Original article

Arguments for mesh implantation at the treatment of pelvic organ prolapse, enabling the benefit of uterine preservation: outcome in 459 procedures

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Abstract: Urogynecologists are constantly looking for simple, safe and durable methods to cure pelvic organ prolapse (POP). We used a novel surgical technique utilizing synthetic mesh (Prolift®, Gynecare, Summerville, NJ, USA) to reinforce the pelvic floor in cases of POP with high risk of recurrence, while preserving the uterus. The aim of this study was to analyze cure rates as well as peri-operative data and peri-operative complications. Patients with advanced POP and being at risk for recurrence were enrolled into the study and underwent Proift mesh implantation, hysterectomy was performed for indications other then prolapse or upon patient's request. Previous POP surgical reconstruction, first degree relative with significant pelvic floor fascial defect and poor pelvic supportive tissue were regarded as risk factors for POP recurrence. Pre-operative demographic data, operative details and immediate postoperative follow-up data were prospectively collected for all patients. A total of 459 POP patients were subjected to the mesh operation in an overnight setting. Two hundred and thirty patients (50%) were operated for prolapse of the anterior compartment, 229 (50%) for prolapse of the posterior compartment and 302 (66%) for both, with 85 (18%) of them undergoing implantation of both anterior and posterior pelvic floor meshes; the others had a single pelvic floor compartment mesh implantation with opposite side colporrhaphy. Uteri were preserved with 291 (95%) patients suffering uterine prolapse. Peri-operative complications included bladder penetration (1%) and rectal laceration (0.2%). Early and late adverse outcome were hematoma (1%), vaginal mesh exposure (2%) and recurrence (4%). Total un-favorable outcome was 7%. All these women were cured with no morbid sequela. The mesh POP reconstruction operation carries a low complication rate. Uterine preservation is feasible and safe. The current study supports the previously reported favorable therapeutic outcome of this procedure.

Key words: Mesh; Pelvic organ prolapse; Pelvic floor reconstruction.

INTRODUCTION

POP (pelvic organ prolapse) occurs in up to 50% of parous women. It causes a variety of urinary, bowel and sexual symptoms. POP is surgically treated in 11% of the total female population. Furthermore, up to 30% of those who undergo traditional non-mesh surgery will eventually go through repeat prolapse surgery, some of them following hysterectomy.[1-4]

Operation for POP cure, such as vaginal hysterectomy, colporrhaphy, with or without plication of the utero-sacral ligaments, as well as sacro-spineous and sacral colpopexies, are also associated with up to 30% recurrence rate, as determined by objective POP scoring and prolapse-related subjective symptoms. Previous POP surgical reconstruction, first degree relative with significant pelvic floor fascial defect and poor pelvic supportive tissue were regarded as risk factors for POP recurrence.[5-11]

Experience with abdominal wall herniorrhaphy showed that the mesh implant concept had a low recurrence rate, and it was therefore subsequently implemented for pelvic floor herniation repair.[12]

However, unlike abdominal wall hernia vertical mesh repair, the vaginally implanted horizontal meshes are subjected to relatively high levels of physical pressure, including sexual intercourse, thus should be well secured to solid pelvic structures such as the sacro-spineous ligaments (SSL), the pre-sacral fascia, the arcus tendineus fascia pelvis (ATFP) or the utero-sacral ligaments. The preferred anchoring method involves passing the mesh arms through the ligaments, since that probably results in longer lasting support than suture methods of mesh fixation.

Furthermore, just a thin and fragile mucosa layer covers the vaginal mesh, compared to the thick abdominal wall coverage of the abdominal hernia mesh; hence, mucosal erosion and vaginal mesh exposure are possible post-operative complications in the former. Steps should be taken to minimize mucosal erosion and the hazards of vaginal mesh protrusion.

The first innovative procedure for the correction of the apical vaginal support defect and used a vaginal approach was replacement of the utero-sacral ligament by a synthetic sling positioned at the levator plate level was the Posterior Intra-Vaginal Sling (PIVS). Restoration of the uterosacral ligament support and re-suspend the uterine isthmus, making the addition of vaginal hysterectomy unnecessary.[13-18] By not removing the uterus, the cervical ring, a solid central pelvic anchoring point is preserved. This provides extra stability for the pelvic floor by recruitment of the related web ligamentary architecture for the pelvic reconstruction and avoids potential iatrogenic weakening of the pelvic floor due to surgical impairment of innervation and blood supply. In contrary, adding hysterectomy to mesh pelvic floor reconstruction significantly increases (O.R. = 15 add confidence intervals) the risk of post-operative vaginal mesh exposure. Other occasional adverse outcomes of hysterectomy are vaginal shortening and psychological effects in terms of the woman's body image and self esteem.[19-28]

This study goal is to evaluate the newly developed Profit operation for pelvic floor reconstruction without additive vaginal hysterectomy, in terms of cure and failure rates as well as related complications rates and safety.

PATIENTS AND METHODS

Patients experiencing stage 3 or 4 vaginal apical supportive defects, diagnosed clinically in accordance with the International Continence Society (ICS) Pelvic Organ Prolapse Quantification (POPQ) standard scoring system, and who were at increased risk for recurrence of the POP, were referred for Prolift® (Gynecare, Summerville, NJ, USA) implantation operation. Risk factors for recurrence included previous POP reconstruction surgery, first degree relative with a significant POP or poor pelvic floor tissue as assessed clinically.[29-32] Patients with mild POP and not at risk for recurrence were referred to conventional non mesh opera-

tions. Patients who had undergone previous pelvic irradiation, or with an immuno-depresive state, active infection, systemic steroid use or poorly controlled diabetes were excluded.

Thorough informed consent was obtained. All patients were given one gram Monocef (Cefonicid, Beecham Healthcare) intravenously, half an hour prior to surgery. All patients were prepared by an iodine antiseptic vaginal wash prior to the commencement of surgery. Spinal or general anesthesia was elected upon patient's request.

Patients with an anterior vaginal wall defect, with or without an apical vaginal support defect had an anterior Prolift® implantation through a longitudinal median anterior wall incision and para-vesical lateral dissection. The mesh was spread from one pelvic side wall to the other, from the bladder neck to the uterine cervix or vaginal apex, so as to replace the whole anterior compartment endo-pelvic fascia. Proper mesh placement required a rather large para-vesical dissection, along the bony pelvis up to the iliac spines laterally and posteriorly and to the pubic bone anteriorly. The mesh arms were passed through the ATFP ligament to prevent weakening. The mesh was also secured to the fascial ring of the uterine cervix or to the vaginal apex at the insertion point of the former sacro-uterine ligaments so as to recruit the endo-pelvic ligaments for improved support. Mesh fixation to the para-urethral tissue was also done to ensure better stabilization of the construction.

For patients with posterior vaginal wall defect (recto-enterocele), with or without apical prolapse, a posterior Prolift® was implanted. This was carried out through a longitudinal median posterior wall incision, then freeing the vaginal wall from the rectum and the herniated peritoneal sac of the enterocele. A para-rectal dissection was then performed to the level of the SS ligaments. The mesh was spread from one pelvic side wall to the other, from the vaginal apex to the perineal body, to replace the whole posterior compartment pelvic endo-pelvic fascia. The mesh was also secured to the fascial ring of the uterine cervix or to the vaginal apex at the insertion point of the former sacro-uterine ligaments so as to recruit the endo-pelvic ligaments for improved support. Mesh was fixed to the perineal body to ensure better stabilization of the construction. Special surgical steps to prevent mesh exposure were undertaken. This included implying meticulous tension free technique with both, vaginal wall and mesh, refraining from excessive vaginal mucosa trimming and dissecting below the sub-mucosal fascia, so as to preserve blood supply and nerve endings. This avoids ischemia, poor healing and tissue necrosis, which might potentially lead to vaginal mesh erosion. It is important to replace sufficient portions of the endo-pelvic fascia, beyond the borders of the herniating endo-pelvic fascia and pelvic floor herniation, with the mesh. This is best achieved by spreading the mesh from one pelvic side-wall to the other, from the urethra and bladder neck to the vaginal apex, through the posterior compartment all the way down to the perineal body.

Patients presenting with additional significant features of pelvic floor relaxation underwent anterior or posterior colporrhaphy, as well as anti-incontinence surgery when indicated, at the same time as the Prolift® operation. Vaginal hysterectomy was carried out for indications other than prolapse or upon patient's request, otherwise was the uterus preserved. With these patients was the uterine cervix amputated if it was elongated.

Pre-operative demographic data, operative details and immediate postoperative follow-up data were prospectively collected for all patients. Intra-operative and post-operative complications of all patients were recorded prospectively. The patients were interviewed at the first and sixth postoperative months and yearly thereafter. Subjective data recording included symptoms as urgency, frequency, stress and urge incontinence of urine or feces, sexual function impairment, voiding habits and pelvic pain and bulging. The objective data collection was carried out by a non involved surgeon and included a physical pelvic examination, verification of urine or feces incontinence, and pelvic floor and organs assessment, in accordance with the ICS standards terminology.

RESULTS

Between January 2006 and January 2009, 459 Prolift® procedures were performed. All demographic, personal and clinical details are tabulated in Tables 1 and 2.

One hundred and fifty-six (34%) patients had undergone a previous hysterectomy – a third of them vaginaly and the rest abdominally. Two hundred and thirty patients (50%) had advanced prolapse of the anterior compartment, 229 (50%) had advanced prolapse of the posterior compartment and 302 (66%) had both. Nevertheless, only 85 (18%) needed implantation of both anterior and posterior Prolift®, the others had a single pelvic floor compartment Prolift® and opposite side colporrhaphy. Vaginal hysterectomy was performed in 12 patients (3%) – for indications other than prolapse or at the patient's request, 47 (10%) underwent partial amputation of a significantly elongated uterine cervix. Ninety-three patients (20%) underwent anti-incontinence surgery (TVT SECUR® or TVT-Obturator®, Gynecare, Summerville, NJ, USA) in addition to Prolift® implantation (Tab. 3). Five patients (1%) suffered intra-operative bladder injury; four were corrected vaginally and one required laparotomy, as the laceration was adjacent to the trigone. One suffered a rectal laceration that was corrected immediately, six (1%) lost more than 300 ml of blood intra-operatively, blood transfusion was not indicated. Eight (2%) had post-operative vaginal mesh exposure, resected at office, 32 (7%) had de-novo over-active bladder symptoms. Six (1%) patients had a post-operative hematoma within the pararectal fossa. These patients were treated orally with prophylactic broad-spectrum antibiotics; all patients with

TABLE 1. – *Patients' demographic and personal details.*

Age (Yrs, Av., range)	65 (43-91)
Parity (Av., range)	3.0 (0-6)
Chronic illness* (No, %)	184 (40%)
Previous hysterectomy (No, %)	156 (34%)
Vaginal (No, %)	58 (13%)
Abdominal (No, %)	98 (21%)

* Diabetes mellitus, bronchial asthma, hypertension, etc.

TABLE 2. – *Clinical data.*

Cystocele, C>2* (No, %)	230 (50%)
Rectocele, C>2* (No, %)	229 (50%)
Cystocele & rectocele, C>2* (No, %)	302 (66%)
Uterine prolapse, C*>2 (No, %)	307 (67%)
Previous POP reconstructive surgery (No, %)	289 (63%)
First degree relative with significant POP (No, %)	58 (13%)
Poor pelvic floor tissue (No, %)	162 (35%)

* According with the ICS POP-Q system.

Table 3. – *Operative details.*

Anesthesia	
408 (89%)	General (No, %)
51 (11%)	Regional (No, %)
Prolift® surgery	
230 (50%)	Anterior Prolift® (No, %)
229 (50%)	Posterior Prolift® (No, %)
{85 (18%)}	{Anterior & posterior Prolift® (No, %)}
302 (66%)	Additional surgery
12 (3%)	Contra lateral compartment colporrhaphy (No, %)
93 (20%)	Vaginal hysterectomy (No, %)
47 (10%)	Anti-incontinence surgery (No, %)
Cervical amputation	
291 (95%)	Preservation of prolapsed uterus (No, %)

adverse effects recovered with no morbid sequelae. The incidence of persistent and de-novo fecal constipation urinary emptying difficulties, bladder over activity symptoms and dispareunia are tabulated (Tab. 4). Seventeen patients (4%) presented with operative failure: four had recurrence of anterior compartment prolapse, one had posterior compartment prolapsed recurrence and 12 (3%) had apical recurrence. In 423 patients (92%) were the results satisfying, being both – free of complications and cured, as defined by the POPQ criteria (Tab. 4). This includes patient's satisfaction with the anatomical results and cure of the debilitating introital lump related to the prolapse as well as proper function of the pelvic organs: the vagina, the bladder and the ano-rectum.

Table 4. – *Operative and post operative (P/O) data.*

5 (1%)	Operative bladder injury
1 (0.2%)	Operative rectal laceration
3 (0.6%)	Operative bleeding > 300 ml
0 (0%)	Operative field infection (No, %)
6 (1%)	P/O hematoma (No, %)
4 (1%)	P/O granulation tissue
8 (2%)	P/O mesh protrusion (No, %)
4 (1%)	Further mesh segmental resection (No, %)
28 (27%)	P/O Persistent fecal constipation at previously constipated 104 patients (No, %)
0	De novo fecal constipation
9 (21%)	P/O persistent Difficult urination at previously obstructed 42 patients (No, %)
6 (1%)	De novo difficult urination
103 (44%)	P/O persistent OAB symptoms at previously 234 OAB patients (No, %)
32 (7%)	De novo OAB symptoms
14 (7%)	P/O persistent dispareunia at sexually active 211 patients (No, %)
15 (7%)	De novo dispareunia
4 (1%)	P/O post anterior Prolift® cystocele (No, %)
1 (0.2%)	P/O post posterior Prolift® rectocele (No, %)
12 (3%)	P/O apical prolapse (No, %)
423 (92%)	Patients satisfied with overall therapeutic results (No, %)

*OAB: Over active bladder.

DISCUSSION

A large scale study of women suffering advanced POP, undergoing the Prolift® procedure with prolapsed uterus preservation, is presented. The feasibility, curability and safety of this procedure do not appear to be inferior to previously reported operative techniques. In fact, this technique has less intra-operative and post-operative complications with relatively high short-medium terms cure rate.

There is sparse evidence-based data in the English literature regarding anatomical and functional long term outcomes of POP surgery for both – mesh and non-mesh operations. This is true for vaginal hysterectomy with advanced uterine prolapse, for paravaginal and site-specific prolapse repair and for abdominal sacral colpopexy. Nevertheless, vaginal sacrospinal fixation and abdominal sacrocolpopexy have remained the "gold-standard" for the repair of vaginal apical suspension defects.[33] Similarly, questions regarding the use of mesh, the preferred mesh type, size, shape and anchoring points for reinforcement of the pelvic floor compartment and for conservation of the prolapsed uterus remain unanswered for the time being. The decision as to which mesh to use – if at all, depends heavily on the individual surgeon's training and experience. This is obviously an insufficient basis for proper decision-making, which should clearly be evidence based.[34-44]

A Cochrane review analyzing 22 trials with 2368 patients showed that abdominal sacro-colpopexy (SCP) result in lower POP recurrence rates and less dispareunia than does vaginal colpo-sacro spineous fixation (VCSSF). On the other hand, VCSSF has the advantage of a shorter operation time and recovery period. Mesh implants were found to reduce prolapse recurrence following anterior vaginal wall reconstruction, and the vaginal approach was found to be superior to the trans-anal for posterior compartment repair. Many authors acknowledge that the paucity of relevant data regarding the operation of choice for POP does not provide adequate information to guide practice. At the same time it is recognized that non-mesh POP reconstructive surgery carries an unacceptably high rate of POP recurrence. Thus, and in spite of the relative lack of evidence-based information regarding long term efficacy and safety, the use of mesh grafts for POP vaginal reconstruction is growing rapidly. There is also considerable debate regarding the place of vaginal hysterectomy in POP surgery.[35-49]

Presented here is the peri-operative data regarding 459 advanced POP patients, being at risk for recurrence with conventional non-mesh POP repair operations. All had anterior or posterior Prolift® mesh implantation, 85 (18%) of them had both. Hysterectomies were not performed unless for indications other then uterine prolapse or upon patient's request. At the end of the first post-operative year was the failure rate 4% (17 Pts) with cumulative patient overall outcome satisfaction of 92% (423 Pts). The relatively low mesh vaginal protrusion incidence was achieved by implementation of some surgical steps, designed to avoid such.[50] Rates of post operative persistence and de-novo fecal constipation, urine flow obstruction, bladder over activity and dispareunia were found to be at rather low levels. Unfortunately, comparison of these to other operation for POP cure is not feasible on the grounds of lace with relative solid data. No significant or un-curable negative long term influence on patient's well being was recorded. Conservation of the prolapsed uterus does not seem to carry any deleterious effects, and probably the contrary is true. This includes shortening of hospitalization and recovery periods reducing potential hysterectomy related adverse outcome, including psychological and physical. Preservation of the prolapsed uterus permits recruitment of the residual pelvic ligamentary architecture, attached to

the uterine cervix, to the web of pelvic floor reconstruction. This is likely to further increase pelvic floor reinforcement. Pelvic floor mesh reconstruction operations involve extensive deep pelvic dissection. Hence, it is mandatory that surgeons be thoroughly familiar with the anatomy, with accurate surgical technique, potential hazards and preventive measures, and management of complications before embarking on the implantation of such meshes. It is suggested that surgeons undergo a meticulous training program with an expert prior to undertaking this procedure. [51]

Mesh implantation must be considered carefully for each potential candidate, taking into account that the ultimate goal is quality of life improvement, by correcting both the anatomical and functional derangements. It is widely agreed that mesh implantation should be further investigated prior to the retraction of recommendations regarding their usage.

CONCLUSIONS

The pelvic floor reconstruction mesh (Prolift®) operation, designed to prevent POP recurrence, provides a safe, feasible and curative surgical technique. POP reconstruction with anterior, posterior or total Prolift® was successfully achieved in 423 (92%) of 459 patients in this study group, with a reasonably low rate and severity of complications. Comparison with older operative techniques was not feasible because the absence of sufficient and solid relevant data. However, this rather new procedure, for either post-hysterectomy POP or for advanced uterine prolapse with or without uterine preservation involves potentially hazardous surgical steps, hence meticulous training is mandatory.

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Pelvic Floor Digest

*This section presents a small sample of the Pelvic Floor Digest, an online publication (**www.pelvicfloordigest.org**) that reproduces titles and abstracts from over 200 journals. The goal is to increase interest in all the compartments of the pelvic floor and to develop an interdisciplinary culture in the reader.*

FORUM

Do we see what we think we see? The complexities of morphological assessment. *Hamilton PW, van Diest PJ, Williams R, Gallagher Ag. J Pathol. EPUB: 2009-03-18.* There is a paucity of research in the field of decision-making. Understanding the complex processes involved in it is the starting point to improve both diagnostic reproducibility and the definition of diagnostic groups that underpin all our experiments. Reliable pathological interpretation for instance is vital to so many aspects of tissue-based research as well as being central to patient care. Work in this area should be encouraged since there are many opportunities and technologies available to support this type of research.

1 – THE PELVIC FLOOR

Pelvic reconstructive surgery in renal transplant recipients. *Shveiky D, Blatt A, Sokol AI et al. Int Urogyn J Pelvic Floor Dysf. EPUB: 2009-02-12.* This study describes an experience with pelvic reconstructive surgery in renal transplant recipients. Vaginal hysterectomies with vault suspension, anterior and posterior repairs, synthetic midurethral slings were safely performed without intraoperative or postoperative complications.

2 – FUNCTIONAL ANATOMY

Increased colonic transit in rats produced by a combination of a cholinesterase inhibitor with a 5-HT(4) receptor agonist. *Campbell-Dittmeyer K, Hicks GA, Earnest DL et al. Neurogastroenterol & Motil. EPUB: 2009-02-13.* The acetylcholinesterase inhibitor neostigmine and the 5-HT(4) receptor partial agonist tegaserod have a prokinetic activity and increase ACh at cholinergic synapses innervating intestinal smooth muscle. In combination, low doses of the two agents which did not produce significant effects alone, cause, as a synergistic effect, significant increase in fecal pellet output in rats. Combinations of higher doses did not display synergy. This may be a useful therapeutic approach to treat conditions associated with slow GI transit.

Influence of naloxone on rectal sensorimotor function in health. *Geeraerts B, V Oudenhove L, Vos R, et al. Neurogastroenterol & Motil. EPUB 2009-02-19.* Endogenous opioids are involved in both the regulation of gut motility and the processing of sensory information. Abnormal rectal motor physiology and visceral hypersensitivity are implicated in the pathogenesis of irritable bowel syndrome. The suppression of endogenous opioid function by naloxone on rectal sensorimotor function was studied in 18 healthy subjects with a rectal barostat. Naloxone does not alter rectal sensitivity but abolishes rectal adaptation in response to repeated balloon distention. These observations suggest that the endogenous opioid system is involved in control of rectal tone rather than rectal sensitivity.

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