Original article

Pelvic organ prolapse repair with Prolift® mesh: a prospective study

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Abstract: Our objective was to evaluated anatomical and symptom specific outcome measures of prolapse repair with prolift mesh®. In this longitudinal prospective observational study we collected data on a total of 64 women with International Continence Society pelvic organ prolapse stage 2 or more. In the anterior prolift group, objective success rate for the anterior compartment was 85.7% and 88.9% at 6 and 12 months respectively. The posterior prolift corrected vault and posterior compartments successfully in 85.2% and 78.9% respectively and the total prolift mesh had a success rate of 82.6% and 81.3% respectively. Bladder injury occurred in 6.3% and one patient required a blood transfusion. The mesh erosion rate was 4.7%. De novo bladder symptoms developed postoperatively in 9.4% of the women. P-QOL and UDI-6 scores improved significantly at 6 and 12 months follow up in all groups ($p<0.001$). Vaginal surgery with prolift mesh® is an effective and safe procedure to correct pelvic organ prolapse over one year follow up.

Key words: Pelvic organ prolapse; Prolift; Tension-free vaginal mesh; TVM.

INTRODUCTION

The long term durability of conventional surgical repair of vaginal prolapse has been questioned in recent years. In a frequently quoted publication Olsen et al.[1] estimated that the lifetime risk (up to age 80 years) of undergoing surgery for vaginal prolapse was 11%. Between 29% and 40% of prolapse surgery is for recurrence [1, 2] and in 60% of re-operations the prolapse is at the site of the original procedure.[3] There is no widely accepted and standardised technique for the management of recurrent prolapse. Multiple surgical techniques have evolved each supported enthusiastically by their proponents and some of the techniques involve the use of synthetic mesh material. The abdominal sacral colpopexy with mesh is well accepted and has been found to be superior to the vaginal sacrospinous ligament suspension for correcting upper compartment prolapsed.[4-6] However, little comparative data are available suggesting the superiority of vaginal prolapse repair with mesh overlay.[7-9] Despite this lack of long term data, the use of vaginally implanted mesh to correct the perceived poor durability of conventional surgery is expanding rapidly due to the enthusiastic marketing of surgical mesh kits with a perceived simplicity of use. Currently most information on the outcomes of vaginal surgery with synthetic implants comes from short term follow up [10-12] or exists in non-peer review publications such as conference abstracts.[13, 14] This paper describes a prospective cohort study using monofilament polypropylene mesh kits (Gynecare Prolift®, Ethicon, Somerville, NJ, USA) for the management of vaginal prolapse over the first year of implantation including complications, anatomical success rates and functional outcomes using longitudinal QOL data.

MATERIALS AND METHODS

Sixty four women were recruited between July 2005 and June 2007 for transvaginal pelvic floor repair with mesh in a single urogynaecology practice. Before surgery, all women underwent an assessment for prolapse at maximal straining in the semi recumbent position using the pelvic organ prolapse quantification system (POP-Q). The examination conformed to the standards recommended by the International Continence Society.[15] Urodynamic studies were performed when bladder symptoms were present. Inclusion criteria were a POP-Q stage ≥ 2 with recurrent prolapse or cases that were judged to be at significant risk of failure of conventional repair in view of their activity level, employment history or associated conditions such as chronic pulmonary disease and constipation. Satisfactory physical and mental health and fluency in English on order to complete the questionnaires were also required. Postoperative surgical outcomes were evaluated by the operating surgeon (MIF) and patients were invited for review at 6 and 12 months after surgery. With regards to anatomical outcome, a POP-Q stage 2 or more on follow up was considered a surgical failure irrespective whether the patient complained of symptoms. We used the prolapse quality of life questionnaire (P-QOL) [16] and the short version of the urogenital distress inventory (UDI-6) [17] to assess subjective outcomes. Prolapse-related bowel symptoms were estimated based on five bowel specific questions extracted from the P-QOL questionnaire.

Some points of surgical technique

Tension free vaginal mesh kits for anterior, posterior or total repair were utilised according to the general manufacturer guidelines for Gynecare Prolift®. We also adhered to the following principles:

– Patients were given ev antibiotic prophylaxis at induction of anaesthesia and oral antibiotics for 5 days post operatively.

– The operative field was cleaned with iodine antiseptic solution following our routine practice. The mesh was not washed in any antibiotic solution nor handled in any special manner.

– Vaginal tissues were liberally infiltrated with a 0.125% solution of marcain with adrenaline 1:800,000 prior to dissection. Up to 40ml of solution was used in each compartment.

– Short surgical incisions were made where possible and care was taken to keep the endopelvic fascia adherent to the vaginal skin by careful dissection.

– The mesh was placed completely tension free and was not divided in case of total Prolift®.

– There was minimal fixation of mesh at the bladder neck and the vaginal vault only with 2-0 polydioxone sutures (PDS - Ethicon).

– In case of posterior Prolift the lower third of the vagina was kept free of mesh. Low rectovaginal fascia defects were repaired with two layers of 2-0 PDS. There was no corresponding fascial repair of the anterior compartment.

– The vaginal incisions were closed loosely with a continuous non-locking 2-0 polyglactine suture.

– An indwelling catheter and lubricated vaginal pack were inserted after the procedure and removed 24 hours later.

A more detailed description of the surgical technique and anatomical landmarks are published elsewhere.[11, 18]

Descriptive statistics were used on demographic and surgical characteristics. Between groups comparison of non-parametric skewed dependent variables were performed using the Wilcoxon matched-pairs test and with a significance level of 0.1%. All data were analysed with SPSS software (SPSS inc., Chicago, Illinois, USA).

This study was approved by the Human Research Ethics Committee of the Gold Coast Hospital, Queensland, Australia and followed the Declaration of Helsinky (approval number 200546).

RESULTS

Fourteen patients were found suitable for pelvic floor repair with anterior vaginal mesh, 27 underwent repairs with posterior vaginal mesh and in 23 cases the total Prolift® mesh kit was used. The mean age in our study population was 60.1 ± 9.0 (SD), mean BMI was 26.0 ± 3.4 (SD) and median parity was 2 (range 0-5). In the anterior mesh group, 28.5% (4/14) of the patients has had previous anterior compartment repairs. In 40.7% (11/27) of the posterior mesh group and 8.7% (2/23) of the total mesh group a previous repair had been performed in the respective compartment that was subsequently reinforced with mesh. In total, 41 patients (64.1%) had previous pelvic floor surgery which was dominated by hysterectomy (57.8%), vaginal wall repairs (34.4%) and surgery for urinary incontinence (14.1%). Demographics are summarized in table 1 and listed per type of surgery performed.

We performed concomitant vaginal surgery in 43.8% (28/64) of the cases including a vaginal hysterectomy in 14.1% (9/64), anterior or posterior fascial repairs in 10.9% (7/64) and suburethral tapes for stress urinary incontinence in 25% (16/64). Intra-operatively, four bladder injuries occurred (6.3%) including one bladder puncture with a trans obturator trocar and three cystotomies during dissection. The trocar was withdrawn from the bladder and replaced. The cystotomies were repaired in two layers intra-operatively and the mesh repair completed. An indwelling catheter was left for 48 hours in these cases. One patient suffered a significant haemorrhage (>500 ml) from the obturator area requiring a blood transfusion.

Post-operatively, one patient was taught intermittent self catheterisation for short term urinary retention. A suburethral tape for stress urinary incontinence had been inserted at the time of repair. Three mesh exposures (4.7%) were diagnosed over the time of follow up two of which were diagnosed only at 12 months after surgery. The exposed mesh areas were surgically excised in a day case setting. Four patients (6.3%) reported dyspareunia after vaginal mesh repair. Three cases settled within the first six months of follow up and one patient required division of an arm anchored through the sacrospinous ligament of a total Prolift® mesh for relief. De novo bladder symptoms were found in six patients (9.4%) postoperatively. Two women (3.1%) presented with de novo stress urinary incontinence after total prolift mesh repair and underwent a subsequent successful suburethral tape surgery. Four patients (6.3%) suffered with short term de novo urgency and were treated conservatively with exercises and anticholinergic therapy. Surgical characteristics as well as postoperative complications are summarised in table 2. The objective anatomical success rate for the anterior compartment in the anterior Prolift® group was 85.7% (12/14) at 6 months follow up. The two patients considered as failures developed a POPQ stage 2 cystocele. One of them was also diagnosed with a stage 2 rectocele at the same time. Nine patients of the anterior prolift group were available for 12 months postoperative review. All presented with unchanged POPQ measurements except for one patient who developed a stage 2 rectocele. Twelve months after surgery, the objective success rate for anterior vaginal mesh repair was therefore 88.9% (8/9) for the anterior compartment alone and 77.8% (7/9) when taking all vaginal compartments into consideration. POPQ measurements per compartment are listed in table 3. We registered significant improvement in median POPQ measurements for the anterior and middle compartment at 6 and 12 months in the anterior mesh group. For the posterior mesh group, prolapse of the posterior and middle compartment was successfully corrected in 85.2% (23/27) at 6 months follow up. Seven patients developed recurrent prolapse of the anterior compartment of whom two underwent a subsequent successful anterior mesh repair. At the 12 months postoperative review, two women (2/19) were found to have de novo stage 2 rectocele and cystocele respectively. The POPQ score for all other women was not

TABLE 1. – *Demographics*.

Total group n = 64	***Anterior mesh n = 14***	***Posterior mesh n = 27***	***Total mesh n = 23***
Age mean ± SD	62.4 ± 9.1	62.4 ± 9.0	56.2 ± 7.0
BMI mean ± SD	25.5 ± 4.0	26.4 ± 3.1	26.2 ± 3.3
Parity median (range)	2 (1-4)	2 (0-5)	2 (0-5)
Previous surgery: n (%)			
– None	3 (21.4)	5 (18.5)	15 (65.2)
– Hysterectomy	9 (64.3)	21 (77.8)	7 (30.4)
– Vaginal repairs	7 (50)	13 (48.1)	2 (8.7)
– Vault suspension	1 (7.1)	1 (3.7)	0
– Colposuspension (Burch)	2 (14.2)	3 (11.1)	0
– Suburethral tape	2 (14.2)	2 (7.4)	0

TABLE 2. – *Surgical characteristics including concomitant surgery, inter and post operative complications*.

	Anterior mesh n = 14	***Posterior mesh n = 27***	***Total mesh n = 23***
Concomitant surgery: n (%)			
– vaginal hysterectomy	1 (7.1)	0	8 (34.8)
– anterior colporraphy	0	4 (14.8)	0
– posterior colporraphy	3 (21.4)	0	0
– Suburethral tape	3 (21.4)	7 (25.9)	6 (26.0)
Per operative complications: n (%)			
– cystotomy	2 (14.3)	1 (3.7)	1 (4.3)
– haemorrhage > 500 ml	0	0	1 (4.3)
Post operative complications: n (%)			
– CISC	0	0	1 (4.3)
– mesh erosion	1 (7.1)	1 (3.7)	1 (4.3)
– dyspareunia	2 (14.3)	0	2 (8.7)
– de novo SUI	0	0	2 (8.7)
– de novo urgency	1 (7.1)	3 (11.1)	0
– RUTI	0	1 (3.7)	0

CISC: clean intermittent self catheterisation; RUTI: recurrent urinary tract infections.

TABLE 3. – *Pelvic organ prolapse quantification measured in cm and ordinal stages at baseline, 6 and 12 months postoperative follow up for anterior Prolift® mesh repair.*

Pelvic component	*Pre-operative n = 14*	*6 months postoperative n = 14*	*P value **	*12 months postoperative n = 9*	*P value **
Anterior					
Aa	2.5 (–2 to 3)	–2.5 (–3 to 0)	.001	–2 (–3 to –1)	.007
Ba	3 (0 to 4)	–3 (–3 to –1)	.001	–3 (–3 to –2)	.007
Stage	3 (2 to 3)	1 (0 to 2)	.001	1 (0 to 2)	.007
Posterior					
Ap	–2.5 (–3 to 0)	–3 (–3 to –1)	.176	–3 (–3 to –1)	.236
Bp	–3 (–3 to –2)	–3 (–3 to –1)	.206	–3 (–3 to –2)	.046
Stage	1 (0 to 2)	0 (0 to 2)	.140	0 (0 to 2)	.129
Middle					
C	–5.5 (–8 to 1)	–8 (–9 to –5)	.005	–8 (–9 to –8)	.007
D	–9 (–9 to –5)	–9 (–9 to –8)	.157	–9 (–10 to –8)	.102
Stage	1 (0 to 2)	0 (0 to 1)	.003	0 (0)	.007
gh	5.5 (4 to 8)	5 (4 to 6)	.017	5 (4 to 6)	.317
pb	3 (2 to 6)	4 (3 to 5)	.341	4 (3 to 4)	.041
tvl	9 (8 to 10)	9 (8 to 10)	.414	9 (8 to 10)	.317

gh: genital hiatus; pb: perineal body; tvl: total vaginal length. All figures are median (range). * Wilcoxon matched-pairs test ($p < 0.001$).

significantly different from their previous 6 months postoperative assessment. The objective success rate for posterior vaginal mesh repair at 12 months was 78.9% (15/19) considering the middle and posterior compartment separately and 63.2% (12/19) when taking all vaginal compartments into account. These findings are reflected in the calculation of the POPQ stage for the middle and posterior compartment that were significantly improved at 6 and 12 months and listed in table 4. Prolapse in the total mesh group was successfully corrected in 82.6% (19/23) at 6 months follow up. Two women were diagnosed with a recurrent cystocele, one with a rectocele and one with significant uterine descent. At 12 months postoperative review, the objective success rate was still 81.3% (13/16) and with one recurrent cystocele in the group. Median POPQ scores for the total prolift mesh group are summarised in table 5. All three vaginal compartments measured a median POPQ score that was ≤ 1 (range: 0-3) at 6 and 12 months after surgery. Results of the prolapse quality of life questionnaire (P-QOL) are shown in table 6. Scores were combined and transformed into nine health dimensions, with a potential score between 0 and 100. Lower scores indicating a better perceived quality of life. At 6 months, outcome for all groups improved significantly except for women's general health perception, social limitations and personal relationship domains and these findings remained stable at 12 months review. Five bowel symptom specific questions could be extracted from the P-QOL questionnaire. Answers

TABLE 4. – *Pelvic organ prolapse quantification measured in cm and ordinal stages at baseline, 6 and 12 months postoperative follow up for posterior Prolift® mesh repair.*

Pelvic component	*Pre-operative n = 27*	*6 months postoperative n = 27*	*P value **	*12 months postoperative n = 19*	*P value **
Anterior					
Aa	–3 (–3 to 0)	–3 (–3 to 2)	.921	–3 (–3 to 0)	.257
Ba	–3 (–3 to 0)	–3 (–3 to 2)	.746	–3 (–3 to –1)	.317
Stage	1 (0 to 2)	0 (0 to 3)	.409	0 (0 to 2)	.059
Posterior					
Ap	2 (–3 to 3)	–3 (–3 to 0)	.000	–3 (–3 to 0)	.000
Bp	2 (–3 to 5)	–3 (–3 to 0)	.000	–3 (–3 to 0)	.000
Stage	3 (0 to 3)	0 (0 to 2)	.000	0 (0 to 2)	.000
Middle					
C	–3 (–9 to 4)	–9 (–10 to –6)	.000	–9 (–10 to –6)	.000
D	–4.5 (–9 to 4)	–9.5 (–10 to –9)	.068	–10 (–10 to –9)	.109
Stage	1 (0 to 3)	0 (0 to 1)	.000	0 (0 to 1)	.000
gh	5 (4 to 8)	5 (3 to 6)	.000	4 (3 to 6)	.002
pb	4 (2 to 6)	4 (3 to 7)	.006	4 (3 to 7)	.114
tvl	9 (7 to 10)	9 (7 to 10)	.480	9 (7 to 10)	.705

gh: genital hiatus; pb: perineal body; tvl: total vaginal length. All figures are median (range). * Wilcoxon matched-pairs test ($p < 0.001$).

TABLE 5. – *Pelvic organ prolapse quantification measured in cm and ordinal stages at baseline, 6 and 12 months postoperative follow up for total Prolift® mesh repair.*

Pelvic component	*Pre-operative n = 23*	*6 months postoperative n = 23*	*P value **	*12 months postoperative n = 16*	*P value **
Anterior					
Aa	3 (–2 to 3)	–2 (–3 to 1)	.000	–2 (–3 to –1)	.000
Ba	4 (–3 to 6)	–3 (–3 to 3)	.000	–3 (–3 to –2)	.000
Stage	3 (1 to 3)	1 (0 to 3)	.000	1 (0 to 2)	.000
Posterior					
Ap	0 (–2 to 2)	–3 (–3 to –1)	.000	–3 (–3 to –1)	.000
Bp	–1 (–3 to 6)	–3 (–3)	.000	–3 (–3)	.001
Stage	2 (1 to 3)	0 (0 to 2)	.000	0 (0 to 2)	.001
Middle					
C	0 (–7 to 8)	–9 (–10 to 3)	.000	–9 (–10 to –5)	.000
D	–5.5 (–8 to 2)	–9 (–10 to –2)	.017	–9 (–8 to –9)	.068
Stage	2 (1 to 3)	0 (0 to 3)	.000	0 (0 to 1)	.000
gh	6 (4 to 8)	4 (3 to 6)	.000	4 (3 to 5)	.001
pb	4 (2 to 6)	4 (4 to 6)	.004	4 (3 to 5)	.265
tvl	9 (9 to 10)	9 (8 to 10)	.166	9 (8 to 10)	.157

gh: genital hiatus; pb: perineal body; tvl: total vaginal length. All figures are median (range). * Wilcoxon matched-pairs test ($p < 0.001$).

ranging on a scale from 'not at all', 'little', 'moderate' to 'a lot' were transformed into scores between 0-3 and their median outcomes are summarised in table 7. At 6 as well as 12 months from baseline, the sensation of a bulge interfering with defecation and the feeling of incomplete emptying improved significantly.

We divided the UDI-6 questionnaire in three bladder specific subgroups including irritative symptoms, stress urinary symptoms and symptoms of voiding obstruction/discomfort. Outcomes were converted to a score between 0-100 with a lower score representing less symptoms. At 6 months follow up, irritative symptoms as well as obstructed voiding/prolapse discomfort were significantly improved. It was mainly the reduction in obstructive/discomfort symptoms that contributed to a significant improvement of the total score at 12 months (Tab. 8).

DISCUSSION

Dissatisfaction with conventional surgical repair of prolapse has led over the last decade or so to the use of vaginally implanted mesh to reduce recurrences, which is been a problem especially for the anterior compartment and the vault following hysterectomy. The success of mesh use in general surgical hernia repair seems to have added impetus to this increase. Regardless of the modifications in technique, choice of suture material and changes in peroperative care, the risk of recurrence of inguinal and abdominal hernia repair is high if mesh is not used. Since the introduction of mesh the failure rate of hernia repairs has decreased markedly.[19, 20] Of course it is one thing to implant artificial material in the groin or abdominal wall and quite another to introduce a potentially irritant material into a structure such as the vagina. Lessons have been from experiences with the tension free suburethral tape which is by now one of

TABLE 6. – *Prolapse - Quality of life.*

P-QOL	*Pre-operative*	*6 months postoperative*	*P value **	*12 months postoperative*	*P value **
Madian (range)	n = 49	n = 47		n = 32	
General Health	25 (0 - 100)	0 (0 -100)	.268	0 (0 -50)	.021
Prolapse Impact	66.7 (0 - 100)	0 (0 - 100)	.000	0 (0 - 66.7)	.000
Role Limitation	33.4 (0 - 100)	0 (0 - 66.7)	.000	0 (0 - 16.7)	.000
Physical limitation	33.4 (0 - 100)	0 (0 - 66.7)	.000	0 (0 - 33.4)	.000
Social Limitation	0 (0 - 100)	0 (0 - 55.6)	.002	0 (0 - 16.7)	.007
Personal Relationship	16.7 (0 - 100)	0 (0 -100)	.003	0 (0 - 66.7)	0.112
Emotions	22.2 (0 -100)	0 (0 - 77.8)	.000	0 (0 - 22.2)	.000
Sleep / Energy	25 (0 - 100)	16.7 (0 - 66.7)	.000	8.3 (0 - 33.3)	.000
Severity measures	25 (0 - 100)	0 (0 - 50)	.000	0 (0 - 25)	.000

* Wilcoxon matched-pairs test ($p < 0.001$).

TABLE 7. – *Bowel specific questions.*

Bowel symptoms	*Pre-operative*	*6 months postoperative*	*P value **	*12 months postoperative*	*P value **
Madian score (range)	n = 51	n = 49		n = 33	
Vaginal bulge interfering with you emptying your bowels	1 (0 - 3)	0 (0 - 2)	.000	0 (0 - 3)	.000
Straining to open bowels	1 (0 - 3)	0 (0 - 3)	.001	0 (0 - 3)	.002
Bowels do not feel completely empty after opening	1 (0 - 3)	0 (0 - 3)	.000	0 (0 - 3)	.000
Do you help emptying your bowels with your finger	0 (0 - 3)	0 (0 - 2)	.055	0 (0 - 1)	.023
Constipation; difficulty in emptying your bowels	1 (0 - 3)	0 (0 - 3)	.038	0 (0 - 3)	.027

* Wilcoxon matched-pairs test ($p < 0.001$).

TABLE 8. – *Urogenital distress inventory – 6.*

UDI-6	*Pre-operative*	*6 months postoperative*	*P value **	*12 months postoperative*	*P value **
Madian score (range)	n = 51	n = 49		n = 33	
Irritative symptoms	11.1 (0 – 33.3)	0 (0 – 27.8)	.000	5.7 (0 – 33.3)	.025
Stress symptoms	5.6 (0 – 33.3)	5.6 (0 -27.8)	.219	0 (0 – 22.2)	.119
Obstruction / discomfort	16.7 (0 – 33.3)	0 (0 – 16.7)	.000	0 (0 – 16.7)	.000
Total score	33.3 (0 – 100)	11.1 (0 – 61.1)	.000	11.1 (0 – 38.9)	.000

* Wilcoxon matched-pairs test ($p < 0.001$).

the most thoroughly investigated and documented minimal invasive procedures to treat stress urinary incontinence.[21] The use of type I monofilament polypropylene mesh with large poor sizes is currently recommended to reduce complications such as mesh erosion, extrusion, inflammation or infection.[22, 23] Nevertheless, in our current state of knowledge enthusiastic reinforcement of entire vaginal compartments with synthetic material should not an cannot be recommended uncritically. Its use may cause change in functionality and will confront us with potential dilemmas in case of surgical failure.

This study reports on 64 women who underwent pelvic floor reconstructions with anterior, posterior or total mesh reinforcement. The overall cure rate at 6 and 12 months respectively was 85.7% and 88.9% for the anterior Prolift® group, 59.3% and 63.2% for the posterior Prolift® and 82.6% and 81.3% for the total Prolift® group. In the group with Posterior Prolift® mesh, five patients (18.5%) developed de novo cystoceles. The appearance of a new prolapse in a previously well supported compartment is an issue which occurs after all prolapse surgery whether conventional or using mesh. This finding seems to be comparable to what has been reported after sacrospinous colpopexy and, given that the mesh is fixed through the sacrospinous ligament bilaterally, may well be for the same reason.[24, 25] We used an ordinal POPQ stage 2 as a definition of anatomical failure irrespective of symptoms. Because of this, a reported failure in this paper does not necessarily mean an unhappy patient. We saw improvement in all nine health dimensions of the P-QOL questionnaire which remained stable at 12 months review and also bladder and bowel specific symptoms related to prolapse improved considerably. In retrospect it would have been valuable to have included some measure of overall patient satisfaction with the mesh surgery as well as more detailed data on sexual function. Such data is beginning to emerge now and rates of dyspareunia varies from 14-36% after pelvic floor reconstruction with mesh.[22, 26] In contrast to our results, Fatton et al.[11] stated explicitly that they did not consider postoperative asymptomatic stage 2 prolapse as failure at all. As an obvious consequence their "success" rate with Prolift® was higher than we have reported. How cure is defined makes comparisons between published papers difficult and sometimes confusing. Well accepted guidelines on how success should be reported in trials of prolapse treatments would be extremely useful to researchers in the area.

But what is "cure" and how are we to define it? A woman presenting with a prolapse seldom asks for an "anatomical cure". What she wants is a resolution of her symptoms of a vaginal lump as well as a resolution of any associated bowel and bladder dysfunction. A woman who is sexually active clearly does not want a new problem of painful intercourse. A perfect result is sometimes not achievable in out current state of knowledge – perhaps a perfect result may never be achievable. A colpocleisis is a classic example of a very "non-anatomical" treatment that nevertheless has high satisfaction rates in a highly selected population.[27] So if we do not need to produce a perfect anatomical result to resolve symptoms, what in that case is "cure"?

If we suggest that cure is complete resolution of current symptoms without the production of new problems then we may be setting ourselves a very high bar indeed. In case of the celebrated TVT versus colposuspension study of Ward and Hilton,[28] if cure was defined in this way, then the TVT "cured" only 9% and colposuspension 6% of patients.[29] Hilton's comments in the same paper regarding the difficulties of performing studies on the surgical outcome of stress incontinence procedures have equal relevance to prolapse

surgery. Hilton emphasised the need for a multidimensional approach to the evaluation of continence. He suggests no single outcome measure is likely to be adequate to summarise the effects of treatment. If this is true for stress incontinence it is likely to be even truer for the complexity of prolapse repair outcomes.

In our series, surgical complication rate directly related to the use of mesh placed with trocars was 3.1% (2/64) including one bladder piercing and one haemorrhage from the obturator area. Thorough but careful dissection of the surgical field is believed to be a key element contributing to the reduction of trauma to surrounding organs and a Breisky-Navratil retractor was used where appropriate for extra protecting of bladder and bowel. While the three cystotomies that had occurred during dissection did not cause the surgeon to refrain from mesh use after repair, we believe that mesh should never be introduced in a potential contaminated area as would be the case after a proctotomy.

Concerns continue to be voiced regarding risks of chronic infection, mesh erosion or exposure [30] and the potentially disastrous consequences of mesh within a hollow viscus such as the bladder or rectum. We found only minor instances of mesh exposure in our follow up and all were easily managed with excision and suture resulting in complete resolution of symptoms. None of the mesh erosions in our series were in association with a hysterectomy. Since we performed vaginal hysterectomy in only 9 out of 64 patients our study may be too small to make any definitive comment on whether concomitant hysterectomy increases the risk of mesh exposure. The intervention needed to repair failure would be far more significant. Commentators continue to persistently fear mesh exposure more than the substantial procedure required for recurrence.

We are well aware of some of the deficiencies in our paper. A decrease in study population after prolonged follow up is a common problem which was also the casein this study. Secondly, for convenience, all follow up examinations were performed by the operating surgeon which may be a source of potential bias. We would make the point that many previously reported studies do not specify the status of the post operative assessor at all. Nevertheless, it is one of the first case series of its kind with medium term follow up.

CONCLUSIONS

This prospective study confirms the intra-operative safety of the Prolift® mesh kits for prolapse correction. Follow up at one year shows minimal serious morbidity, continued anatomical support and significant improvement in QOL measures. Large randomised trials of conventional surgery versus mesh insertion will be necessary to answer detailed questions of efficacy, both anatomical and functional. Of necessity such trials will require to be large, probably multicentre and expensive to mount.

CONFLICTS OF INTEREST: None.

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