CHAPTER 21

Committee 17

Surgery for Pelvic Organ Prolapse

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I. INTRODUCTION

Pelvic organ prolapse (POP) is a common condition in women and its surgical treatment is one of the most common surgical indications in women. Using data from a large US northwest health maintenance organization database, Olsen et al reported the risks of POP or urinary incontinence surgery by age 80 is 11.1 [1]. Surgery for POP with (22%) or without (41%) continence surgery accounted for 63% of this risk, or a lifetime risk of 7.0%. Boyles et al reported that over a nearly twenty-year period reviewed, the rate of procedures decreased slightly, but not significantly and that the surgical indication for approximately 7-14% of hysterectomies is listed as POP. Data from the US National Hospital Discharge Survey (NHDS) data indicates that approximately 200,000 women undergo POP surgery annually [2].

Concomitant surgery is common at time of POP repair. Multiple authors have documented that slightly more than 50 percent of patients with POP had more than one procedure performed during a single surgery [2, 3]. Brown et al presented US data from the National Hospital Discharge Survey (NHDS) for surgical rates [3], indicating that approximately 22.7 per 10,000 women had some form of POP surgery in one year. Approximately 21% of these women had concomitant continence surgery. As expected, surgical rates varied with age, peaking in the sixth decade with an average age at surgery of 55 years. Racial differences were also reported with Caucasian women having a 3-fold greater rate of POP surgery than African-American women. In the US, women in the South had a 2-fold higher rate of surgery than those in the Northeast. A report from the United Kingdom Oxford Family Planning Association Study reviewed more than 17,000 women (1968-1994), finding that the incidence of surgical repairs was 1.62 per 1000 person-years.

Waetjen et al reported US NHDS data for 1998 continence surgery rates [4]. The rate of surgery was 13.4 per 10,000 women, and approximately one third had concomitant POP surgery. Subak et al estimated that annual direct cost of POP surgery in the United States was approximately $1012 million [5].

POP surgery is common, costly and often performed with other procedures. Rectal prolapse is an important form of pelvic organ prolapse and it surgical treatment will be included in the next edition of this text. This chapter will review the state of scientific evidence regarding genito-urinary POP surgery.

II. INDICATIONS FOR POP SURGERY

POP symptoms are often vague and it may be difficult to correlate specific symptoms with the site or severity of POP [6]. Symptoms of POP may overlap from one compartment to the next and include – a sensation of pelvic pressure or vaginal ‘heaviness’, recurrent irritative bladder symptoms, voiding difficulty, incontinence or defecatory difficulty. Other symptoms such as low back or pelvic pain may or may not be related to POP. Any or all of these symptoms may be an indication for POP surgery despite the fact that there are scant data correlating these symptoms with anatomical findings. The level of evidence to support the claim that surgery consistently alleviates these problems is poor.

Stage II prolapse is common in vaginally parous women (see Chapter on Physical Examination) and it is unlikely that the risk of POP repairs is warranted

for minor symptoms. More than two thirds of parous women have objective evidence of POP on clinical examination. The majority of these defects are asymptomatic and fewer than 15% of them will require surgical intervention [7, 8]. Surgery for prolapse repair is also indicated when pessary treatment is unsuccessful or complicated by refractory ulcerations or erosions.

III. SURGICAL ROUTE

1. Selection of surgical route

There are hundreds of individual procedures described for the correction of POP, but there are only two routes of access for POP surgery, abdominal or vaginal. Variations on the specific techniques employed for vaginal or abdominal access (for example, vaginal trans-obturator access or abdominal laparoscopic access) do not change the facts that 1) patients are usually positioned on the operating table with the surgeon's intent to complete the procedure via either the vaginal or abdominal route and 2) surgeons rarely change their route of access in mid-operation. The primary goal of this section is to examine the evidence on which to base the decision regarding the route of surgery, the first critical decision made by a surgeon after a woman has decided to proceed with surgery for her prolapse.

2. Risk Factors for POP and Their Relationship to the Choice of Surgical Route

Experts believe that it is important to understand the specific risk factors for an individual patient, as this may affect decisions about surgical planning. There are limited data regarding risk factors for POP recurrence after surgery but expert opinion supports the concept that there are certain women who are at high risk for primary and/or recurrent POP. It has been hypothesized that POP results from a continuum of predisposing, inciting, promoting, and decompensating factors[7]. The major accepted inciting factors (vaginal childbirth and hysterectomy) are unlikely to occur after POP surgery and the most common decompensating factors (aging, debility, comorbidities) primarily influence surgical risk and will not be considered here.

Although infrequently documented in the medical literature, overt anatomic and neurological abnormalities, such as bladder exstrophy [9, 10] or myelodysplastic lesions [11, 12] are commonly recognized by experienced clinicians as being associated with early onset POP, often without a classical inciting event. There is also evidence that variations in collagen synthesis and structure that may place individuals at increased risk for pelvic floor disorders [13-15].

Also infrequently documented but commonly discussed is prolapse occurring in young women [16] and in nulliparous women [17]. While such women with POP have been demonstrated to be more likely to have some identifiable risk characteristics (congenital anomalies, neurological disease, connective tissue disease; [16] than older or parous women, for most no obvious clinical risk factor is identified [16, 17]. Nonetheless, while no risk factors may be obvious, the surgeon needs to consider what unknown factor(s) predisposed the young or nulliparous woman to develop POP and how these factors might predispose to POP recurrence. This concern is supported by a recent report that age less than 60 years significantly increased the risk of recurrent prolapse one year after vaginal surgery (OR 3.2, 95% CI 1.6, 6.4, p=.001) [2]. In addition, consideration should be given to the fact that a 35-year-old woman's prolapse surgery will likely need to work several decades longer than a 65 year old woman's surgery.

In summary, women with known predisposing factors for POP or those with characteristics suggesting that they may have unknown predisposing factors may be candidates for the route and combination of procedures that prove most durable for their specific support defects.

• Status of Current Practice

Epidemiologic reports of POP surgery have provided some data regarding route of surgery [1-3]. Reports by Brown (2002) and Boyles (2003) calculated that the number of prolapse surgeries performed in the United States in 1997 was between 205,000 and 226,000. **Table 1** lists the route of prolapse surgery in these three reports. It shows that, when the route could be determined, 80 to 90% of women had their surgery performed via the vaginal route. The obvious limitations of these studies is that all women with prolapse and procedures for prolapse were identified using International Classification of Diseases 9th Revision (ICD-9) codes applied to large databases and the severity of prolapse or the appropriateness of the surgery cannot be verified. Nonetheless, these data provide consistent high-quality epidemiological evidence that the preferred route for most prolapse surgery in the United States is vaginal.

Table 1. Route of prolapse surgical procedures reported in three epidemiological studies from the United States

	Olsen (1997)	Brown (2002)	Boyles (2003)
Total	470[a]	225,964[b]	127,000[c]
Vaginal route	423 (90%)	119,731 (53%) 1	01,000 (80%)
Abdominal route	47 (10%)	13,340 (6%)	26,000 (20%)
Cannot determine route		92,893 (41%)	

[a]Number of individual procedures for prolapse performed in 234 women

[b]Number of women undergoing prolapse surgery in 1997

[c]Number of women undergoing prolapse surgery who had abdominal or vaginal hysterectomies in 1997

3. Level One Evidence for Higher Anatomic Efficacy with Abdominal Route of Surgery

There are four randomized controlled trials designed with the specific aim to compare vaginal and abdominal routes for the surgical correction of POP [18, 19]. Two of these studies provided sufficient information for further analysis and the major outcomes are summarized in **Table 2**. The landmark study by Benson et al demonstrated that the abdominal route was significantly more likely to be associated with an optimal result 1 to 5.5 years (mean 2.5 years) after surgery compared with the vaginal route. However, differences between the two routes were not significant for the rate of combined optimal/satisfactory outcomes, rate of unsatisfactory outcome, or rate of re-operation, although numerically all of these rates favored the abdominal route.

The study was stopped prematurely given that the interim analysis revealed a "disparity between the groups" after 124 women were randomized over the course of the 26.5 months study. Of the 101 randomized, 10 decided against surgery after randomization, 3 refused their abdominal route randomization assignment, and 8 were not available for long-term evaluation, leaving a sample size of 80 women. A significant proportion of participants who were randomized to the abdominal group also had vaginal procedures performed (anterior colporrhaphy 30% and posterior colporrhaphy 50%). Finally, the specific primary prolapse procedures performed (vaginal group: bilateral sacrospinous suspension [20], vaginal paravaginal repair [20], and Pereyra needle urethropexy [21]; Abdominal group: Sacrocolpopexy [22], retropubic paravaginal repair [23], and Burch colposuspension [24] were likely more responsible for any differences in outcome than the surgical route.

The combination of a needle urethropexy and sacrospinous ligament suspension has been shown to predispose to the early development of prolapse of the upper anterior vaginal segment and failure of bladder neck support [25]. Bonney (1934) cautioned 70 years ago that fixed vaginal retroversion predisposes to anterior segment prolapse. Other investigators have echoed this concern with respect to sacrospinous ligament suspensions due to the resulting exaggerated retroversion of the vagina exposing the anterior segment to increased pressure[25-28]. The prevalence of cystocele from one to five years after sacrospinous vault suspension has been reported to be 16-18 percent, [26, 29]36% [25] and 92 percent [28]. The combination of marked retroversion of the vaginal apex resulting from the sacrospinous suspension and the marked anterior deflection of the anterior segment resulting from the needle bladder neck suspension and paravaginal repair place inordinate stresses on the upper anterior vaginal wall leading to much earlier and more severe recurrent anterior segment prolapse, evident in 12 of 14 cases requiring re-operation in the Benson series. Thus, the only randomized comparison of vaginal and abdominal routes of prolapse surgery used a combination of vaginal procedures associated with a predisposition for recurrent prolapse, a combination publicly abandoned by one group of surgeons [25].

Other outcomes and complications are compared in **Table 3**. Prolonged catheter use, urinary tract infection, postoperative urinary incontinence and dyspareunia were all significantly more common in the women who underwent the vaginal procedures. Women in the vaginal group, who experienced recurrent POP, also experienced their recurrence significantly earlier than women in the abdominal group. In contrast, women randomized to the abdominal group had significantly more potentially serious complica-

Table 2. Primary efficacy outcomes from the RCT by Benson (1996)

Outcome	Abdominal Route (38)	Vaginal Route (42)	P
Optimal[a]	22 (58%)	12 (29%)	
Satisfactory[b]	10 (26%)	16 (38%)	
Unsatisfactory[c]	6 (16%)	14 (33%)	
Reoperation[d]	6 (16%)	14 (33%)	
RR for Optimal Outcome[e]	2.03 (95% CI = 1.22, 9.69)		
RR for Reoperation or Unsatisfactory Outcome[e]		2.11 (95% CI = 0.9, 4.94)	
OR for Optimal Outcome[f]	3.44 (95% CI = 1.24, 9.69)		.015
OR for Reoperation or Unsatisfactory Outcome[f]		2.67 (95% CI = 0.8, 9.55)	.121

[a]No symptoms of POP + apex above levator plate + no vaginal segment beyond hymen
[b]No symptoms of POP + POP improved from preoperative status but did not meet optimal criteria
[c]Symptoms of POP with >50% apical descent or vaginal segment beyond hymen
[d]Reoperation for POP or SUI: Anterior segment (12 vaginal group; 4 abdominal group); Apical segment (5 vaginal and 1 abdominal); Posterior segment (1 vaginal group; 2 abdominal group); Continence surgery (5 vaginal group; 1 abdominal group)
[e]Relative risk based on analysis from original paper
[f]Odds ratios based on reanalysis of data from paper

Table 3. Other outcomes and complications from the RCT by Benson (1996)

	Vaginal Route (42)	Abdominal Route (38)	P
Clinical Outcomes			
Change in Hb (gm/dl)	2.6	3.0	ns
Number transfused	0	2	ns
Discomfort rating[a]	4.4	5.3	ns
Dyspareunia[ab]	15/26 (58%)	0/15	<.05
Catheter >5 days	75%	48%	<.05[c]
Febrile morbidity[a]	4%	8%	ns
Postoperative incontinence[a]	44%	23%	<.05
Time to recurrent POP	11.2 months	22.1 months	<.05
Operative Complications			
Urinary tract infection	9	0	<.05[c]
Wound infection	0	3	ns
Vaginal band requiring excision	1	0	ns
Sciatica	0	2	ns
Wound infection	0	3	ns
Cystotomy	1	1	ns
Phlebitis	0	1	ns
Obturator nerve injury	0	1	ns
Vaginal suture erosion	0	1	ns
Perioperative hemorrhage	0	1	ns
Ileus	0	1	ns
Enterotomy	0	1	ns
Total excluding UTI[d]	1	12	<.05[c]
Nonclinical Outcomes			
Hospital charges[a]	$6537	$8048	<.05
Hospital stay	5.1 days	5.4 days	ns
Operating time	196 minutes	215 minutes	<.05

[a]not defined in the manuscript [b]denominator is the number of women who were sexually active
[c]P-value not calculated in original manuscript [d]Variable not reported in original manuscript

tions and had significantly longer operation times and hospital costs than women in the vaginal group. These latter differences are particularly important when one considers that prior abdominal surgery (>2 procedures), morbid obesity, and prior inflammatory bowel or pelvic disease excluded patients from the study.

In summary, the findings of this commendable and difficult study support the superiority of the abdominal route procedures compared with the vaginal route procedures as measured by the durable restoration of anatomy and lower urinary tract and vaginal function.

The recently published study by Maher and colleagues (2004) reported that abdominal sacral colpopexy and unilateral vaginal sacrospinous suspension were equally effective in the treatment of post-hysterectomy vaginal vault prolapse with a mean follow-up of 24 months (range 6-60 months), although a review of the data presented in the paper supports anatomic superiority of the abdominal route[1]. **Table 4** summarizes the outcome data from this important study.

This study differs from that of Benson (1996) in that all subjects had already undergone hysterectomy, no patients in the vaginal group had either a needle urethropexy or vaginal paravaginal repair, and the minimum allowed duration of follow-up was 6 months (mean 22-24 months) rather than 12 months (mean 30 months). Like the earlier study, a substantial minority of patients had surgery by both routes; 11 (23%) patients from the abdominal group had posterior colporrhaphies and 15 (31%) from the vaginal group had Burch colposuspensions. Again, the comparison is between a group of procedures more than the route of surgery. The study finds the vaginal sacrospinous colpopexy and the abdominal sacral colpopexy to be equally effective in subjective,

Table 4. Outcomes from the RCT by Maher (2004)

Outcome	**Abdominal Route (47)**	**Vaginal Route (48)**	**P**
Lost to follow-up	*1 (2%)*	*5 (10%)*	*.21f*
Subjective cure[a]	43/46 (94%)	39/43 (91%)	.19
Objective cure[b]	35/46 (76%)	29/42 (69%)	.46
Satisfaction with surgery[c]	85%	81%	.78
Re-operation[d]	6/47 (13%) 6/46 (13%)	7/43 (16%)	.86[f]
Recurrent anterior and/or apical POP	OR.18 (95% CI .05, .55)[f]	19/42 (45%)	.01
Recurrent posterior POP	15/46 (33%) 2/22 (9%)	8/42 (19%)	.22
De novo stress incontinence	OR.20 (95% CI .02, 1.24)[f]	8/24 (33%)	.09
Complications	6	4	
Mean operating time	106 min	76 min	<.01
Mean time to return to activities of daily living	34.0 days	25.7 days	<.01
Cost of surgery	6450 $Australian	4575 $Australian	<.01

[a]No symptoms of POP

[b]No POP ≥grade 2 (modified Baden Walker classification)

[c]As scored on a visual analog scale from 0 to 100

[d]Re-operations included: Abdominal group – incisional hernia (2), TVT (2), vaginal mesh removal (1), posterior colporrhaphy (1); Vaginal group – TVT (2), urethral implant (1), Fenton repair for dyspareunia (2), anterior colporrhaphy (2), posterior colporrhaphy (1)

Odds ratio and selected p values are based on reanalysis of data from the paper

objective and patient determined outcomes. The reoperation rates for prolapse or incontinence were similar in the groups with the vaginal approach being quicker, less expensive and associated with a quicker return to activities of daily living. The vaginal approach was associated with a significantly higher rate of combined recurrent anterior and apical prolapse. This difference in objective evaluation was offset by an increased rate of posterior compartment prolapse following the sacral colpopexy, resulting in an overall similar objective outcome between the two groups.

In summary, these trials provide level 1 evidence that the overall outcome (which would include quality of life) is similar between abdominal and vaginal surgery. Sacrospinous-based vaginal procedures have a higher anterior and apical anatomical recurrence rate than sacrocolpopexy-based abdominal repairs. However, abdominal surgery has a higher morbidity, at least in the short term.

4. Safety Issues Related to the Choice of Surgical Route

As already noted, there was evidence in the Benson study (1996) that serious peri-operative injuries are more common with abdominal than vaginal surgery surgery [1-3]. That study also demonstrated that vaginal surgery required less time than abdominal surgery. Boyles (2003) and Brown (2002) both demonstrated that the risk of complications increased as the number of procedures increased but presented no data specifically related to the route of surgery. Moreover, the number of procedures is usually dependent upon the severity and distribution of the prolapse and not upon the route of surgery.

Boyles (2003) [2] concluded that preexisting comorbidities did not increase the risk of complications, although this counterintuitive finding does not take into account the route of surgery or specific steps taken by surgeons to minimize the risks for their more medically fragile patients. This study also demonstrated complications were associated with 6.55% of laparoscopically performed POP surgeries, slightly higher than the rate of 5.53% for all POP procedures. Women undergoing laparoscopy were significantly more likely to develop pulmonary edema but less likely to experience urinary complications.

Boyles (2003) [2] also examined mortality risk in some detail. Although the mortality rate was low (.53 per 1000 women), women who died were significantly older than those who survived (69.1 versus 52.1). Details on the route of surgery were incompletely reported, but 50.9% of deaths were associated with rectocele or cystocele repairs (which represented 48.8% of the total surgeries in 1997) and 29.6% with abdominal hysterectomy (which represented 8.9% of the total surgeries in 1997).

In summary the commonly held opinion that vaginal POP surgery is safer than abdominal surgery is in agreement with the limited existing data and this may be an important consideration when deciding on the route of surgery for individual patients.

5. Abdominal Route: Laparoscopic Surgery

There are multiple reports of the feasibility of various abdominal prolapse repairs being performed using laparoscopic surgical techniques, most reporting good short- and intermediate-term results. As of January 2004, no randomized controlled trials have been reported comparing laparoscopic to conventional abdominal POP procedures based on a search of the OVID Medline 1996 to week 3 2004 Database and Current Contents/All Editions 1993 to week 6 2004 database using the terms “Prolapse” and “Laparoscopy” or “Laparoscopic Surgery.” There is no reason to believe that the same procedure performed in precisely the same manner using the same materials would have any different outcome using the laparoscopic abdominal technique compared with the open abdominal technique. However, as procedures are modified to allow them to be more easily performed laparoscopically, it is essential to establish independently the effectiveness of the modified procedures. Also to be established are the learning curves and the procedure volume and frequency necessary for maintenance of proficiency for both prolapse surgery by all routes and techniques.

6. Route of Surgery Summary

Textbooks of pelvic surgery often describe both abdominal and vaginal route POP procedures without commenting on the basis for the selection of the route of surgery. When mentioned, most authorities repeat the mantra that the pelvic surgeon should be proficient at procedures from both routes and should tailor the procedure to the patient and her specific defects, decrying the “one procedure fits all” concept. Relative indications cited for abdominal surgery include other reasons that mandate an abdominal approach such as pelvic masses, the likelihood

of dense pelvic adhesions, or the need of other extra-pelvic abdominal procedures and procedures that can only be performed by one route, such as sacral colpopexy or perineal reconstruction [30, 31]. Additional factors mentioned for consideration are the patient's medical condition, weight, and the surgeon's preference and expertise [32]. Vaginal colpocleisis may be recommended as the procedure of choice for the extremely frail patient who has not had success with conservative therapy and whose health status precludes extensive surgery [33], such as abdominal sacral colpopexy. In the end, most authorities conclude that there are not good data on which to base the decision for the route of surgery [31].

There is level I evidence that abdominal route surgery is more effective and durable in correcting anatomy and more effective in correcting or preserving vaginal and lower urinary tract function and that vaginal route surgery has fewer serious perioperative complications [18, 19]. Maher also demonstrated that sacrospinous colpopexy was faster and cheaper to perform with a quicker return to activities of daily living [19]. In addition, there is level I evidence that vaginal route surgery employing either the unilateral or bilateral sacrospinous apical suspension has a significantly higher risk or recurrent anterior-apical prolapse than abdominal route surgery employing a mesh sacral colpopexy technique [18, 19]. However, the overall quality of life following either route of surgery appears similar.

There is level II and III evidence that constipation with chronic straining, obesity, cigarette smoking and chronic obstructive pulmonary disease, and high occupational or recreational physical stress or impact may contribute to the development of POP and could represent risk factors for recurrence of POP that could be considered when deciding on the route of surgery.

The epidemiological evidence indicates that most POP surgery in the United States is performed via the vaginal route.

IV. CONCOMITANT HYSTERECTOMY

Hysterectomy is a frequent procedure at the time of POP repair, however, there is a lack of evidence suggesting that hysterectomy improves the outcome of POP surgery. By vaginal route, hysterectomy concomitantly with the repair of pelvic support defects is still the standard practice in most parts of the world despite descent of uterus itself being a result, not a cause of prolapse. But increasingly, women may wish to avoid hysterectomy. The delay in childbearing until a later age, the belief that the uterus is important for sexual satisfaction and the successful conservative managements for meno-metrorrhagia, can explain this evolution. Some authors [34] [35] don't agree with routine hysterectomy, challenging the need for removing the uterus as part of the primary POP procedure. There are no prospective studies comparing sacrocolpopexy and sacrohysteropexy, or any studies which compare sacrocolpexy with total versus subtotal hysterectomy. Constantini [36] reported a series of 21 patients who underwent colposacropexy (5 patients), hysterectomy and sacrocolpopexy (9 patients) and hysterocolposacropexy (7 patients) with a median follow-up of 31.6 months. Fedorkow [37] compared sacrovaginopexy and sacrovaginopexy with concurrent hysterectomy. While overall morbidity is similar with the 2 procedures, the operating time is significantly shorter without hysterectomy. The other studies were performed to assess anatomic results of sacrohysteropexy (**Table 5**), hysteropexy case series (**Table 6**) and vaginal suspension with and without hysterectomy **(Table 7).**

The main use of the sacrospinous uterine fixation is to resolve POP and preserves fertility. However, this operation can also be used for older women [38]. There a few case series regarding uterine preservation in the case of uterine prolapse, including sacrospinous ligament suspension, the Manchester and various other techniques including high uterosacral ligament suspension, endopelvic fascial fixation, coccygeous muscle fixation, or iliococcygeus fascial attachment. The small numbers in these diverse case series do not allow any recommendation about these procedures.

Three studies compare vaginal hysterectomy with uterine-preserving vaginal reconstruction (**Tables 8 and 9**). Uterine preservation or removal did not appear to affect the risk of POP recurrence. A series of colposacrospinous fixation reports by Nieminen K. et al., suggests that concomitant hysterectomy caused a statistically significant increase in the duration for the procedure [39]. Based on his follow-up evaluation of 122 patients at mean of 24 months (1-141 m.), Nieminen reports that surgeon skill (OR = 2.72 if less than 20 operations), the post-operative infectious complications (particularly urinary with OR = 3.65) and vaginal cuff infections with (OR =

Table 5. Case series for sacrohysteropexy

Authors Year	Operative technique	No	Follow-up months	Success	Anatomic Recurrence ant	median	post	Hospital stay (days)
Banu 1997 [31]	Sacrohysteropexy mersilene mesh	19	3-5 years	100%	Sites not reported separately			
Leron 2001 [32]	Sacrohysteropexy Teflon mesh	13	15.6 months (4-49)	92.3%		7.6% 1/13	4.6 (4-6)	
Barranger 2003 [33]	Sacrohysteropexy mersuture mesh	30	44.5 months (2-156)	93,3%	3.3% 1/30 cystocele grade II	3.3% 1/30 hysterocele grade II + elongated cervix	?	

Table 6. Case series for others techniques of hysteropexy

Authors Year	Operative technique	No	Follow-up months	Success rate	Anatomic Recurrence	Hospital stay (days)
Rimailho 1993 [34]	abdominal anterolateral hysteropexy (Kapandji)	92	60	87%	4 patients underwent re-operation	?
Cornier 1994 [35]	laparoscopic assisted anterolateral hysteropexy(Kapandji)	7	≥ 12	100%	?	6-7
Maher 2001 [20]	laparoscopic high Mc Call	43	12+/-7 (6-32)	79%	?	5 (2-10)

6.13), patient age and duration of follow-up affect the risk of POP recurrence [40]. However, he did not find that preoperative prolapse grade, nor the associations with hysterectomy have a significant role. There is unclear evidence regarding functional outcomes when hysterectomy is added to POP procedures. The concerns with sexual, urinary and bowel function require significant additional research.

The Manchester operation, with an induced infertility estimated to be as high as 60% to 80%, an increased risk of miscarriage and premature labour, and a dystocia rate severe enough to induce 20 to 55% of Caesarean sections, is limited to historic interest. There are some reports of deliveries after uterine fixation, most of these by Caesarean section [34, 35]. Nevertheless, some spontaneous vaginal deliveries have been recorded, with a post-partum prolapse recurrence rate between 0 and 40% [41, 42].

There is an urgent need for well-designed RCT comparing these prolapse procedures with and without hysterectomy.

V. CONCOMITANT FUNCTIONAL DISORDERS

There is good evidence that POP and POP repairs impact on urinary, sexual and anorectal function. A common misperception has been that most patients with anterior vaginal wall prolapse also experience stress incontinence, however, there is no defining degree of anatomic abnormality that links anterior wall prolapse with SUI. Women with Stage III or IV POP may have normal lower urinary tract function, may have difficulties with control of urine, (both from a problem of urethral sphincteric incompetence or a compliance abnormality) may have irritative voiding symptoms (frequency, urgency, dysuria and/or nocturia) and finally they may have problems with voiding dysfunction (hesitancy, incomplete emptying, retention). At least one study has shown that the symptoms of lower urinary tract dysfunction are statistically significantly more prevalent in women with pelvic organ prolapse than in those

Table 7. Vaginal surgery: comparative studies with or without hysterectomy: functional results

authors year	Intervention with hysterectomy									Intervention with uterine preservation								
	surgery	No	follow-up	success	results				return to activity	surgery	No	follow-up	success	results				return to activity
					urinary	bowel symp.	sexual	others						urinary	Bowel symp.	sexual	others	
Maher 2001 (20)	VH + SSF	29	36	86%	2 SUI		3% dyspar	1 buttock pain	34 j	SS hysteropexy	27	26	78%	1 SUI		7% dyspar	2 buttock pain 2 completed pregnancies 4 postmenop bleeding	32 days
Hefni 2003 (2)	VH + SSF	48	34		0 de novo urinary symptoms		1 vaginal adhesions	2 buttock pain		SS hysteropexy	61	33		0 de novo urinary symptoms		1 narrow introitus	2 buttock pain	
Van Brummen 2003 (14)	VH + US fixation	30	10		50% with UI symptoms					SS hysteropexy	44	19,4		39% with UI symptoms				More quickly*

* significant VH = vaginal hysterectomy, SSF = sacrospinous fixation, US = uterosacral, SUI : stress urinary incontinence, UI : urge incontinence

Table 8.Vaginal surgery : comparative studies with or without hysterectomy

authors year	study	intervention with hysterectomy					intervention with uterine preservation				
		surgical procedure	No	operation duration min	concomitant procedures	per-op complications	surgical procedure	No	operation duration min	concomitant procedures	post-op complications
Maher 2001 (1)	retrospective	VH + unilatéral SSF	36	91*		blood loss 402 ml*	Unilateral Sacrospinous hysteropexy	34	59*		blood loss 198 ml*
Hefni 2003 (2)	prospective non randomised	VH + unilateral sacrospinous fixation	48	77 +/- 15 *	+/- perineorraphy	1 rectum injury blood loss : 135 +/- 45 ml *	Unilateral sacrospinous hysteropexy	61	51 +/- 13 *	+/- perineorraphy	blood loss 46 +/- 20 ml *
van Brummen 2003 (14)	retrospective	VH + US fixation	49	?	+/- ant/post colporraphy	2 hemorrage **	Unilateral sacrospinous hysteropexy	54	?	+/- ant/post colporraphy	1 hemorrage **

* significant, ** non significant VH = vaginal hysterectomy, SSF = sacrospinofixation

Table 9. Comparative studies sacrospinous fixation with or without hysterectomy : anatomic results

Authors Year	Intervention with hysterectomy									intervention with uterine preservation								
	technique	No	follow-up months	success	recurrence ant	recurrence middle	recurrence post	hospit stay (days)	post-op complications	post-op complications	technique	No	follow-up months	success	recurrence ant	recurrence middle	recurrence post	Hospit stay (days)	post-op complications
Maher 2001 (1)	VH + SSF	29	36	72%**	28%	7% vault 3% enterocele	1%	7,5**	0 transfusion	0 transfusion	SS hystero pexy	27	26	74%**	22%	7% uterus 0% enterocele	0%	6,4**	0 transfusion
					2 re-operations - 1 sacrocolpexy - 1 vaginal repair										3 réinterventions - 2 uterine prolapse (1post-partum) - 1 hysterectomy for menorrhagia				
Hefni 2003 (2)	VH + SSF	48	34	95,9% (46/48) **	10,4% 5 cases	4,1% 2 cases	0		3 vault hematoma. 2 blood transfusion 2 febrile morbidity 1 thromboembol. 2 voidind dysfunction overall complications rate : 31,2%*	3 vault hematoma. 2 blood transfusion 2 febrile morbidity 1 thromboembol. 2 voidind dysfunction overall complications rate : 31,2%*		61	33	93,5% (57/61) **	11,4% 7 cases	4,9% 3 cases	0		1 febrile morbidity 1 voiding dysfunction overall complication s rate : 11,5% *
					reoperation rate 4,1%										reoperation rate 4,9%				
Van Brummen 2003 (14)	VH + US fixation	30	10*		6,7%** (2/30) prolapse grade ≥ 2						SS hystero pexy	44	19,4*		11,4% ** (5/44) prolapse grade ≥ 2				

* : Significant, ** : non significant VH = vaginal hysterectomy, SSF = sacrospinous

women that have good support of the pelvic floor [43]. Ng et al reported the high rate (42%) of concomitant POP procedures in 264 women undergoing a continence procedure [44]. Ellerkmann, et al, correlated functional symptoms and the location and severity of pelvic organ prolapse in 237 women [45]. Seventy-three percent reported urinary incontinence (13% stress, 3% urge, 5% unconscious leakage and 76% both urge and stress incontinence) and nineteen percent also reported episodes of enuresis. Frequency and urgency were common, and reported by 85% of these women. Symptoms of voiding dysfunction were also common and reported by 34-62% of these women.

There are also studies that have confirmed that motor urge incontinence can occur in conjunction with advanced pelvic organ prolapse. Studies by Wall and Hewitt [46] and Rosenswieg [47] have demonstrated that a significant number of women with advanced pelvic organ prolapse complain of motor urge incontinence which is, at times, documented on urodynamic testing.

Nguyen and Batia noted that there was a resolution in the urge incontinence after surgical repair of pelvic organ prolapse in 24/38 women and it persisted in 14/38 women [48]. So data would seem to indicate that there is a significant correlation of stress, urge and mixed incontinence in patients with pelvic organ prolapse. Whether this truly relates to the pelvic organ prolapse or whether the muscles, nerves and connective tissues of the pelvic floor that are responsible for maintaining pelvic support are also responsible for maintaining bladder control. Factors such as age, vaginal delivery, denervation of the pelvic floor, composition of pelvic support, connective tissue, obesity and a chronic lung disease have been known to increase both urinary incontinence and pelvic organ prolapse. There have also been data to support that advanced pelvic organ prolapse can cause obstruction of the lower urinary tract leading to various types of voiding dysfunction including hesitancy, prolonged time to void, change in position and even elevated post void residuals and urinary retention.

Fitzgerald et al [49] noted that there was a resolution of urinary retention or incomplete emptying in patients after surgery for advanced pelvic organ prolapse in 89% of 35 patients who had stage 3 or stage 4 pelvic organ prolapse. This study noted that the average post void residual was 226 cc preoperatively, with 89% of patients having a post void residual of <100 cc postoperatively.

The correlation and impact of defecatory dysfunction on the surgical correction of pelvic organ prolapse has been looked at in numerous papers, but no level 1 evidence is available. Jackson et al [50] reported that 42 of 250 women with urinary incontinence and/or pelvic organ prolapse also had fecal incontinence for an overall prevalence of 17%. It was interesting that 76% of these women declined referral to a colorectal surgeon and 10 accepted referral. In this same group of women, 70 had isolated pelvic organ prolapse in the absence of any urinary incontinence and five or 7% were incontinent of feces. This study did show a strong association between urinary incontinence and fecal incontinence. Meschia et al [51] evaluated 881 women with symptoms of urinary incontinence and/or genital prolapse, 178 of whom also had anal incontinence. There were a significant number of women with prolapse greater than grade 2 that noted anal incontinence (18% in patients with the prominent prolapse being the cervix or the cuff all the way up to 35% in women where the prominent prolapse was the posterior vaginal wall).

Ano-rectal dysfunction was also commonly reported with approximately 66% reporting constipation, although dyschezia, incomplete evacuation, and the need to place a finger in the rectum or vagina to facilitate defecation were also common complaints. Thirty-six percent reported using either fiber supplements or stool softeners on a regular basis to facilitate defecation, 18% reported using enemas and 31% reported using laxatives. Sixty-three percent of women reported bouts of fecal incontinence that significantly interfered with normal activities, and 56% thought their fecal incontinence was getting worse.

There is a need for research on the optimal evaluation and treatment strategies for these common concomitant disorders.

VI. EFFICACY OF SPECIFIC PROCEDURES

Apical Defects: The apex is the keystone of pelvic organ support. Without good suspension of the uterus or post-hysterectomy vaginal cuff, the ventral and dorsal walls are exposed to intra-abdominal forces that drive these tissues toward the introitus. The best surgical correction of the anterior and posterior walls is doomed to failure unless the apex is adequately supported. While *recognition* of apical defects is one of the biggest problems in diagnosis of pelvic support defects, *surgical correction* of the

apex has several good options with relatively high success rates. Specific procedures to address apical defects can be divided by the absence or presence of the uterus, either post-hysterectomy vaginal vault prolapse or uterine prolapse. The latter include vaginal hysterectomy used to treat the prolapse, prophylactic procedures to prevent future pelvic organ prolapse, or to preserve the uterus in the presence of support defects.

In the case of post-hysterectomy apical defects, vaginal procedures can be either supportive or obliterative. Clark et al [52] reported that the highest rates of reoperation for pelvic floor disorders in a managed care system occurred in women undergoing surgery for apical defects (33% reoperation) or combined anterior/apical (15%) or posterior/apical (12%).

1. Apical support procedures performed *per vaginam* involving the uterus:

Establishment of vaginal support in hysterectomy is recommended by most authorities (level 4 evidence) and may be achieved by a "prophylactic" procedure in cases of normal uterine support: attachment uterosacral ligaments to the vaginal cuff, McCall culdoplasty, and Mayo culdoplasty. There are no reports comparing these procedures. Cruikshank [53] reported better support of the apex with McCall culdoplasty in a randomized trial comparing this procedure with simple peritoneal closure or vaginal Moschowitz procedures (Level 1- evidence). In cases of uterine prolapse at the time of vaginal hysterectomy, multiple procedures have been recommended. In addition to these same culdoplasty techniques recommended in textbooks, there are several reports of uterine preservation with apical support procedures. These are mostly retrospective case series (level 3 evidence) using the sacrospinous ligament fixation involving fewer than 50 subjects with short follow-up and poorly defined outcome criteria [34, 35].

2. Apical support procedures performed *per vaginam* post-hysterectomy

a) Suspensory procedures:

1. High uterosacral ligament suspension (HUSLS).

First reported in 1997, this procedure suspends the vaginal apex to the remnants of the uterosacral ligaments at the level of the ischial spines and cephalad, with attention to incorporation of the rectovaginal fascia and pubocervical fascia into the permanent sutures at the apex (**Table 10**). The procedure maintains the vaginal axis in the midline, allows adjustment of the vaginal length, and can include use of allograft or xenografts in the suspension (level 3 evidence). Intra-operative ureteric injury has been reported to be 1-11% [54], and intraoperative cystoscopy after tension is placed on these sutures is an important part of the procedure. Bowel dysfunction has been described due to narrowing of the rectosigmoid as it passes through the levator plate. Despite these seeming disadvantages, the procedure has largely replaced the sacrospinous ligament suspension in many urogynecologic practices in the U.S. because it optimizes the vaginal length, restores vaginal axis to its original axis to the uterosacral ligaments, and provides good support with permanent sutures.

2. Iliococcygeus fascia fixation.

This procedure is can be used when the intraperitoneal approach is not feasible during vaginal repair of

Table 10. High Uterosacral Ligament Suspension Procedures

	N	f/up in mos (range)	success rate	complications
Pohl & Frattarelli 1997 (Pohl, 1997 #41)	40	6-40	89%	
Jenkins 1997 (Jenkins, 1997 #28)	50	6-48	88%	
Barber 2001 (Barber, 2000 #14)	46	15.5(3.5-40)	90%	11% ureteral
Karram 2001 (Karram, 2001 #29)	202	6-36	895	2.4% ureteral
Shull 2000 (Shull, 2000 #42)	289	(not stated)	87%	
Amundsen 2003	33	28(6-43)	82%	
"culdosuspension" to sacrouterine/cardinal complex				
Comiter 1999	100	17.3(6.5-35)	92%	

the apex (level 3 evidence). It sometimes is performed with a suture-passing device, and is performed bilaterally. Shull et al [55] reported on 42 women with 6wk-5 yr follow-up after iliococcygeus fixation: apical support was optimal in 39 subjects (93%), but eight subjects had apical or other defects (18%). Meeks et al [56] reported a 96% objective cure in 110 subjects followed 3-13 years. In a retrospective case-control study, Maher and colleagues [57] reported similar subjective (94%, 91%) and objective (67%, 53%) success with the sacrospinous ligament suspension (n=78) compared to the iliococcygeus fascial fixation (n=50) (level 2- evidence).

3. MAYO CULDOPLASTY:

This modification of the McCall's culdoplasty was used in a large retrospective series from the Mayo clinic[58], with 82% of patients "satisfied" on subjective follow-up with few intraoperative complications. It may achieve its suspension in a similar mechanism to the uterosacral ligament suspension, although no direct comparisons exist.

4. SACROSPINOUS LIGAMENT SUSPENSION (SSLS) OR FIXATION.

The popularity of this vaginal apical procedure has been somewhat superseded by the high uterosacral ligament suspension, although the SSLS may still be considered in cases where the uterosacral ligament approach is not feasible (such as severe pelvic adhesions preventing access to the cul-de-sac.) The advantage of the procedure is simultaneous repair of the anterior and posterior wall defects, ability to excise excess vaginal skin, and less postoperative bowel dysfunction. See above for two randomized controlled trials [57, 59] with similar results favoring the abdominal approach. The unilateral suspension does not seem to compromise coital function. However, sacrospinous ligament suspension cannot lengthen an already shortened vagina. Infrequent complications include buttock pain or sacral/pudendal nerve injury. The recurrence of cystocele high in the vagina has been reported at 20-22% in several studies [60], and as high as 92% in one series [24]. There is some evidence (level 3) that the Michigan modification, which draws all four vaginal walls in direct contact with the coccygeus muscle using absorbable suture, may avoid this complication [61] **Table 11**).

5. LEVATOR MYORRHAPHY WITH APICAL FIXATION.

This procedure has been reported by a single urology group [62, 63] who describe an apical fixation

Table 11. Sacrospinous Ligament Suspension Procedures*

Citation	N	f/up in mos (range)	success rate	complications
Morley 1988 (Morley, 1988 #38)	92	1 mo-11y	82%	subjective, objective
Imparato 1992 (Imparato, 1992 #27)	155	?	90%	objective
Shull 1992 (Shull, 1992 #43)	81	2-5y	65%	objective
(Pasley, 1995 #39) Pasley 1995	144	6-83 mo	94%	subjective, objective
Benson 1996 (Benson, 1996 #15)	42	12-66 mo	29%	objective (third party), RCT
Hardiman 1996 (Hardiman, 1996 #23)	125	26.4 mo	98%	objective
Penalver 1998 (Penalver, 1998 #40)	160	18-78 mo	85%	objective
Colombo 1998 (Colombo, 1998 #18)	62	4-9y	73%	subjective, objective
Meschia 1999 (Meschia, 1999 #36)	91	1-6.8 y	(94%) **	objective
Sze 1999 (Sze, 1997 #45)	54	7-72 mo	67%***	objective
Lantzsch 2001 (Lantzsch, 2001 #30)	123	6 mo-9y	(97%)****	objective

* using publications reporting more than 50 subjects, interpretable data. One RCT is included in which 42 subjects were randomized to SSLS

** apex only; recurrent cystocele 16%, recurrent rectocele 10%, recurrent enterocele 6%

*** 13/18 anterior wall recurrence

**** apex only; 10 recurrent cystoceles, 1 recurrent rectocele, 1 recurrent enterocele

with closure of the levator ani in the posterior wall, but 3/14 sexually active patients reported dyspareunia. 42/47 patients were described as "cured," but subjective follow-up was available on 35 subjects at a mean of 27.9 months. Five (14%) had undergone subsequent repairs for symptomatic prolapse, and a further 7 were found to have a significant cystocele on examination. One patient had a re-operation for ureteral obstruction, while 5/47 had an intraoperative ureteric compromise requiring release of suture. The procedure was described as safe and effective, but compared to other procedures the rates of dyspareunia and ureteric injury are high, and the levator myorrhaphy cannot be recommended at the present time.

Several additional apical suspension techniques have been proposed, including the posterior intra-vaginal slingplasty. However, at the time of this literature review, scientific manuscripts have not been published and therefore these techniques are not included in this chapter.

b) Obliterative procedures:

1. LEFORT COLPOCLEISIS/TOTAL COLPECTOMY WITH HIGH LEVATOR MYORRHAPHY

These procedures are offered to women with Stage III-IV POP who no longer wish to preserve coital function. With partial colpocleisis, rectangles of vaginal epithelium are excised from the dorsal and ventral surfaces of the prolapse, and the vagina is inverted with the scarring of the raw surfaces (reinforced with sutured skin edges) acting to obliterate the vagina. The enterocele is not addressed, and the uterus is left *in situ* unless there is separate pathology. In colpectomy, all vaginal skin is removed, and a variety of modifications have been reported, including concomitant hysterectomy and/or high levator myorrhaphy.

In the U.S, the number of LeFort procedures has declined from a high of 17,200 in 1992 to a low of 900 procedures in 1997 [22], while the number of vaginectomy procedures ranged from a high of 3229 procedures in 1989 to a low of 32 procedures in 1995. Nevertheless, obliterative procedures have an important role to play in the management of pelvic organ prolapse: in many women, the loss of coital function is balanced by the positive impact on their daily activities. These procedures are performed on an outpatient basis with an immediate return to normal activities, and success rates have been described as high as 100% (level 3 evidence), but the ventral (anterior) wall of the vagina is drawn to the dorsal (posterior) wall; thus, if the bladder neck is incorporated into the obliteration, the risk of urinary incontinence after the procedure can be as high as 42% unless the distal anterior wall is spared or unless an anti-incontinence procedure is performed concurrently. **Table 12** summarized recent studies.

Enterocele repair as a separate entity has been reported by few groups. Tulikangas et al [64] reported that of 49 women undergoing vaginal repair of enterocele using permanent suture at the time of a variety of concomitant procedures, one-third had a recurrence of Stage II prolapse within the mean follow-up period of 16 months, with a loss of vaginal length (median 2.5 cm) and introital caliber (median 2.5 cm) that did not appear to affect sexual function in most subjects.

Table 12. Obliterative vaginal procedures for apical defects

Citation	n	pt age (mean)	follow-up	cure	comments
Partial colpocleisis					
Fitzgerald 2003	64	78y		97%	*
Total colpectomy					
DeLancey 1997	33	78y	35 mos	100%	
Cespedes 2001	38	77y	24 mos	100%	
Harmanli 2003	41		28.7 mos	100%	12 TVH, 10 paravaginal
von Pechmann 2003	62		12 mos	97%	37 TVH
Moore 2003	30		19 mos	90%	3 reoperations for prolapse

*14% takedown rate in patients undergoing concomitant pubovaginal sling

c) Transabdominal POP Procedures

Sacrocolpopexy is a useful procedure for the reconstructive surgeon. It is believed to be durable, teachable, and have an acceptable risk/benefit ratio. As discussed earlier, direct comparisons of route of surgery have used sacrocolpopexy as the abdominal procedure of choice. Although there is level I evidence for the usefulness of this operation in POP, there are many unanswered technical questions, including concomitant procedures and optimization of urinary tract function.

Concomitant operations include continence procedures, hysterectomy and other prolapse procedures. Continence procedures were discussed previously in this chapter. The perceived need for concomitant hysterectomy prior to the sacrocolpopexy varies by country. In the United States, hysterectomy has often been performed prior the sacrocolpopexy. Several, but not all, authors have reported data that indicate concomitant hysterectomy is safe without any appreciable increase in infectious or rejection risks.

Few studies about sacrocolpopexy after previous hysterectomy reported experience with mesh erosion: patients, surgical procedures and synthetic materials were different and comparisons appeared very difficult. Mesh erosion rate range from 2.7% to 40%. Visco et al [65] reported on 155 women and found erosion rate of 3.2% with abdominal sacrocolpopexy, 4.5% when combined with colpoperineopexy, 20% (6/30) with combined abdominal-vaginal approach (16% (4/25) when the sutures and 40% (2/5) when the mesh was vaginally introduced. **Table 13** summarizes these studies.

The role of concomitant culdeplasty has not been determined. Geomini et al reported a 93% success rate for their procedure in the prevention of recurrent vaginal vault prolapse, although 25% of patients in the series developed a moderate enterorectocele postoperatively [66]. The authors attributed this to the selective use of a concomitant culdeplasty, and have thus recommended that a culdeplasty routinely be done with a sacrocolpopexy. Experts vary in their recommendations with advocates believing that culdeplasty assists with the prevention of enterocele. Surgeons who do not perform routine culdeplasty believe the procedure contributes to postoperative defecatory dysfunction. No study has been designed to address this issue, although one on-going United States trial will provide some prospective data on this aspect of sacrocolpopexy (NIH – Pelvic Floor Disorders Network – CARE Study) [67].

There are no standardized outcome measures for sacrocolpopexy. Existing studies have selected either anatomical or symptom outcome measures. Anatomical outcomes generally measure specific vaginal support, using physical exam scoring systems (Baden-Walker scale or Pelvic Organ Prolapse Quantified). New or recurrent prolapse at sites other

Table 13. Sacrocolpopexy versus sacrocolpopexy with concurrent hysterectomy : effect on mesh erosion

Authors year	Study	operative technique	Mesh	No.	follow-up	Mesh erosion
Kohli 1998 [38]	retrospective	sacrocolpopexy	marlex ou mersilene	47	19,9 m (1,3-50)	6/47 : 12,7% €
		hystérectomy + sacrocolpopexy	marlex ou mersilene	9	19,9 m (1,3-50)	1/9 : 11,1% €
Schettini 1999 [39]	retrospective	sacrocolpopexy	prolene	7	15 m	0
		hysterectomy + sacrocolpopexy	prolene	8	15 m	0
Culligan 2002 [9]	retrospective	sacrocolpopexy	synthetic	234	6w - ≥ 4 y	3/234 : 1,3%*
		hysterectomy + sacrocolpopexy	synthetic	11	6w - ≥ 4 y	3/11 : 27,3%*
Brizzolara 2003 [40]	Retrospective case-control	sacrocolpopexy	prolene	52	40 m (1-71)	1/52 : 2%
			cadaver	12	40 m (1-71)	0
		hysterectomy + sacrocolpopexy	prolene	47	29,5 m (1-74)	0
			cadaver	13	29,5 m (1-74)	0

€ erosion of suture (2 patients) or mesh (5 patients) * significant w = week, m = month, y = year

than the apex is important. Several authors have defined success as the lack of any vaginal prolapse, regardless of impact upon success rate. In Benson's study, a single outcome variable called "optimal" was created to combine important aspects of anatomy and symptoms.

There is level one evidence that sacrocolpopexy cures apical vaginal prolapse in approximately 85-90% of patients. Broader outcome measures that include patient satisfaction, anatomic support, complications, other de novo adverse symptoms, or the need for re-operation, would adversely impact the success rate difficult to determine. Most studies do not describe non-anatomic outcome tools or use non-validated measures and therefore the evidence from these trials is of limited value.

Brubaker examined a series of 65 patients who had sacrocolpopexy with posterior attachment. She reported that anterior persistence or recurrence occurred in 19 patients despite cure at the apex and recommended concomitant anterior mesh placement. [68] Baessler reported a case series of 33 sacrocolpopexy patients who had graft placed posteriorly in attempt to correct a rectocele. [69] Fifty-seven percent had persistence or recurrence of rectocele, despite cure at the apex. These studies point out that sacrocolpopexy is effective at correcting apical vaginal vault prolapse, although the risk of prolapse at other sites, and the optimal way to address all potential defects is insufficiently studied.

3. Anterior Wall Support

Ahlfelt in 1909 stated that the only problem in plastic gynaecology left unresolved was the permanent cure of cystocele [70]. In 1913 Kelly [71] described the plication of the sphincter urethral muscle and the anterior colporraphy was born. The success rates anterior colporrhaphy in the management of cystoceles ranges from 80-100% in retrospective series [72-75] Table1. Colombo et al in a randomized control trial on women with cystocele and stress urinary incontinence demonstrated that the anterior colporraphy (97% success rate) was superior to the colposuspension (66%) in the management of the cystocele with long-term follow-up [76]. More recently, Weber et al [77] and Sand et al [78] also in randomized control trials reported the anterior colporraphy to be successful in the management of cystoceles in only 42% and 57% respectively.

An alternative to colporrhaphy was described by George White [79] in 1912 and rediscovered by Richardson [80] in 1976 in his written observations regarding defects in the pubocervical fascia. Richardson also advocated the abdominal paravaginal repair which has a 75-97% success rate for anterior wall support reported in case series[80-84](Table 14). The surgical technique of the laparoscopic paravaginal repair has been technically described and is feasible, but there are no controlled trials describing efficacy of the laparoscopic paravaginal defect repair.

Shull[85] also reported a case series demonstrating the safety and efficacy of the vaginal paravaginal repair in 1994. Although the success rates of the vaginal paravaginal repair for cystoceles in case series vary from 67 –100% [79, 85-89] significant complications have been reported recently. Mallipeddi[88] reported on complications in a series of 45 including: 1 bilateral ureteric obstruction, 1 retropubic haematoma requiring surgery, 2 vaginal abscesses; 2 transfusions. In a series of 100 women Young [89] reported a 21 major complications and a 16% transfusion rate.

Anterior wall prolapse occurs frequently after other prolapse repairs. Paraiso et al[90] reported a 37% cystocele rate after 243 women had undergone sacrospinous colpopexy and suggested the rate of cystocele may decrease with the iliococcygeous fixation as there was less posterior displacement of the vault. Maher et al [91] subsequently reported high rates of cystoceles after both sacrospinous and iliococcygeous fixation. Kohli et al [92] found the concomitant use of transvaginal bladder neck suspension used in conjunction with the anterior colporrhaphy was also problematic. Women undergoing anterior colporrhaphy alone had a 7 % recurrence rate as compared to a 33% recurrence rate after combined anterior colporrhaphy.

No randomized control studies have evaluated the abdominal or vaginal paravaginal repair in isolation. In the previously described trials of Benson et al[93] and Maher et al abdominal paravaginal repair was performed in the abdominal group if required and an anterior colporrhaphy without or without vaginal paravaginal vaginally. Both authors reported the abdominal group to have a statistically lower rate of postoperative anterior vaginal prolapse than the vaginal group.

Raz et al [94] popularized the needle suspension type procedure for cystoceles and success rates in case series vary from 90-98% [94-96]. The addition of polyglactin mesh to the repair appears to have little impact on the success[97]. Dmochowski et al [98] was not able to reproduce these results although a stricter definition of success was employed than in previous reports (**Table 14**).

Table 14. Describes various surgical options in the treatment of anterior wall prolapse.

Author	No.	Review	Success rate (Variably defined)
Anterior Colporrhaphy			
Stanton [72]	54	up to 2 yrs	85%
Macer [73]	109	5-20yrs	80%
Walter [74]	76	1.2yrs	100%
Porges [75]	388	2.6yrs	97%
Colombo [76]	33 AC 35 colposupension	8-17yrs 8-17 yrs	97% 66%
Sand [78]	70 AC 73 AC& mesh	1yr 1yr	57% 75% no mesh complications
Weber [77]	57 AC 26 AC+mesh	23 month 23 month	37% 42% no mesh complications
Vaginal Paravaginal Repair			
White [79]	19	up to 3yrs	100%
Shull [85]	62	1.6yrs	67%
Grody [86]	72	0.5-3yrs	99%
Elkins [87]	25	0.5-3yrs	92%
Mallepidi [88]	35	1.6yrs	97%
Young [89]	100	11 months	78%
Abdominal Paravaginal Repair			
Richardson [80]	60	1.7yrs	97%
Richardson [81]	213	0.5-6yrs	95%
Shull [82]	149	0.5-4yrs	95%
Bruce [83]	27 APR& sling 25 APR	17 months 17 months	93% 76%
Scotti [84]	40	39 months	97%
Concomitant Sling Support			
Raz [94]	107 AC & needle suspension	2yrs	98%
Raz [96]	50	2.8yrs	90%
Gardy [95]	58 AC & needle suspension	2yrs	95%
Safir [97]	112Ras + polyglactin mesh	21 months	92%
Dmochowski [98]	47 Raz type	47 months	43%
Cross [155]	36 AC & pubovaginal sling	20 months	92%
Goldberg[99]	53 AC& sling procedures 90 AC	1 yr 1yr	81% 58%
Benirzi [156]	36 AC & vaginal wall sling	17months	95%

APR Abdominal paravaginal repair

AC Anterior colporrhaphy

Goldberg et al [99]demonstrated in a case control study that women with cystocele and stress urinary incontinence that the addition of the pubovaginal sling to the anterior colporrhaphy significantly reduced the recurrence rate of cystocele from 42% in the control group to 19% in the anterior colporraphy and sling group (P<0.05).

4. Posterior Wall Support

The posterior vaginal compartment includes perineum, rectum and the peritoneum of the cul-de-sac. The relationship of the rectum dominates this compartment and the vaginal, transanal and abdominal approaches are available for the management of rectoceles. Two randomized control trials comparing the vaginal and transanal approaches to rectocele have been completed [100, 101]. Khan randomonly allocated 57 women with symptomatic rectoceles to transanal (n=33) or transvaginal (n=24) repair and provided mean review at 2 years. Nieminen et al randomonly allocated 30 women with symptomatic rectoceles, 15 to each arm, with review at 1 year. Women with prolapse other than rectoceles were excluded. Both trials demonstrated that the transvaginal approach was associated with fewer subsequent prolapse procedures than the transanal approach. Khan reported 10 of 33 (30%) required further surgery for rectocele or enteroceles in the transanal group as compared to 3 of 24 (13%) in the transvaginal arm. Nieminen reported 67% had persisting posterior wall prolapse on review in the transanal group as compared to 7% in the transvaginal group (p=0.01). Improvement in prolapse symptoms was seen in 93% in the vaginal group as compared to 73% in the transanal group (P=0.08). Both authors demonstrated the vaginal approach to significantly reduce the point Ap on the posterior vaginal wall as compared to the transanal approach. Postoperative defecography also demonstrated a non-significant decrease in depth or rectocele in the vaginal group as compared to the transanal. Postoperatively symptoms of impaired evacuation improved significantly in both groups. However, a retrospective review has suggested a greater dyspareunia rate after vaginal rectocele repair as compared to the transanal approach [102]. De novo dyspareunia was reported in one woman in the transvaginal arm of Khans study and Nieminen actually reported improved sexual function after the correction of the rectocele in both groups.

While the transvaginal approach to posterior wall is superior to the transanal approach significant variation exist in the literature on the method of transvaginal repair. Francis and Jeffcoate described the traditional levator ani plication where the puborectalis muscle is plicated transversely in 1961. The levator ani placation (LAP) produced an acceptable anatomical result but 50% described significant dyspareunia [103]. Kahn and Stanton produced similar anatomical results with less successful functional outcomes including dyspareunia increasing from 18% preoperatively to 27% postoperatively [104] (**Table 15**).

Milley and Nichols recommended transverse plication of the rectovaginal fascia as a means of correcting rectoceles and recognized the non-anatomic result from levator plication [105]. Richardson attributed rectoceles to be due to breaks in the rectovaginal fascia and advocated the isolated repair of the focal defects [106]. Following his work several reports have demonstrated favorable anatomical outcomes from the discrete defect repairs while sexual activity frequently improved as demonstrated in Table 15 [107-109]. Obstructed defecation defined, as a need to use digital pressure in the vagina, perineum or rectum to aid in bowel evacuation is a common symptom experienced by 30% women with uterovaginal prolapse[110] and between 30 –100% of women with symptomatic rectoceles in Table 15. While the discrete fascial repair offers an excellent anatomical outcome and does not adversely affect sexual function the ability to correct obstructed defecation ranges from 35-50% [107-109]. More recently Singh et al [111] and Maher et al [112] advocated the midline fascial plication reporting similar anatomical outcomes while successfully correcting obstructed defecation in over 80% and frequently improving sexual function (Table 15).

Abramov et al [113] retrospectively compared the midline fascial plication and discrete site specific repair for rectoceles. They noted a significantly higher recurrence rate of rectoceles following the discrete site-specific repair (32%) as compared to 13% following the midline fascial plication (P=0.015). The correction of the rectovaginal fascia defect that allows entrapment of feces on straining in significant rectoceles maybe to large to be repaired with the discrete approach [107] and appears to be corrected by the more robust midline fascial plication. A randomized control trial is required to compare the discrete fascial repair and the midline fascial plication in the management of rectoceles.

Lyons [114] reported on the laparoscopic approach to the rectocele repair in 20 women who where pros-

Table 15. Describes the anatomical and functional outcome for various surgical techniques for transvaginal correction of rectocele.

Author	No.	Review	Type repair	Preoperative	Postoperative
Mellegren [24]	25	12 months	LAP*	Anatomical prolapse	- -
				Obstructed defecation	48% 0%
				Constipation	100% 88%
				Dyspareunia	6% 19%
Khan [5]	171	42 months	LAP	Anatomical prolapse	64% 31%
				Obstructed defecation	_ 33%
				Constipation	22% 33%
				Dyspareunia	18% 27%
Cundiff [9]	69	12 months	discrete fascial	Anatomical prolapse	62% 12%
				Obstructed defecation	39% 25%
				Constipation	46% 13%
				Dyspareunia	29% 19%
Kenton [8]	55	12 months	discrete fascia	Awareness prolapse	86% 5%
				Obstructed defecation	30% 15%
				Constipation	41% 20%
				Dyspareunia	28% 24%
Porter [10]	125	18 months	discrete fascial	Anatomical prolapse	100% 18%
				Obstructed defecation	30% 14%
				Constipation	60% 50%
				Dyspareunia	67% 46%
Singh [12]	26	18 months	midline fascial plication	Anatomical prolapse	78% 8%
				Obstructed defecation	57% 36%
				Constipation	- -
				Sex Dysfunction	31% 37%
Maher [13]	38	12 months	midline fascial plication	Anatomical prolapse	100% 11 %
				Obstructed defecation	100% 13%
				Constipation	76% 24%
				Dyspareunia	14% 2%
Abramov [14]	53	1yr	midline fascial	objective success rate	87%
	59	1yr	discrete fascial	objective success rate	68%

* LAP: Levator Ani Plication

pectively evaluated. At 1 year 80% of the women had symptomatic resolution of prolapse and digital defecation.

Baessler and Schuessler [20] described the abdominal approach to rectocele with a posterior mesh extension at sacral colpopexy. On objective examination at mean of 26 months, 57% were found to have recurrent rectoceles. The authors recommended a posterior vaginal repair are incorporated for low rectocele at time of sacral colpopexy. Alternatively, Fox and Stanton[115]described a 93% success rate for rectoceles at 14 months in 29 women undergoing sacral colpopexy and post mesh extension to the perineum for vault prolapse and rectocele. Sullivan et al [116]described their experience with the total abdominal approach using a Marlex (Bard) mesh for recurrent prolapse or combined rectal and vaginal prolapse. At 5-year review 28% women required further surgery for rectocele or rectal mucosal prolapse and 10% required surgery for complications specific to repair.

In conclusion level 1 evidence demonstrates that the vaginal approach to rectocele appears to have a lower risk of subsequent prolapse than the transanal approach [100, 101]. Within the vaginal approach the levator ani plication has been largely superceeded by fascial repairs on the basis of multiple case series (Level 3 evidence). Level 3 evidence suggest that the midline fascial plication may offer a superior anatomical and functional outcome as compared to the discrete site-specific fascial repair [111-113]. A prospective randomized trial comparing these procedures is required. The laparoscopic approach and the posterior extension of mesh at time of sacral colpopexy, in the treatment of posterior compartment prolapse require further evaluation.

VII. THE ROLE OF MATERIALS FOR POP SURGERY

Where primary anterior or posterior colporrharphy fails, gynaecologists involved in reconstructive pelvic floor surgery frequently employ synthetic or biological grafts to re-inforce subsequent vaginal repairs. A wide variety of biological and synthetic grafts are currently available. The proposed advantage of employing a graft is that it will optimise surgical outcome without compromising vaginal capacity or coital function. The ideal prosthesis should be biocompatible, inert, lack an allergic or inflammatory response, be resistant to mechanical stress, sterile, non-carcinogenic and available in a convenient and affordable form for use [117, 118]. Prostheses may be classified as autologous, synthetic, allograft or xenograft (Table 13) [119]. A working understanding of their inherent strength, surgical handling, reaction within human tissues and potential morbidity is required to allow appropriate selection.

1. Biological Grafts

Autologous grafts may be harvested from the vagina, thigh or abdomen. The latter options are associated with increased peri-operative morbidity and may predispose to incisional hernia or unsatisfactory cosmetic results. In addition, in women with prolapse these tissues may be inherently weaker than normal, predisposing to fragmentation and surgical failure. Donor fascia lata avoids the morbidity associated with autologous tissue harvesting and reduces the risk of graft erosion compared with synthetic meshes. These grafts are harvested from cadavers using an aseptic technique and are soaked in antibiotics [120]. Microbiological cultures are obtained and a screen performed for HIV, Hepatitis B and C and T-Lymphocyte virus type 1. The prostheses are freeze-dried and sterilized using gamma irradiation in keeping with FDA guidelines. Although preparation and screening is scrupulous there is a small risk of prion or HIV transmission (1 in 1.67 million)[121]. Adequate preparation is intended to eradicate antigenic expression but some studies have suggested residual antigenic effects, which may lead to a 'graft versus host' type immunological reaction resulting in autolysis and surgical failure [121]. Alternatively surgical failure may arise due to intrinsic deficiencies in the strength of the graft. Biomechanical testing and standardisation of grafts is recommended to ensure quality control. Human derived durra mater has been used in the USA but is currently not available in the EU countries because of concerns regarding prion transmission [122].

Porcine and bovine derived xenografts lack the ethical implications associated with cadaveric grafts and are more readily available. No significant inflammatory response has been observed in animal trials using xenograft material. Remodelling and infiltration by fibroblasts with collagen deposition appears to occur without shrinkage or surgical failure [123, 124]. The most widely used grafts are derived from porcine small intestinal submucosa (SIS) and porcine dermis or bovine pericardium. Strict FDA guidelines are in place with regard to processing of these grafts. This includes knowledge of animal herd, vac-

cination status, feed source, abattoir approval and BSE clearance. There are still some concerns however, regarding the latent animal zoonoses. Processed SIS is strong, durable, biocompatible, and infection-resistant and induces less host reaction compared to bovine dermis or pericardium. It is believed that host tissues gradually replace it over an 18 to 24 month period [123, 124].

2. Synthetic Grafts

Synthetic prostheses are sub classified into type 1-4 according to the type of material, the pore size and whether they are mono or multifilament. The pore size will influence the flexibility of the prosthesis and mechanical anchorage [119, 125, 126]. The ideal prosthesis should be flexible and facilitate the passage of macrophages/leukocytes. There has been a great deal of emphasis placed upon the use of mesh with a pore size greater than 75 microns to facilitate the migration of macrophages and leukocytes. It should be noted however, that the mean diameter of leukocytes is (9–15 microns) and macrophages (16–20 microns), should allow adequate passage through pores less than 75 microns in size [127]. In multifilament grafts, the distance between the interstices is very important. If these are less than 10 microns than they will allow the passage of small bacteria (< 1 micron) but not leukocytes, increasing the risk of infection [127].

The main risks associated with synthetic prostheses are that of extrusion or erosion. Extrusion may result from inadequate vaginal closure, superficial placement of the graft, atrophy or infection. The risk of extrusion may be increased by the use of local infiltration increasing tissue volume, resulting in placement of the graft at an insufficient tissue depth. Erosion may occur at anytime following surgery and may be asymptomatic or present with symptoms of discharge, dysparenuia or vaginal pain. The risk of erosion or vaginal irritation is also likely to be influenced by the stiffness or flexibility of the graft. The latter is influenced by both the fiber and pore size. While conformity of the synthetic graft to the defect site is important, care should be taken to allow sufficient excess for re-modelling as most synthetic grafts will shrink by approximately 20% over time. For the same reason care should be taken where grafts are incorporated into apical suspension procedures eg. sacrospinous fixation. However, even in the absence of erosion local reaction to the graft may result in inflammation or fibrosis causing vaginal pain and dyspareunia. Polypropylene a type 1 synthetic graft has the lowest rate of erosion (<3%) and is therefore the most commonly employed. There is huge variation however, in the type of polypropylene grafts available and the route of insertion may also influence the risk of complications. Combined absorbable and non-absorbable prostheses have been introduced to further reduce mesh complications but there is little evidence to support this claim and early re-absorption of as much as 50% of the graft may allow insufficient time for adequate fibrosis to take place resulting in surgical failure.

3. Anterior compartment

Biological and synthetic grafts have been used in women undergoing anterior repair for primary and recurrent cystocoele. Benson was one of the first to describe cystocele repair involving mesh but Julian was the first to publish a clinical study evaluating cystocele repair with and without prosthetic re-enforcement in 1996 [128]. Twenty-four women with recurrent cystocele following two or more previous repairs were allocated to two groups a) repeat anterior repair and b) repair with re-enforcement using Marlex, a type 1 polypropylene graft (Bard, Billerica, Mass, USA). At 24 months follow-up the success rate was 100% in those who underwent prosthetic re-enforcement compared to 66% in those who underwent anterior repair alone. Mesh erosion was recognized in 25% necessitating surgical excision.

Flood et al evaluated anterior repair re-enforced with Marlex mesh in 142 women with a primary cystocele. The success rate was 100% and 2.1% of women developed mesh erosion [129]. Natale described placement of a 'tension-free' polypropylene prosthesis during anterior repair in 138 women with a recurrent cystocele. Recurrent prolapse was identified in 2.2% at 18 months follow-up [130]. Canepa et al and Nicita et al have also evaluated anterior compartment prolapse repair using polypropylene mesh with excellent results. However the surgical technique and duration of follow-up varies and there was no control group in either study [131, 132]. Composite grafts of polypropylene and polyglactin 910 have also been evaluated. Migliari employed a mixed fiber prosthesis in 15 women undergoing primary and recurrent cystocele repair [133]. Only one recurrence was identified at follow-up. There have been two subsequent randomized controlled trials evaluating a polyglactin absorbable mesh (Vicryl, Ethicon, Summerville, NJ, USA) [134, 135].

In the first study by Sand et al evaluated 161 women undergoing primary and recurrent cystocele repair

(18). At 12 months follow-up 43% without mesh versus 25% with mesh re-enforcement developed clinically significant recurrent cystocele. In Weber's, study 140 women were assigned randomly to three different techniques of anterior repair: standard anterior repair, standard plus polyglactin and ultralateral anterior colporrhaphy. 109 women were reported on and (83)76% were available for follow-up. At a median follow-up of 23.3 months, satisfactory (stage 1) or optimal anatomical results (stage 0) for points Aa and Ba on the POP-Q evaluation was reported for 30% of the standard anterior colporrhaphy, 42% standard +mesh and 46% undergoing ultralateral anterior colporrhaphy. The author concluded that the three techniques for anterior colporrhaphy provide similar symptomatic and anatomic cure rates and that the addition of polyglactin 910 did not confer any advantage over standard anterior repair [135]. Kobashi has reported on a total of 172 women undergoing primary cystocele repair with a cadaveric fascia lata sling and pubic bone anchors with a mean follow-up of 12.4 months (range 6 to 28). 132 were available for follow-up. 2(1.5%) had a grade 2 cystocele recurrence 13(9.8%) had recurrent or de novo apical vaginal prolapse [136].

Bader et al (2004) evaluated the efficiency of vaginal interposition of a tension-free polypropylene monofilament mesh for the repair of cystoceles in 40 consecutive women. The mesh was positioned under the bladder without any fixation and lateral extensions introduced into the para-vesical spaces in contact with the arcus tendinus fascia pelvis. At a mean follow-up of 16.4 months +/- 4.7, the early complication rate was 7.5% (two vaginal erosions and one complete exposition of the mesh) [137]. Von Theobald (2003) described a triple operation for prolapse in 92 women with anterior, middle and posterior compartment prolapse using polypropylene mesh and a posterior retro-and trans levator vault suspension sling. There were three cases of vaginal erosion and one hematoma of the pararectal fossa with secondary abscess formation requiring ablation of the implant. There was one immediate anatomic failure but the long-term outcome is unclear. Function was good with no reports of dyspareunia or dyschesia [138]. Yan et al (2004) evaluated cystocele repair by a synthetic vaginal mesh secured anteriorly through the obturator foramina in 30 women with a grade 2-3 cystocele. At a mean follow-up interval of 6.7 months (range: 2-12), 90% of the patients had a grade 0 and 7% a grade 1 cystocele. One patient had no improvement. Two vaginal erosions (7%) were observed at 6 and 9 months. For the 14(47%) who were sexually active after surgery, 2(14%) complained of anterior dyspareunia (23).

There is a paucity of data on the role of xenografts in women with primary and recurrent cystocele although several randomised trials are currently in progress. Salomon has assessed the feasibility and efficacy of a porcine skin collagen implant by the transobturator route for the treatment of anterior vaginal wall prolapse in 27 women together with bilateral sacrospinous fixation. There was no rejection of the porcine grafts, but 19% had a persistent asymptomatic grade 1-2 cystocele at a median follow-up of 14 months (range 8 to 24) [139].

4. Posterior Compartment

There has been a reluctance to employ prosthetic material in the posterior compartment because of the risk of erosion and concerns regarding dyspareunia. A new operation for rectocele, which placed Marlex mesh in the rectovaginal septum was described by Parker in 1993 [140]. This study on 4 women reported significant improvement in defecatory function following surgery. Watson et al in 1996 reported on a similar technique involving transperineal placement of Marlex mesh in 9 women with defecatory dysfunction [141]. While significant improvement in defecatory dysfunction and the size of the rectocele assessed by defecating proctography was noted at a median follow-up interval of 29 months, there was no objective assessment of the degree of vaginal prolapse in either study before and after surgery. Visco reported on the outcomes of sacrocolpopexy experience with the introduction of prostheses through a vaginal incision, an approach that was discontinued due to a high rate of erosion [142]. In the anterior segment Polyglactin 910 mesh study by Sand et al 132 women who underwent rectocele repairs were randomly assigned to have mesh folded into the imbricated fascia at a level just cephalad to the deep transverse perineal muscles [134]. There was no difference in recurrence rates between those with reinforcement compared to those who had a standard repair. Kohli and Miklos in 2003, described rectocele repair in 43 women using a dermal allograft to augment site-specific fascial repair. There were no major complications reported. Thirty-three women were available for follow-up (mean 12.9 months) with a 93% surgical cure rate defined by POP-Q evaluation [143]. Adhoute et al reported on the outcome of 52 non-consecutive women undergoing transvaginal rectocele and or cystocele repair using a non-

reabsorbable synthetic prosthesis (Gynemesh). Urinary incontinence was reported in 65% of patients, and 30% of women had previous pelvic surgery. Depending on the prolapse components, the operation comprised anterior or posterior mesh implantation, hysterectomy and TVT insertion. Patients were reviewed at 3, 6 and 12 months (mean follow-up of 27 months). The anatomical success was 95% for cystocele, and 100% for rectocele. Vaginal erosion by the mesh occurred in two cases after cystocele repair (3.8%) [144].

5. Materials Summary

There are insufficient data at present to make any definitive conclusions with regard to the role of prosthetic materials in prolapse surgery. Part of the problem arises from the paucity of baseline data regarding the efficacy of 'traditional' anterior and posterior vaginal repairs. As a result of this the efficacy of adding prosthetic material for primary or recurrent prolapse affecting these compartments is difficult to assess. While adding synthetic or biological grafts suggests a theoretical advantage this must be balanced against potential morbidity and cost [145]. There is also a need for further long-term prospective studies ideally in the form of randomized controlled trials as well as from structured personal series audits in order to determine the long-term efficacy and potential morbidity associated with the use the use of prosthetic materials in primary or recurrent prolapse repair. Standardized criteria for staging POP, adequate follow-up and assessment of effects of surgery on bladder, bowel and sexual function are required to determine whether or not the use of these grafts confers any advantage over standard prolapse repair and in which category of patient they should be employed. This will allow appropriate selection of both the type of prosthesis and the optimal surgical approach in women requiring reconstructive pelvic floor surgery. However, biological or synthetic prostheses will not compensate for poor surgical technique or poorly conceived procedures.

VIII. ASSESSING POP SURGERY OUTCOMES

The need for outcomes research was highlighted in the early 1980s when work by McPherson, Wennberg and colleagues (1982) demonstrated significant geographic variation in the frequency of common surgical procedures such as hysterectomy and hernia repair.[1] This variation occurred, even though there were no significant differences in the underlying rates of disease across the geographic areas studied. It was also recognized that there was often no substantial results or outcomes information for patients who underwent a particular procedure. Additionally, there were very few comparative studies to demonstrate which intervention was most effective. In light of this information, the Agency for Health Care, Policy, and Research (AHCPR), now the Agency for Health Care, Research, and Quality (AHRQ), made outcomes research a strategic planning goal.

IX. GOALS OF OUTCOMES RESEARCH IN PELVIC ORGAN PROLAPSE

Outcomes research seeks to provide evidence about the risks, benefits, and results of therapy, so that both surgeons and patients can make more informed decisions. In some disease states, pertinent outcome measures are obvious, such as cancer trials where survival is the primary outcome of interest. In other conditions, such as POP, appropriate outcomes may be more difficult to select. Historically, clinicians have relied primarily on objective anatomic measures to judge the results of surgery. Researchers have discovered, however, that these measures are often not the most important outcomes to patients. Patients are often more concerned about symptomatic improvement, rather than anatomic results.

In an effort to reach some consensus regarding minimum data sets for clinical trials of pelvic organ prolapse, in 1998 and 1999 the National Institute of Child Health and Human Development (NICHD), with participation from other institutes within the National Institutes of Health (NIH), sponsored workshops to examine the state of basic, epidemiological and clinical research addressing female pelvic floor disorders. One of the objectives of these meetings was to develop a minimum data set of standard, validated baseline and follow-up variables to be applied as uniformly as possible in studies of pelvic floor disorders. These recommendations were published in 2001 (Weber et al). The Terminology Workshop recommended that in general, minimum data for all pelvic floor disorders should be recorded and reported from at least five domains: the subject's observations (symptoms), quantification of symptoms, the clinician's observations (anatomic and functional), quality of life data, and socioeconomic measures.

1. Validity

The issues of study design are discussed elsewhere in this book. However, specific issues for POP surgery include a careful description of patient population that includes participant characteristics such as age, race, prior medical, gynecological, and obstetrical history should be described, using standard terminology. The methods of the study should include measurements of pelvic support anatomy and clearly described measurement techniques. A standard, validated, and reliable method of describing subject anatomy such as the International Continence Society Pelvic Organ Prolapse Quantification system [146] should be used before and after the intervention.

Baseline pelvic symptoms should be characterized. While restoration of normal anatomy may be a primary goal of the clinician, the most important goal for a patient undergoing treatment of pelvic organ prolapse is an improvement in her quality of life via relief from the symptoms. Symptom and quality of life scales specific for urinary function (IIQ [147], MESA [148], pelvic disorder (PFDI [149], PFIQ [149], sexual (PISQ [150], and colorectal function (FIQ [151] are available, as well as more generic instruments that measure general social and emotional well-being (UDI [147], SF-36 [152], YIPS [153], Bristol [154]. These should be utilized before and after the study intervention to adequately assess its impact on the patient.

In studies involving surgical outcome, the surgical procedures involved, as well as postoperative management (i.e., suprapubic tube removal) should be described in detail. Investigations involving surgical procedures that take place over a long time period or with multiple surgeons should include an assessment of all efforts made to minimize changes or differences in technique. All investigations or examinations that are used to document surgical outcomes should be described clearly.

2. Current Status of Outcome Measures in Pelvic Organ Prolapse

In order to assess and compare the current quality of reported outcomes, in comparison to the recommendations of the National Institutes of Health Terminology Workshop for Researchers and Female Pelvic Floor Disorders, 32 articles were reviewed. These articles were selected for recent publication date, primary focus on surgical treatment for pelvic organ prolapse, and a stated primary goal of reporting outcomes. The articles were graded by Oxford Levels of Evidence; 12 of the 32 articles were graded as either Level 1 or 2, 3 articles were graded Level 3, and 17 were graded Level 4. Symptoms were categorized in 27 of the 32 articles (84%); however, standardized symptom questionnaires were sporadically used. Urinary symptoms were reported in 20 of 32 (63%), fecal symptoms in 8 of 32 (25%), and both urinary and fecal symptoms in 7 of 32 (22%).

Sexual function was reported in 16 of 32 articles (50%). All papers used some outcome measure as a gauge of anatomic success. Ten of 32 articles (31%) used the POPQ. Five of 32 (16%) used a Modified Baden Walker Scale, and the remainder used some other method. In 6 of 32 articles (19%), quality of life data were available, at least in a limited form. Complications were reported in 29 of 32 (90%) papers and no articles gave significant socioeconomic data, with only 4 of 32 (13%)reporting on length of stay data.

3. Goals for the Future

A review of the literature of the outcomes described above suggests that most current literature on surgical therapy of pelvic floor disorders report symptomatic, anatomic, and complication outcomes. There is a need to consistently utilize validated symptom questionnaires and report urinary, fecal and sexual function symptoms in all patients.

The International Continence Society POPQ scale is used most commonly in the most recent series. Most reports that are used other anatomic measures predate the creation of the POPQ index in 1996. It is anticipated that as time goes on, the POPQ will become the standard in the literature. Quality of life data is sparse and often limited to a global question of the patient's satisfaction or well being. Disease-specific and general quality of life instruments are rarely used. The most deficient area is in socioeconomic data, with essentially no cost data reported, and only limited length of stay and time to return to full activity data reported.

In summary, pelvic organ prolapse surgery is commonly performed but under-researched. There is an important opportunity for health care teams to

improve the surgical care of women with pelvic organ prolapse with high-quality research that answers clinically relevant questions.

X. SUMMARY OF EVIDENCE

Level I –

Overall outcomes indicate that abdominal and vaginal surgery are relatively equivalent.

Sacro-spinous-based vaginal procedures have a higher anterior and apical anatomical recurrence rate than sacrocolpopey-based abdominal repairs.

Abdominal surgery has a higher morbidity, at least in the short term.

Level II–

Transvaginal placement of permanent mesh may reduce anterior wall recurrent but has a unacceptable high rate of complications that include erosion, infection, sepsis, dyspareunia and other functional symptoms.

Incontinence or voiding dysfunction may follow POP surgery and these outcomes are variable and unpredictable.

Level III –

Iliococcygeus and sacrospinous suspensions offer high cure rates with moderate rates of anterior wall recurrences.

Utero-sacral ligament suspension has high cure rates and increated rates of ureteric compromise.

Reconstructions that surgically distort the normal vaginal axis are associated with persistent or de novo POP.

Anatomic efficacy is superior to functional outcomes for posterior vaginal repairs.

The site-specific posterior repair has a comparable short-term cure rate with fewer de novo sexual dysfunction symptoms than the posterior repair with levator plication.

The transanal posterior repair may have a lower rate of sexual dysfunction that the transvaginal approach.

Transvaginal placement of biological grafts may reduce anterior prolapse recurrence rates, although the evidence is conflicting.

There is no evidence that transvaginal placement of biological grafts reduced posterior prolapse recurrence rates.

Colpectomy/colpocleisis effectively resolves POP in women who agree to a vaginal closure procedure.

There are no data to recommend one technique of posterior wall repair over any other.

Laparoscopic sacrocolpopexy is feasible and has acceptable short-term outcomes.

Laparoscopic procedures which deviate from established open techniques require scientific evaluation.

XI. RESEARCH RECOMMENDATIONS

Grade A Recommendation

Sacrocolpopexy-based abdominal POP surgery is likely to result in a better and possibly more durable anatomical outcome than sacrospinous-based vaginal reconstruction.

Abdominal surgery has increased short-term morbidity.

Grade B Recommendation

Levator plication increase the risk of sexual and defecatory dysfunction, therefore use of this technique should be limited.

Transvaginal permanent grafts for prolapse repair have a poor risk/benefit ratio, therefore use of these materials should only occur in approved clinical trials.

Grade C Recommendation:

Assessment of POP surgery should include a minimum data set that describes anatomy, symptoms and function, quality of life and cost efficacy.

Grade D Recommendation:

There is no evidence to support the routine use of biological or permanent synthetic grafts for transvaginal POP repair.

There is no evidence that indicates that any transvaginal apical repair is superior to another.

XII. RESEARCH PRIORITIES

The relationship between anatomy, function and quality of life required urgent scientific study.

There is a need to determine what surgical technique at the time of hysterectomy reduced subsequent POP.

A standard definition of anatomical cure should be determined.

There is a need to define categories of surgical outcomes that address both anatomy and function.

Standardized nomenclature is needed to allow pooling of surgical series.

Further research is needed in the epidemiology of prolapse, the cultural and geographical differences in POP and the cost efficacy of POP.

Techniques to reduce recurrent rates, especially in the anterior wall, are urgently needed.

Clinical trials are needed to establish the need for ancillary transvaginal material in POP repairs.

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