the lateral defects suggesting to treat isolated paravaginal defects by transabdominal or laparoscopic repair (24780).

2.5.2 Abdominal / laparoscopic approach

Several abdominal colposuspension and bladder neck procedures have been described in cystoceles combined with stress incontinence (12735, 13095, 17045, 24398, 24399) using absorbable (chromic catgut) and non-absorbable sutures (Prolene, Nylon).

Advocates of the paravaginal repair, performed transvaginally, laparoscopically or abdominally (24780, 24781) claim that plication of the pubocervical fascia in the midline – as in anterior colporrhaphy combined with Kelly plication – actually increases the paravaginal defect by pulling the anterolateral vaginal sulcus event further from the arcus tendineus (white line). Paravaginal repair, on the other hand, is perceived as good for support of the urethra and lateral bladder wall. It may fail, however, because it does not correct the central herniation of the bladder. Another disadvantage is the laparotomy with its increased morbidity and longer hospital stay compared with the vaginal approach. It is also important to note that the Burch colposuspension is complicated by a high incidence of genital prolapse, rectocele and enterocele (15553).

For severe anterior vaginal wall prolapse (grade IV cystourethrocele), Raz et al (24785) and Cross et al. (24787) recommend a combination of bladder suspension and anterior colporrhaphy.

2.6 Posterior vaginal wall repair (rectocele)

Rectocele is characterized by an outpocketing of the anterior rectal and posterior vaginal wall into the lumen of the vagina (24458). It is frequently detected when patients undergo diagnostics for constipation. Other symptoms caused by a rectocele are: sensation of rectal pressure, incomplete rectal emptying, vaginal symptoms from the herniation into the vaginal wall such as sensation of a vaginal mass, dyspareunia, decreased sensation during intercourse (24784).

Posterior vaginal wall prolapse is most commonly repaired using a posterior colporrhaphy (24195) which is predominantly performed vaginally (24460, 22209, 22211).

Principle of vaginal technique: Excess vaginal skin is excised and the underlying connective tissue and levator muscles plicated before closure of the skin. There is, however, concern with the adverse effect of this procedure on sexual function because of the high vaginal stenosis rate and resulting dyspareunia (20%, 24458). This had led to the search for alternative methods of repair, such as mesh repair, laparoscopic approaches and rectal repair (24637, 24459, 24460, 24461), although there is debate on the latter, as the defect is considered a vaginal defect, not a rectal one (24637).

The literature search has revealed the following studies, on the use of meshes:

Vicryl mesh - laparoscopic approach (24637)
Polyglycolic acid mesh – vaginal approach (24746)
Marlex mesh – transperineal approach (20288)
Prolene mesh – vaginal approach (22211)

2.7 Vaginal vault prolapse

Vaginal vault prolapse is a complication of abdominal or vaginal hysterectomy or other pelvic surgery and occurs in up to 5% (18456, 24195, 24732). It is frequently combined with cystocele, rectocele, enterocele and urinary stress incontinence. (24180).

There are three main surgical techniques addressing this complication.

2.7.1 Vaginal approach

Vaginal sacrospinous fixation (sacrospinous ligament fixation) using various absorbable (Vicryl, Dexon, Maxon, PDS) or nonabsorbable (Prolene, Ethibond) sutures or mesh slings (Marlex, Prolene, Mersilene, Gore-tex) (12108, 1188, 8827, 15548, 24180, 1189, 22265, 12108, 18548, 20827). The advantage of sacrospinous fixation, compared to sacrocolpopexy, is its easy combination with other prolapse repair such as cystocele and particularly rectocele which is virtually impossible to repair using the abdominal approach. (24732)

2.7.2 Abdominal approach

The abdominal approach – sacrocolpopexy or sacropexy – is also common using the same suture materials as for sacrospinous fixation. Its major disadvantage is the increased morbidity associated with a laparotomy (24732).

Several authors have reported on their experience using various meshes or other grafts for abdominal sacrocolpopexy:

Mersilene mesh (157, 9644, 12470, 15269, 15548, 22210, 22263, 24099)
Teflon / Gore-tex strips (12426, 15548, 16160, 22144, 22210, 22491, 24099)
Prolene mesh (12873, 16505, 20017, 22211)
Marlex mesh (16160, 22210)
Vicryl polyester mesh (20414)
Vicryl mesh (18548)
Lyodura (5883, 22144) Complications with grafts presented as

Mesh rejection in 2 to 20% (24099, 15548, 22210)
Fistula in 1.6 to 4.5% (16160, 22210)
Mesh erosion in 5.1 to 11 % (22210)
Discharge in 8.7 (22210)
Infection in 2.4 to 7.7% (22210)

There have also been reports on laparoscopic sacrocolpopexy (16505, 18548, 20017, 22211).
The success rate of sacrocolpopexy is quoted at 68 to 100 % (24732).

There is evidence that sacrocolpopexy is associated with a slightly longer functional vaginal length as compared to sacrospinous fixation. (24732).

The vaginopexy (Williams-Richardson) is performed by suspending the vagina from the external oblique muscle using fascial strips (5883, 7279, 8827, 20773, 23703). This method is not as popular as the two others described earlier.

As vaginal vault prolapse is frequently combined with cystocele, rectocele, enterocele and urinary stress incontinence, additionally anterior and posterior colporrhaphy, urethropexy, hysterectomy are performed.

2.8 Experience with meshes in pelvic floor repair

Iglesia et al (22210) carried out an Ovid search of the English literature on the use of mesh in gynecologic surgery, together with a hand search of Index Medicus from 1950 to 1965. All studies on mesh identified consisted of retrospective case series (21x suburethral sling, 15 x sacrocolpopexy articles, 5 x pelvic sling). No randomized prospective trials were available.

Apart from using meshes as slings for procedures to treat stress incontinence, meshes have been used in pelvic floor repair , predominantly for abdominal sacrocolpopexy and vaginal sacrospinous fixation, to a lesser extent for rectocele and cystocele repair.

2.8.1 Nonabsorbable meshes

For cystocele combined with stress incontinence , Nicita (24802) has used a nonabsorbable mesh cut in a hammock shape. The mesh is fixed to the bladder neck, to the cervix and laterally to openings through pubic bone insertions of the arcus tendineus. Nicita mentions that the lateral edges of the mesh could also be fixed to the abdominal rectus muscles.

Julian (20827) compared the results of 12 patients treated with Marlex mesh to a group of 12 patients without mesh, both groups with two or more postsurgical recurrences of severe anterior vaginal wall prolapse. Apart from the mesh implant, both patient groups underwent the same combined procedure consisting of Pereyra urethropexy, anterior colporrhaphy, bilateral transvaginal and paravaginal defect repairs , sacrospinous ligament fixation or prespinous

fixation, enterocele and rectocele repair. At two years follow-up, there were four cases of recurrent prolapse of the anterior vaginal segment in the control group and none in the treatment group.

However, there were three long-term graft complications, all noted within 6 months of surgery, the most significant being a 0.5 cm opening below the graft that caused abnormal discharge. To prevent this type of erosion, the author modified his technique using the vaginal flaps created during dissection of the anterior segment to close one over the other.

The author concludes from his experience that mesh reinforcement is an effective treatment for severe recurrent prolapse of the anterior midvaginal wall, but should not be used as a primary repair.

Grody (20827, discussion) prefers a double-layered Mersilene mesh anchored with rapidly absorbable synthetic suture. He does not perform a urethropexy, but uses deep pubovesicocervical paracystourethral fibromuscular flaps in a sling-like fashion.

As a reinforcement of the anterior colporrhaphy, Flood et al (22910) routinely used a Marlex mesh, 4 cms long and 1 cm wide, placed under the vesicourethral junction and secured at the level of the bladder neck with four absorbable sutures in order to prevent migration of the mesh in the immediate postoperative period. During the follow-up time of 3.2 years (mean), no patient experienced recurrence. Only three patients (out of 142) experienced mesh erosion, which developed at 3 months, 4 years and 7 years, respectively. All were cured by simple trimming of the exposed mesh area. There were no infections observed, nor any case of erosion into the bladder or urethra. This complication rate is low, compared to mesh-related complications reported in the literature otherwise: (22210)

10% sinus tract formation (Gore-Tex)

Erosions (9% with Marlex, Mersilene, Gore-Tex, 11% with Teflon)

Urethral erosion 4% (Marlex)

Fistula 1.4%

Mesh removal rate 6%

Overall revision and removal rate among 961 synthetic suburethral slings was 7.3%

After sling procedures with Gore Tex up to 35% removal rate

Overall revision and removal rate among 592 sacrocolpopexy was 2.7%.

2.8.2 Composite meshes

Villet et al. (20414) used a Vicryl-Dacron composite mesh for treatment of vaginal prolapse for sacrospinous fixation in 32 patients with good results. No infectious complication was observed and the material was perfectly tolerated. Dubuisson and Chapron (23449) confirmed the good results with the composite mesh performing the sacrospinous fixation laparoscopically in 2 patients.

Migliari and Usai (23679) who used the same type of composite material in 15 patients with grade IV cystocele as an addition to the classic 4-corner bladder base and neck suspension

procedure , observed new onset enteroectocele in 2 patients after 6 months following surgery, as a procedure-related complication. There were no mesh-related complications.

2.8.3 Absorbable mesh

To treat cystocele grade IV , Albo et al. (24784) used Dexon-mesh to reduce the central defect of the cystocele in 58 patients of whom 92% had no recurrence during the follow-up (range 6-24 months. Lyons and Winer (18548) describe the use of Vicryl mesh for laparoscopic colposacropexy.

Other authors , however, are concerned to use absorbable mesh – such as Vicryl mesh or Dexon mesh - when extended support is desired (22210).

3. Pelvic Floor Repair – Surgeon's Feed-back on Mesh Concept

Feed-back was obtained through conversations and interviews with 23 surgeons from US, UK, Sweden, Finland, France, Italy, The Netherlands and Germany.

The following summarizes the individual interviews:

Surgeon 1 has the following annual procedures at his hospital:

270 abdominal colposuspension (Burch) for stress urinary incontinence treatment
80 TVT for stress incontinence in older patients (abt. 60 and older)
81 180 vaginal repairs (80 for cystocele, 100 for rectocele)
90 sacrocolpopexies for vaginal prolapse

Surgeon 1 thinks these numbers are high, for two main reasons: 1. His patients come from the rural areas and carry a high risk to develop vaginal prolapse because of obesity, multiple vaginal deliveries, heavy work, smoking habits, 2. He has patients from distant areas (even from Aachen), because he is renowned for pelvic floor surgery and because gynecologic surgeons with these special skills are rare in Germany.

He states that many of the patients who are referred to him for anterior or posterior vaginal wall prolapse, do not have any clinical symptoms. He usually operates only when the patient complains about symptoms, he does not do this operation for cosmetic reasons. But he states that there are many surgeons who do exactly that, they treat the bulge they see inspecting the vagina from inside, even though the patient had not uttered any complaint at all with that bulge. The anterior and posterior colporrhaphy may lead to narrowing of the vagina to such an extent that sexual intercourse causes considerable pain. So often it happens that the patient who was symptomless before the operation, suffers after treatment.

The sacrocolpopexy is carried out by him following a technique described by Richter. He uses a vaginal approach and Ethibond sutures. The failure rate is 1-2 cases out of the 90. There is a risk of mechanical bowel obstruction in that area.

Surgeon 1 would like to use mesh for this operation, ideally a combination of long-term absorbable and short-term-absorbable. He is confident that the adhesions formed will remain, once the mesh has totally been absorbed. The mesh must be cuttable without fraying.

He has used Vicryl Mesh, Gynemesh or Prolene Mesh for repair of extreme rectal prolapse. The current polypropylene meshes are considered too thick and too rigid, not only at the edges, but in general. One patient in whom he had used polypropylene mesh for rectocele repair, had experienced an erosion with infection. Therefore he does not use polypropylene mesh any longer for rectocele repair. He also had tried Mersilene Mesh, yet abandoned it also, because of infections.

He would never use mesh material for anterior vaginal wall repair, because he thinks this is a very delicate area, with the nearness of the bladder neck and a risk of the mesh eroding into the urethra, bladder neck or bladder.

His experiences with biological materials for rectocele repair, such as bovine pericardium, are disappointing, he stopped its use because of severe tissue reactions. He has used lyophilized dura or xenogenic fascia lata, but with both materials he has observed fast degradation resulting in recurrence.

Surgeon 1 emphasizes that the pelvic floor pathology is a challenging area for the surgeon. With his awareness of the need to improve surgical techniques in pelvic floor repair, he has been trying to improve his technique for the past 19 years and yet has not reached a stage of satisfaction with his results so far.

Surgeon 2: His preferred technique to treat cystocele, is the anterior vaginal colporrhaphy, with Vicryl Z-suture for reduction of cystocele, minimal tissue resection. The procedure can easily be combined with TVT, however requiring spinal anesthesia.

For rectocele he does a posterior colporrhaphy.

For vaginal prolapse repair he prefers the colposacropexy using Ethibond sutures. In recurrences he uses Prolene Mesh, he would prefer Soft Prolene Mesh in these cases.

He thinks that Vypro is too elastic for colposacropexy. In some patients tissue incorporation is not very strong, so here he fears that the elasticity of the remaining Prolene mesh (after absorption of the Vicryl portion) is too high resulting in recurrence.

Surgeon 3 has done 200 pelvic floor repairs, anterior, posterior, combinations of both, and sacrocolpopexy, for the past two years, first using Gynemesh, then switching to Vypro after he had become aware of this new mesh.

Gynemesh: is perceived as too bulky and rigid. Also, when cutting the mesh, small particles are released that migrate through the vaginal wall causing pain during intercourse. Surgeon 3 thinks that Gynemesh will never be a success, also for cost reasons. Many surgeons would buy the cheaper Prolene mesh, cut it themselves and then resterilize it. This could obviously not be done with the Vypro mesh.

Vypro Mesh:

The advantages he sees: thin, elastic, cuttable without fraying. Should be offered in different sizes, e.g. 5 x 15 cms for the anterior colporrhaphy, 7x12 cms for posterior colporrhaphy. He uses Gore tex suture for fixation. To be improved: the mesh should have minimum retraction when incorporated in the fibrous tissue. For handling, some added stiffness would be preferred. The mesh is well incorporated, at postoperative examination, the vaginal wall above the mesh feels soft, no resistance can be felt, whereas Prolene mesh could easily be felt through the vaginal wall by the examiner (the patients themselves did not complain). In his series of 200 patients he has seen two cases of erosion, one with Prolene the other with Vypro. Both patients had

hematoma before. Wound healing disturbances totalled 10 % (exact rate for Vypro yet to be evaluated).

According to surgeon 3, wound healing disturbances are frequent in vaginal surgery – rather the rule than the exception, also with conventional colporrhaphy using sutures.

Surgeon 4 is renowned for his experience with pelvic floor surgery, a recognized centre of competence within the area . So he thinks that his number of 35 cases with large cystoceles per year, is high.

He has used Vypro mesh, 10x15 cms, for pelvic floor repair in about 20 patients so far and he has agreed to send us his report on preliminary results. He treats particularly large cystoceles, including medial and paravaginal parts, with mesh. Large cystoceles are sometimes 10 cms in diameter. He fixes the mesh with Prolene sutures to the muscular fascia (arcus tendineus) . Following Vypro mesh implantation, the patients always had a very soft elastic vaginal wall (which was not so with Prolene mesh which through its stiffness and bulkiness, could easily be felt through the vaginal wall tissue).

Surgeon 4 likes the Vypro mesh, he regards it as much better than Prolene mesh or any other mesh on the market, and he will continue using it, but he also states that it is not the optimum solution.

He has observed two issues:

1. Patients complain of lateral pains. He thinks that this could be due to fixation using the nonabsorbable sutures that come under tension while the mesh retracts during tissue incorporation. He has also observed this phenomenon with Prolene mesh.
2. He has had some patients (number to be determined) with wound healing disturbance following Vypro implantation. Wound healing was compromised in the middle of the vaginal incision. But it did not become necessary to remove the mesh.

Surgeon 5 has used Gynemesh / Prolene Mesh for anterior colporrhaphy in recurrent cystocele. He has not encountered any infection with Prolene Mesh which he sees as inert and biocompatible. He reduces the cystocele first by absorbable sutures before implanting the mesh. He suggests a mesh size of 7x7 cms.

He thinks that Vypro mesh could be a good alternative to the present bulky Gynemesh. He sees an advantage in having less foreign body material remaining.

He would not use any mesh material for rectocele repair, implanting it between posterior vaginal wall and rectum, as he is concerned that there may be complications because of the vicinity of the bowel, with a potential risk of bacterial contamination.

For sacrospinal fixation, he uses Ethibond sutures.

Surgeon 6 thinks that a lot of cosmetic surgery has been done to repair cystoceles. He will not operate on any asymptomatic cystocele.

According to his experience, medial pelvic floor defects are frequent, lateral defects are rather rare.

In a patient with both, symptomatic cystocele and stress incontinence, he will first complete the TVT procedure, then 2 cms beneath the incision for TVT, he will do the incision for a conventional anterior colporrhaphy.

He has not used mesh implants for pelvic floor repair, but would consider using a fine mesh (e.g. Vypro mesh) for recurrent cystocele. However, it is not clear to him how the mesh could be fixed, since the tissue is too fragile for anchoring sutures. The mesh should stretch equally in both directions. He thinks that the mesh repair will probably delay the recurrence, but not avoid it completely, as with aging, the pelvic floor continues to descend.

Surgeon 6 is sure that a totally absorbable mesh material will not work long-term, since the long-term effect depends on the tissue reaction to the implant material. Once the material is gone, the tissue reaction will subside. He explained his experience with intravaginal sling procedure for stress incontinence therapy, using Mersilene tape. With the hypothesis that the Mersilene tape was required only for a certain time, he took it out after 60 days. At first, the results remained good, obviously because of the adhesions in place, but after some time the patients gradually became incontinent again.

Surgeon 7 has already some experience with Vypro mesh. He uses it for recurrent anterior vaginal wall prolapse (cystocele). He would very much like to carry out a clinical study with Vypro Mesh for that indication. His technique: he reduces the cystocele by a Vicryl purse string suture, with sparse tissue resection, then he buttresses the suture repair with a Vypro Mesh, a square sized 5 x 5 cms is considered sufficient.

For sacrocolpopexy he uses Mersilene Mesh which he doubles so that it gets the shape of a tube. He thus avoids sharp edges and the risk of eroding the bowel wall. Mersilene and Prolene meshes both have too sharp edges, according to him. Ideally surgeon 7 would like to have a long-term totally absorbable mesh for all these indications. He is confident that the buttressing effect will remain after the implant material has disappeared.

Surgeon 8 is convinced that there are much more lateral and apical defects than medial cystoceles. He also believes that many gynecologists do not perform the examinations correctly to assess the defects properly. Sometimes patients are sent to him for operation who have a cystocele but no symptoms. He will not operate on these.

For anterior vaginal wall prolapse repair (cystocele), he always uses the laparoscopic approach. So in patients with combined stress incontinence and cystocele, he will not use TVT, he will do a laparoscopic paravaginal repair combined with laparoscopic Burch colposuspension, using Ethibond sutures.

He has used Prolene Mesh or Gore Tex for laparoscopic colposacropexy. Particularly the Gore Tex he finds supple and easy to work with. He has not used mesh for anterior or posterior vaginal wall repair.

Surgeon 8 thinks the Vypro mesh is an interesting material. It could be worth trying it as a buttress material for his paravaginal suture repair (laparoscopic approach).

Since 1995, **surgeon 9** has used Gynemesh to treat recurrent cystocele, now he has started using it also on primary repairs.

According to his experience, 70% of the cystoceles start in the centre, where the fascial tissues is very fragile, anyhow. By the time the patient comes to see the gynecologist, usually the lateral parts are already involved, too.

Surgeon 9 uses the grading system to decide on whether to treat or not.

Grade I and II: no correction needed.

Grade III and IV : to be corrected

He does not think it is necessary to bring the cystocele back to 0 in elder patients. It is quite adequate to restore it to grade I.

Cystocele repair: Small incision in the vaginal wall about 1-2 cms beneath the usual incision site for TVT. Vaginal approach like in conventional anterior colporrhaphy.

Gynemesh is fixed tension-free with 4 corner Prolene sutures to the paravaginal fascial tissue (earlier, surgeon 9 used Dexon or Vicryl, but he abandoned absorbable sutures after a case of wound healing problem). Surgeon 9 does not resect any tissue when closing the vaginal wall wound. He just approximates the wound edges , it does not matter if the tissue is very loose hanging a bit into the vagina, according to his experience. The surplus tissue will gradually disappear leaving a smooth vaginal wall.

If the patients has both, stress incontinence and cystocele, surgeon 9 first starts with TVT, then repairs the cystocele and last completes TVT.

The advantage oft tension-free repair: the patient does not experience pain postoperatively. Usually, after conventional colporrhaphy, the patient is suffering considerably, as the suture to reduce the cystocele is placed under tension.

Surgeon 9 perceives the bulkiness of the Gynemesh as disadvantageous. The mesh can be felt beneath the vaginal wall. He demonstrated great interest in Vypro mesh.

Surgeon 10: When the concept of tension-free mesh placement for pelvic floor management was presented to him he stated that in his opinion, to be successful, a device concept was needed, not just a mesh implant, perhaps a mesh with glueing properties, or a long-term absorbable mesh with incorporated active proteins. So far, surgeon 10 does not have a specific concept for pelvic floor management. The idea of tension-free mesh is ok, but not optimum. He will have to look into this more deeply.

Surgeon 11 has carried out a study using Gynemesh for repair of isolated cystocele, without other concomitant pelvic floor defects. 20 patients were recruited and operated on. Technique: Vaginal wall incision abt. 2 cms away from the incision as done for TVT. Dissection of vaginal wall from bladder. Both structures are connected with each other by connective tissue layers. Dissecting causes very little bleeding. Gynemesh is placed between bladder and vagina

and it is fixed tension-free with a total of 5 stitches Vicryl, at the two proximal corners, at the 2 distal corners and 1 distal in the centre of the mesh edge, to the paravaginal connective („fascial“) tissue .

The cystocele is not reduced by purse string or other sutures as is generally done in conventional colporrhaphy.

This means that the concept is truly tension-free. Following mesh implantation, the vaginal wall wound is closed with Vicryl in a continuous suture. Scarce resection of surplus tissue.

In two patients, surgeon 11 has observed a wound healing disturbance right in the middle of the vaginal wall wound . The wound did not close above the mesh. There was no infection and the patients were not aware of the erosion. To overcome this problem, surgeon 11 will change to a technique described by Julian who sutures the vaginal wall in a double layer above the mesh implant, because he feels this overlapping could prevent mesh erosion.

Surgeon 11 likes the Gynemesh , but he thinks a thinner mesh could be more acceptable to surgeons. He could not tell if he would prefer Vypro or just another thinner mesh such as Soft Prolene Mesh. Both concepts seem plausible to him. It is important that the mesh can be cut to individual sizes, it must not fray nor release particles.

He does not see mesh rigidity as a problem. The stiffness of the mesh helps to restore the former bulge without adding sutures. The cystocele bulge is no longer visible after the operation. It has completely disappeared .

According to **surgeon 12**, urinary stress incontinence and cystocele are often combined. He could not tell, however, in what percentage. He thinks the cystoceles are predominantly medial. He is not aware of lateral defects.

It is also quite frequent that the patient presents only with a cystocele and no stress incontinence is demonstrable in preoperative urodynamic evaluation, but some months after the cystocele repair, the patient develops urinary incontinence.

In patients with cystocele only , surgeon 11 repairs only the cystocele by vaginal anterior colporrhaphy. Once the patient returns with stress incontinence, he will carry out a second operation , implanting TVT.

He has no experience with mesh implants, but may consider their use in future.

For cost reasons, **surgeon 13** has not used Gynemesh, but strips of Prolene mesh which he cut and resterilized. On principle, he uses meshes only in recurrent anterior and posterior vaginal wall prolapse, for anterior and posterior colporrhaphy. Although he is aware that results of this primary repair are unsatisfactory, with 30% recurrence, he is concerned with using meshes for primary repair, because there is always the risk of erosion or extrusion. At this stage, it is not possible to predict whether the use of mesh for primary repair would improve 5 year results.

Thinner meshes such as Soft Prolene Mesh or Vypro would certainly be an improvement to the current Prolene Mesh which is very thick. As the mesh always must be cut to individual sizes, it is of utmost importance that the mesh is cuttable and that it does not fray nor release particles after cutting. The small particles migrate and cause pain during intercourse.

For improved handling during implantation, the mesh should not roll at the edges (such as the Ughary mesh, 110).

Surgeon 13 does not know what biomechanical requirements a mesh must fulfil to withstand the forces on the pelvic floor. He assumes that pressure is higher at the pelvic floor level than at the abdominal wall.

Surgeon 14 stated he will not use any mesh for pelvic floor repair. In the past, his colleagues were quite enthusiastic about meshes. Later on, there was the disappointment, with meshes leading to erosion and extrusion. He has no experience himself. This is what he heard from other surgeons.

Surgeon 15 said he had never thought of using meshes for pelvic floor repair. He does the usual vaginal anterior and posterior colporrhaphy. He does not feel that he could comment on such a concept.

Surgeon 16 is not a TVT user. He would use PP mesh for pelvic floor, but he considers the use of meshes as last choice for pelvic floor repair. They are a just a sort of „ band aid „ for pelvic floor defects.

Surgeon 17 will repair a vaginal wall prolapse only if the patient has symptoms or if he thinks it is justified to do the repair.

He carries out the usual vaginal anterior and posterior colporrhaphy. He is happy with the results. He has never used meshes for pelvic floor repair and does not see a need to do so in future.

Surgeon 18 stated that for vaginal wall prolapse, vaginal anterior and posterior colporrhaphy were the preferred techniques at his hospital.

Occasionally, meshes have been used, but he is not aware which mesh products. He would have to ask the OR nurse.

He himself would prefer to do the repair by laparoscopy, as this approach allows you to overview and judge the stage of descensus very well. However, there is a lack of appropriate equipment and instrumentation for laparoscopic mesh repair. For example, laparoscopic sacrospinal fixation using meshes would require a finer stapler. Suturing with curved needles is difficult in laparoscopy.

Surgeon 19 has experience with Prolene mesh which he uses in strips of abt. 5 cms x 1.5 cms, for bridge plasty. The mesh is placed beneath the medial part of the urethra, double fixation with Vicryl to the pubococcygeus muscles.

Before using Prolene mesh, Fascia lata was the material of choice.

The disadvantage of Prolene mesh he sees is its thickness. One could feel it through the vaginal wall when examining the patient surgeon 19 has observed erosions in a number of patients, which he attributes to mechanical irritation of the mesh. He treated those erosions by simply cutting off the mesh at the erosion site. There was never a case of infection and the wound always healed. He considers the Prolene mesh as really inert material. However, he would be happy with a thinner mesh, soft Prolene Mesh of Vypro would probably both do well. He is not sure if he really needs an absorbable part in the mesh.

Surgeon 19 thinks the biomechanical requirements for a mesh for pelvic floor repair correspond to those of abdominal wall closure, probably even less. He believes that a totally absorbable material would not do the job, but lead to recurrence long-term.

Surgeon 20 has about 100 patients with cystocele grade III and IV. He advises them to use a pessary device for a couple of weeks to identify those abt. 10% patients who have accompanying stress urinary incontinence.

He does a vaginal anterior colporrhaphy, Kelly plication using Vicryl sutures. The procedure can easily be combined with TVT.

So far, he does not have any experience with mesh implants in these operations. But he feels that the material should both be strong to withstand the forces exerted on the pelvic floor (more or less comparable to those on abdominal wall closure) and it should also be soft to avoid irritating the bladder.

Out of the three meshes demonstrated to him - Vypro, Vypro 2, SPM - he would favour Vypro. He would certainly try it once it is available.

He estimates that 18.000 pelvic floor prolapse procedures are done annually in the Netherlands. He himself does abt. 80 vaginal anterior repairs per year, often combined with posterior (rectocele) repair.

If an abdominal hysterectomy is done at the same time, he will add the Burch colposuspension for prolapse repair. So far, he has used Gynemesh, fixed with 4 Vicryl sutures, in 4 anterior repairs, in one he observed an erosion in the middle of the vaginal incision.

Therefore, he would like to know the rejection rates of a new mesh.

He favours the Vypro for anterior and posterior repair for its thinness and elasticity. He thinks the Gynemesh is too thick and stiff. The aim particularly of anterior vaginal wall repair is to create a thin scar tissue. The scar must not be too thick, because in that area the original fascial tissue is very thin and fragile and anything too bulky could have a negative effect on the bladder neck area. The tissue there is not comparable to muscular fascia. It is a loose connective tissue that connects the bladder and vagina with each other.

Surgeon 21 is not aware of any study that would address the forces exerted on the pelvic floor. He believes they are comparable to those on the abdominal wall. He therefore thinks that biomechanical properties of Vypro are adequate. However, he questions the necessity to add

Vicryl. According to him, the Prolene part should be sufficient. He would definitely like to try Vypro and he strongly believes that Vypro would be a successful product in the pelvic floor market.

For sacrospinous fixation, he favours SPM, as - according to his experience - adhesions formed in that area around a mesh implant may be reduced in some patients. So Vypro could be too elastic once the Vicryl part was absorbed, leading to recurrence.

Surgeons 22 and 23 were both mildly positive in the sense that they see potential value in a concept of using mesh for pelvic floor repair. They trust synthetic materials very much and in no case prefer biologic materials. Both would immediately use a thin pliable synthetic mesh. Both mentioned that the mesh needs to have some degree of flexibility to comply with the movements of the pelvic floor.

Dr. B. Hellhammer
June 6, 2000

4. Annex

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