Original article

A preliminary report on the use of a partially absorbable mesh in pelvic reconstructive surgery

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Abstract: The physical characteristics of a synthetic implant used in pelvic reconstructive surgery are thought to play an important role in the causation of erosion and other complications of mesh implantation. This is in addition to the significant role of surgical technique and a patient's own risk factors. In this report the physical characteristics of non reabsorbable and partially reabsorbable meshes are examined and compared including weight, breaking strength, flexural rigidity and pore size. A preliminary study is reported where thirty patients underwent prolapse surgery with bilateral sacrotuberal fixation of the vault and mesh implants in the anterior and/or posterior vaginal wall using a partially reabsorbable mesh. Mean follow- up at 1 year demonstrated an erosion rate of 4-4.5% with a recurrence rate only in the anterior compartment of 12%.

Key words: Pelvic reconstructive surgery; Mesh erosion; Partially absorbable mesh.

INTRODUCTION

Conventional procedures for reconstructive vaginal surgery are burdened with recurrence rates of up to 30%.[1, 2] Many of these operations can result in a poor anatomical result and loss of the physiological vaginal axis. This may lead to secondary pelvic defects and functional pelvic problems. Since the introduction of mesh in pelvic organ prolapse (POP) surgery good anatomical restoration appears to be associated with lower recurrence rates and good functional outcome. Polypropylene tapes have proven to have good biocompatibility in vaginal tissues,[3] but there are complications such as mesh erosion and extrusion.

In 2005 the International Urogynaecology Association (IUGA) Grafts Roundtable proposed a classification of simple and complex healing abnormalities [4] which differentiates between them based on the timing of presentation relative to implantation, site of the lesion relative to suture line, the presence of inflammatory tissue and whether there are any affected viscera. Clinical experience has shown that most cases of erosion or extrusion are simple healing abnormalities. The density of graft material and other physical characteristics like pore size may play a significant role in tissue acceptance of mesh. Partially absorbable meshes have the advantage of weight reduction after resorption of a component of the graft. The aim of this retrospective study was to demonstrate the efficacy and safety of a partially absorbable polypropylene / polyglycolacid / ε-caprolacton mesh in pelvic reconstructive surgery especially in regard to the incidence of mesh erosion. We also describe the physical characteristics of this graft material in comparison to non absorbable meshes that are currently available.

MATERIALS AND METHODS

Between September 2006 and February 2007, a series of 30 consecutive patients underwent surgery for vaginal prolapse. The International Continence Society (ICS) Pelvic Organ Prolapse Quantification (POP-Q) staging system was used to assess the severity of pelvic organ prolapse.[5] All patients reported in this study were assessed as POPQ Stage 3 or Stage 4. Tension-free placement of a partially absorbable mesh beneath the bladder or between the vagina and rectum was performed using a vaginal approach. The anterior transobturator mesh (ATOM) repair was performed in 25 of the 30 patients, while 22 underwent posterior graft implantation and all 30 underwent bilateral sacrotuberal fixation. In 13 cases a concomitant hysterectomy was done for uterine prolapse POPQ Stage 2 or 3. Seventeen patients had a post-hysterectomy prolapse and 6 had suffered a recurrence following a traditional colporrhaphy. Mean age of patients was 68.5 yrs (range 53-80) with mean parity of 2.3 (range 1-8). After an interval of 2 weeks and again at a mean follow-up at 1 year (range 10-14 months) the patients were reassessed.

The surgical procedure involved a transvaginal placement of a mesh in areas of vesicovaginal and rectovaginal dissection according to the description of Fischer.[6] In the posterior compartment a posterior vertical midline incision enabled the vagina to be dissected from the underlying tissues and the rectum separated from the vagina. The pararectal fossa was opened on each side. On each side 2 to 3 non resorbable sutures were fixed at the sacrotuberal ligament. The posterior mesh (SeraGYN® PFI, SERAG- WIESSNER, Germany) was cut to measure 6-8 cm in width and 10-15 cm in length. The upper part of the graft was attached to the vault and the sacrotuberal ligaments with the prefixed non resorbable sutures. The lateral edges of the mesh were fixed to the levator ani muscle and the lower edge to the perineum without tension. In this way a new rectovaginal septum with vault suspension by bilateral sacrotuberal fixation was performed.

When performing an anterior prolapse mesh procedure the bladder was dissected free from the vagina following an anterior vertical midline incision. The paravesical fossa was opened on each side. Bilateral transobturator passage of the trapezoid, four-armed mesh (Seratom® A PA, SERAG-WIESSNER, Germany) through the arcus tendineus fasciae pelvis was performed using the anterior transobturator mesh (ATOM) technique. The upper edge of the implant was attached to the sacrotuberal ligaments using sacrotuberal prefixed non resorbable sutures. A new vesicovaginal septum was thus created with bilateral sacrotuberal vault suspension.

The partially absorbable mesh consists of polypropylen (PP), polyglycolacid (PGA) and ε-caprolacton (PCL) as components of a monofilament thread. Six filaments of PP are coated with a co-polymer of PGA and PCL (Fig. 1). The distance between the PP-filaments is > 10 µm.

After 120 days PGA and PCL are absorbed and the multifilament character of the six PP- fibres appears (Fig. 2).

The physical characteristics of the partially absorbable mesh are compared with three other frequently used grafts:

• Prolift®, GYNECARE, Johnson & Johnson, New Jersey, USA;

TABLE 1. – *Comparison of physical characteristics of different meshes in pelvic reconstructive surgery.*

Producer	Gynecare	AMS	Bard	SERAG-WIESSNER	
Product	Prolift®	Apogee® / Perigee®	Avaulta®	Seratom® A	Seratom® A PA (after resorption)
Material	Polypropylene	Polypropylene	Polypropylene + Collagen	Polypropylene	Polypropylene +Polyglycolacid+ ε-Caprolacton
Body structure	Edges are welded; Identical structure of body and arms; Arms and body are all of a piece; Arms unstable under tension (roll in)	Edges are cut; structure of body and arms are not identical Arms are sewed or rivet to the body; Arms are enfolded and unstable under tension (roll in)	Edges are cut; Identical structure of body and arms; Arms and body are all of a piece; middle part covered with collagen; Arms unstable under tension (roll in)	Edges are tongued; Identical structure of body and arms; Arms and body are all of a piece; the arms remain stable under tension	Like Seratom A;
Weight (g)	1.3 (anterior) 0.7 (posterior)	1.5 Perigee® (ant.) 1.0 Apogee® (post.)	0.8 (anterior)	0.5 usable for anterior and posterior repair	0.6 (0.3) usable for anterior and posterior repair
Weight in g/m²	45	55	100	30	45 (15)
Thickness arm, thickness gauge mm	0.4	0.7	0.5	0.5	0.5
body, thickness gauge mm	0.4	0.5	0.4	0.4	0.4
Size of pores (large pores)					
Area of pores (mm²)	7	6	1	11	11
Width of pores mm	3	3	2	3	3
Height of pores (mm)	3	3	1	5	5
Relation of pores in the mesh (body) %	60	50	50	80	70
Relation of pores in the mesh (arm) %		40			
Flexural rigidity					
axial (mg)	4	5	43	16	7 (2)
transverse (mg)	6	5	49	32	14 (3)
Breaking strength					
axial (arm) (N)	60	80	70	90	80

• Apogee®, Perigee®, AMERICAN MEDICAL SYSTEMS, Minnesota, USA;

• Avaulta anterior BioSynthetic mesh®, BARD, Covington, UK.

The subjects are:

– weight in g/m² and per item in g, measured with a precision balance (Mettler Toledo XP 204), accurate to 0.1 mg.

– breaking strength of the mesh arms in Newton (N), Universal Test Machine (Tira), information accurate to 0.01 Newton, test speed 500 mm/min, testing length 100 mm.

– flexural rigidity in mg, measured with Bending Resistance Tester (Gurley Precision Instruments) in both the longitudinal and transverse axis.

– area, width and height of a pore in mm, measuring the sizes of 5 pores with stereo microscope Stemi SV 11 (Zeiss) and calculating the mean, information accurate to 0.01 mm.

– pore content: relation of area of pores to area of the mesh in % after marking an area of 10 x 10 mm, stereo microscope Stemi SV 11 (Zeiss).

– thickness, according to destination of diameters of surgical used threads, thickness measuring gauge (Frank, type 16304, accurate to 0.001mm, test surface 0,8 cm², system test pressure 1,27 N/ cm²).

RESULTS

The prosthetic materials studied differ with regard to shape and physical characteristics (Tab. 1). Polypropylene and macro porosity as a basic structure are common to all of the implants. Avaulta® is additionally coated with a resorbable portion of collagen and Seratom® A PA is coated with polyglycolacid and ε-caprolacton. The Seratom® A PA mesh has the lowest weight after absorption of the resorbable part, while there is no information regarding the weight of Avaulta® after absorption of the collagen coating.

The thickness of each mesh varies between 0.4 and 0.7 mm. The width of the pores does not differ, but there is a wide range in regard to area and height. The areas of the pores make up 50 to 80 % of the total graft area. There is a wide variation in flexural rigidity of the different meshes ranging between 4 (lowest value after absorption: 2 mg) to 43 mg in the longitudinal axis and 5mg (after absorption: 3 mg) to 49 mg in transverse axis. In regard to the partially absorbable mesh itself the flexural rigidity is reduced for 71% (axial axis) - 79% (transverse axis) after absorption. Breaking strength demonstrates less variability between 60 and 90 N over all meshes.

We reviewed our patients 2-3 weeks after surgery. No relapse, mesh erosions or any other complications were observed. At follow up 10- 14 months after surgery anterior

compartment recurrence occurred in 3 patients (12 %) with POP-Q = Stage 2. There was no relapse in the middle or posterior compartment (POP-Q: Stage 0 or 1) (Tab. 2).

Vaginal erosion of the mesh as a simple healing abnormality affected one patient (4 %) after cystocoele and one (4.5 %) after rectocoele repair. The vaginal erosion measured <0.5 cm^2 in area and was treated by partial excision of the mesh as well as local application of estrogen.

There were no bladder or urethral erosions and no vaginal or pelvic infections.

The mean postoperative length of the vagina was 9.5 cm. Functional problems of dyspareunia and de-novo urge occurred in one patient in each case. De-novo stress incontinence was observed in 4 patients. Cystitis and temporary urine retention were seen in 2 cases.

TABLE 2. – *Results of mesh supported prolapse surgery with a partially absorbable graft (Follow-up 10-14 months).*

Compartment	*anterior (n =25) Seratom® A PA*	*Medium (Vault) (n = 30)*	*posterior (n = 22) Seragyn® PFI*
relapse ≥ POPQ II° (%)	12%	0%	0%
mesh-erosion (%)	4% (n = 1)	0%	4,5% (n = 1)

DISCUSSION

A number of parameters affect the ability of a synthetic mesh to act as the perfect graft. These include: kind of material (e.g. polypropylene, polyester), textile construction (mass per unit area), configuration of the thread (monofilament, multifilament, fleece), pore size, elasticity, and the amount of ingrowth of connective tissue. Physical characteristics may play a significant role in respect to the biocompatibility of prosthetic materials in human tissue.

Partially absorbable meshes such as SeraGYN® PFI or Seratom® A PA are likely to have four advantages:

– weight reduction;

– monofilament surface during critical postoperative phase with less risk of inflammation;

– masking the hydrophobic surface of polypropylene. For this reason better acceptance in the tissue is expected;

– more softness, like multifilament grafts.

Previously available composite meshes such as Vypro II® (Ethicon, USA) were made of two separate threads of PP and polyglycolacid and did not meet the criteria of an ideal mesh for induration and shrinkage.[7] The SeraGYN® PFI or Seratom® A PA partially absorbable graft consists of a single thread made up of a coating of polyglycolacid / ε-caprolacton and a core of six PP-filaments. The primary monofilament mesh has the advantage of avoiding early rejection or inflammation then it converts to a hexafilament graft with reduced rigidity after reabsorption of the cover. As the distance between the filaments is > 10 µm, the migration of leucocytes and macrophages, that may counter invading bacteria, is not hindered in contrast to conventional multifilament and microporous meshes (Amid II-IV classification).[8]

Seratom® A PA weighs 15 g/m^2 and contains the lowest proportion of foreign material in comparison with other grafts in this trial (Fig. 3). Despite the reduced weight no deficits were found in our in-vitro testing of stability and flexibility. In relation to flexural rigidity the partially absorbable graft demonstrates at least twofold less stiffness than the non resorbable prosthetic materials. In respect to breaking strength the partially absorbable mesh is as firm as the other grafts.

It is apparent that physical properties of the prosthetic material contribute to the incidence of complications in pelvic floor reconstruction. There has been a lot of effort undertaken within the last few years to produce lightweight biocompatible grafts. Mesh erosions are not only caused by problems with surgical technique and patient's own risk factors but also by the kind of implant (Tab. 3). Julian,[14] in a randomised controlled trial found an erosion rate of 25% with a Marlex PP mesh but in most trials it is quoted at 8-12%.[9] Our experiences with the partially absorbable mesh show a considerably reduced erosion rate of 4-4.5% after a mean follow-up of 1 year (range 10-14 months). The erosions happened in the anterior as well as in the posterior vaginal wall in a very circumscribed area. The problem was resolved by simple excision of the small area of unincorporated mesh. No major visceral complications were seen.

The mesh proved as a safe and effective graft in pelvic floor reconstruction even in advanced vaginal prolapse (POP-Q Stage 3-4). This study is limited in that it is a retrospective survey in a small population without any quality of life questionnaire.

Efficient and objective trials are mandatory to fully evaluate the place for partially absorbable meshes. The Pareto- (**pa**rtially **re**sorbable **t**rans**o**bturatoric) mesh study began in April 2007 as a prospective randomised multicenter study with the study center at the Gynecological Clinic, University of Freiburg, Germany. A non resorbable 6 armed PP-mesh prosthesis for reconstruction of cystocele and vault prolapse is compared with a partially reabsorbable graft of the same size. The primary question that has to be answered is if the erosion rate can be reduced by the use of the partially absorbable mesh. Other factors that are thought to affect the erosion rate will also be examined. These include collagen content, extracellular matrix proteins, degree of proliferation of vaginal epithelium and bacterial colonization. The surgical technique is standardized and follow-up is planned after 3 months, one and three years. First results for publication are expected at the end of 2008.

TABLE 3. – *Factors in aetiology of mesh erosion*

- *As a consequence of operation*
  (simultaneous hysterectomy, inverse T- incision?,[9] excessive excision of vaginal skin, extent of colpotomy,[9] supra-fascial dissection,[10, 12] lack of experience,[11] taut suture of vaginal skin, excessive tension of mesh [13])
- *Patient risk factors*
  (poorly controlled diabetes mellitus, tobacco use,[13] vaginal prolapse, POPQ ≤ 2,[12] repeat procedures, medication of cortisone, vaginal estrogen status, prior history of pelvic irradiation,[13] age ≤ 70 years [11, 12])
- *As a consequence of mesh characteristics*
  (graft according to Amid classification II-IV,[8] large amount of foreign material)

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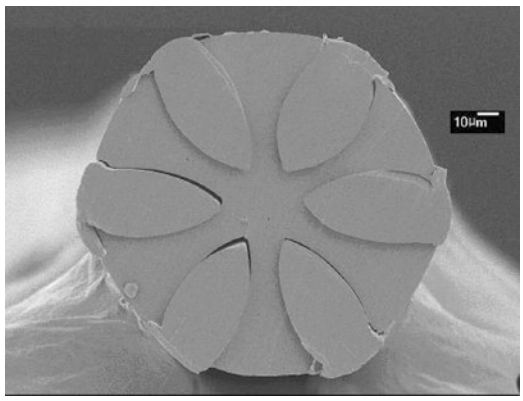

Fig. 1. – Cross section of partially absorbable Seramesh PA® and Seragyn® PFI thread with six filaments of PP and a coat of polyglycolacid and ε-caprolacton (scanning electron microscope). The distance between the PP- filaments is > 10 µm.

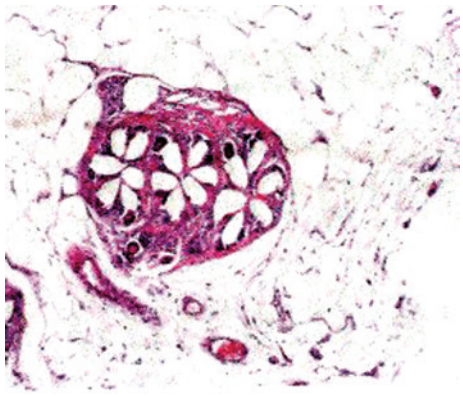

Fig. 2. – Histologic section of Seramesh PA® and Seragyn® PFI thread 120 days after implantation in rat tissue. The hexafilament profile of PP persists after absorption of the co- polymer of PGA and PCL.

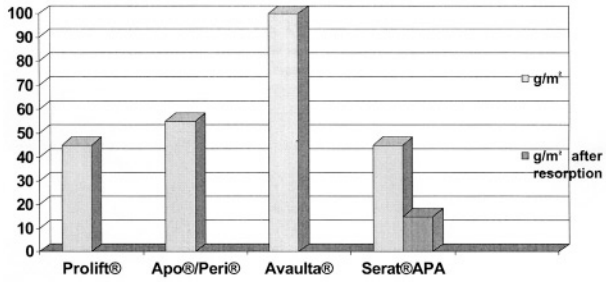

Fig. 3. – Weight of different meshes in g/m^2.

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Interests Declared:

– The authors state that there are no grants, pecuniary interests or financial support in relation to this study.

– The author OG is a textile engineer. As an employee at SERAG- WIESSNER KG. He declares his pecuniary and commercial interests.

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Pelvic Floor Digest

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National trends and costs of surgical treatment for female fecal incontinence. *Sung VW, Rogers ML, Myers DL et al. Am J Obstet Gynecol. 2007;197:652.* This study describes national trends, hospital charges, and costs of inpatient surgical treatment for female fecal incontinence in the United States. From 1998 to 2003 21,547 women underwent inpatient surgery for fecal incontinence. This number has remained stable, with 3423 procedures in 1998 and 3509 procedures in 2003. The overall risk of complications was 15.4% and the risk of death was 0.02%. Total charges increased from $34 million in 1998 to $57.5 million in 2003, a significant economic impact on the health care system.

Prevalence and risk factors of fecal incontinence (FI) in women undergoing stress incontinence (IU) surgery. *Markland AD, Kraus SR, Richter HE. Am J Obstet Gynecol. 2007;197:662.* Women enrolled in a stress UI surgical trial have high rates of FI. Potential risk factors for (at least) monthly fecal incontinence (FI) in women presenting for stress urinary incontinence (UI) surgery are decreased anal sphincter contraction, perimenopausal status, prior incontinence surgery/treatment, and increased UI bother.

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