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**A randomised controlled trial evaluating the use of polyglactin (Vicryl) mesh, polydioxanone (PDS) or polyglactin (Vicryl) sutures for pelvic organ prolapse surgery: outcomes at 2 years.**

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## **Summary**

The effects at two years of polyglactin (Vicryl) mesh inlay and polydioxanone (PDS) or polyglactin (Vicryl) suture material on prolapse symptoms, urinary, bowel, sexual function and prolapse related quality of life (QoL) in women undergoing pelvic organ prolapse surgery were evaluated in a randomised controlled trial with a 2x2 factorial design of Vicryl mesh (n=32) or not (n=34) and PDS (n=33) or Vicryl suture (n=33). The response rate at two years was 82%. There were no differences in the prolapse symptom scores between the randomised groups. Prolapse related QoL score (mean difference: 2.05, 95% CI 0.19 to 3.91) and urinary incontinence score (mean difference: 2.56, 95% CI 0.02 to 5.11) were significantly lower (better) in women who had Vicryl compared to PDS sutures. The apparent superiority of the prolapse-related QoL and urinary incontinence scores in women using Vicryl suture material (versus PDS) needs to be confirmed in a larger trial.

## INTRODUCTION

Pelvic organ prolapse (POP) is seen in 50% of parous women (Beck et al., 1991), and it affects the woman's quality of life by its local physical effects and by its effects on urinary, bowel or sexual function. The lifetime risk of having surgery for POP is 11% (Olsen et al., 1997). Up to 30% of operations are for recurrent prolapse implying that primary surgery has a poor success rate (Olsen et al., 1997; Diez-Itza., 2007). This has led gynaecologists to augment prolapse repair with implantation of synthetic material (absorbable or non-absorbable synthetic mesh, or biological grafts), with the aim of reducing the risk of failure (Jia et al., 2008). Our hypothesis was to test the assumption that mesh would result in less recurrence.

There is limited evidence from the Cochrane review of surgery for prolapse (Maher et al., 2010) regarding the use of mesh and also from the systematic review and meta-analysis by Jia (Jia et al 2008) on the efficacy and safety of using mesh in surgery for anterior and /or posterior vaginal wall prolapse. These two systematic reviews reported short term evidence that mesh significantly reduced objective prolapse recurrence rates compared with no mesh/graft (Maher et al., 2010, Jia et al 2008). However, subjective prolapse symptoms and the impact of surgery on associated pelvic floor symptoms such as bladder, bowel and sexual function, quality of life, cost and patient satisfaction were poorly reported, and there was little information on subsequent surgery for recurrence. Arguably, these outcomes are of more importance to women than clinical observation of recurrence of prolapse (objective failure). Furthermore, patient-reported outcomes are more appropriate than objective recurrence because prolapse symptoms are poorly correlated with prolapse stage (Srikrishna et al., 2008; Ellerkmann et al., 2001).

There are no trials (other than the current study) comparing different types of sutures for prolapse surgery (Maher et al., 2010), and the choice of suture material is also controversial. Polyglactin (Vicryl), a synthetic polyfilament braided suture (size 6-0 and larger) retains approximately 75% of its tensile strength for two weeks. At three weeks, 50% of its tensile strength is retained and the material is completely absorbed by two months. Polydioxanone (PDS), an absorbable monofilament (single strand) suture, maintains 70% of its original tensile strength at two weeks, 50% at four weeks, and 25% at six weeks. Absorption is minimal until about the 90th day postoperatively but essentially complete within six months (Dunn DL., 2005; Karlovsky et al., 2005). The theoretical advantages of PDS are its delayed absorption providing longer support while native tissue is healing and because it is a

monofilament suture, it's presumed lower risk of post operative infection: one study showed that bacteria were least likely to adhere to PDS compared with any other suture materials including Vicryl (Chu et al., 1984). Our hypothesis was that therefore PDS might result in better healing with less infection, and this might result in less recurrence.

The aim of this 2x2 factorial feasibility trial was to compare Vicryl inlay mesh with no mesh and PDS (number 2 0) sutures with Vicryl (number 1) sutures for pelvic organ prolapse surgery. We have previously reported the short-term outcomes at 6 months (Allahdin et al 2008). In this paper, we present the patient-reported outcomes using the Pelvic Organ Prolapse Symptom Score (POP-SS) and change in quality of life (QoL) due to prolapse symptoms at two years after surgery. In addition we report on urinary, bowel and sexual outcomes and their long term effect on condition-specific QoL.

## **MATERIALS AND METHODS**

This feasibility study and its long term follow up were approved by the Grampian Research Ethics Committee. The study protocol was registered in the Controlled Trials register in May 2005. All women admitted for pelvic organ prolapse surgery with Stage 2 or more pelvic organ prolapse in the period between May 2005 to August 2005 in a single teaching Hospital in North East of Scotland were invited to participate in the study. Eight experienced consultant gynaecologists contributed participants to the trial. Women undergoing concurrent hysterectomy or continence procedures were also included. Eligible women provided informed signed consent to both the trial and long term follow-up. Women were excluded if they were unwilling to be randomised or unable to participate in the trial.

Women were randomised to receive Vicryl mesh or not ('Mesh trial') and either a PDS or Vicryl suture for repair of the pubocervical and /or rectovaginal fascia ('Suture trial') using a 2 x 2 factorial design. The design allowed analysis of mesh versus no mesh and PDS versus Vicryl sutures as separate trials, as well as exploring potential interaction between the two interventions. Allocation to groups was carried out using a secure method of concealment of randomisation (remote computer allocation) on the afternoon before surgery. Both the women and the ward staff were blinded to treatment allocation, but blinding of theatre staff and surgeons was not possible. The surgeon performing the operation completed a questionnaire in theatre giving details of the operation performed, complications and deviation from allocated treatment

(S2). Women completed a preoperative baseline questionnaire (S1) and a postoperative questionnaire on the third day after their surgery (S3). Finally they were surveyed by postal questionnaire at six months and two years (S4) after randomisation, thus avoiding interviewer bias (Figure 1). A researcher who was blind to the allocated procedure conducted the data collection and analysis, using study numbers only to identify women and questionnaires.

The primary outcome was women's rating of prolapse symptoms based on the POP-SS (Hagen et al., 2009) and QoL due to prolapse symptoms. Subjective success was assessed as women with no residual prolapse symptoms (POP-SS = 0) and no residual effect on quality of life due to prolapse symptoms. Secondary outcomes were measured using the International Consultation on Continence (ICI) Short-Form Urinary Incontinence questionnaire (Avery et al., 2004), and supplementary bowel and sexual symptom questions. Overall satisfaction was assessed using a five point Likert scale, and by the number of women who would recommend prolapse surgery to a friend.

### **Data analysis**

Descriptive statistics were tabulated reporting baseline demographics and clinical characteristics. Mean, standard deviation (SD), median and interquartile range (IQR), where appropriate, were reported.

All analyses were based on intention-to-treat (women remained in their allocated groups irrespective of receiving allocated treatment). Analysis of covariance (ANCOVA), adjusting for the baseline values where appropriate was used to analyse continuous outcomes and logistic regression used to analyse dichotomous outcomes. Where regression analyses were not possible due to small numbers, the Mann-Whitney-Wilcoxon or Fisher's exact test was used. Interaction between Mesh and Suture allocation was examined. Statistical significance for all endpoints were based on two-sided tests with two sided  $p$ -value  $\leq 0.05$  taken as the criterion for statistical significance.

## RESULTS

Of the 71 eligible women, 66 women were randomised using a 2x2 factorial design (Figure 1). There were no significant differences in the patient characteristics between the randomised groups before surgery (Table I). At two years, 54/66 (82%) women completed the follow-up questionnaire (Figure 1).

Twelve women failed to return their two year follow-up questionnaire. We reviewed their case records: two women had died of unrelated causes (cancer: both had received mesh, one was in the Vicryl group and the other in the PDS group). Of the remaining ten, none had any further prolapse operations in Aberdeen, although one woman required a transobturator sub-urethral tape procedure for stress urinary incontinence.

While the overall POP-SS improved significantly following surgery over time, there were no significant differences between the randomised groups in the mean scores at two years after adjusting for baseline scores (Table II). The number of women reporting subjective success (assessed as no residual prolapse symptoms) at two years in the Mesh trial were: 6/25 (24%) with mesh compared with 8/29 (28%) without mesh ( $p=0.279$ ); in the Suture trial, those who received PDS sutures, 5/26 (19%) had no residual symptoms compared with 9/28 (32%) who had Vicryl sutures ( $p=0.764$ ).

Similarly, the mean QoL score due to prolapse symptoms improved significantly over two years, but there was no evidence of a difference between the groups in the Mesh trial at two years after adjusting for baseline scores (Table II). However, women who received PDS sutures had a significantly higher (worse) QoL score at two years compared to those receiving Vicryl sutures (Table II).

Repeat prolapse repair operation was performed in five women: two women from the no-mesh group had recurrence at the same site (both had anterior repairs, one with PDS sutures and one with Vicryl sutures). The woman from the PDS suture group also had a repair of a de novo posterior prolapse; and three women had a repair of a de novo prolapse, two from the mesh group (both with Vicryl sutures) and one from the no-mesh group (with PDS sutures). One other woman, who had a posterior repair with PDS suture and no mesh, subsequently had a trans-rectal prolapse repaired surgically.

In addition, three women required a pessary for recurrent prolapse after surgery: all three were in the mesh group, while two were in the PDS group and one in the Vicryl group.

### **Satisfaction rate and recommendation to a friend**

Overall, 41/48 women (85%) were fairly or very satisfied with their surgery at two years, and 41/48 (85%) would recommend the operation to a friend. However, there was no evidence of a difference in the satisfaction rate according to the randomised groups (Table III).

### **Urinary symptoms**

At baseline, 49/64 women (77%) were incontinent of urine, and 13 of these 49 women had a concomitant continence operation (retropubic Tension-free Vaginal Tape, Table I). At two years, 18/22 (82%) women in mesh group were wet compared with 16/27 (59%) ( $p=0.164$ ) in the no mesh group. Of women who had PDS sutures, 16/23 (70%) were wet, compared with 18/26 (69%) in the Vicryl suture group ( $p=1.00$ ).

Although the differences in incontinence rates did not reach statistical significance, when the effect of incontinence on quality of life was assessed, women in whom Vicryl sutures were used had significantly better urinary outcomes (versus PDS sutures) at two years, whether assessed using the composite ICI incontinence score, or a simple quality of life score (Table IV). There were no corresponding differences between the mesh and no mesh groups.

### **Bowel Symptoms**

There was no evidence of a difference according to the randomised groups in the three bowel symptoms or their effect on quality of life (Table V). The number of women with bowel symptoms gradually decreased over time. Overall at baseline, 30 (46%) women were constipated sometimes or more often, which decreased to 15 (29%) at two years. For faecal urgency, 17 (27%) had symptoms sometimes or more often, decreasing to 10 (20%) at two years. At baseline 13 (20%) women reported faecal incontinence occasionally or more often, while at two years, 11 (22%) women had it.

### **Sexual symptoms and pain**

At two years, 21 women reported being sexually active. Approximately half started within 3 months of surgery, and half later. Table VI shows that the proportion of women with pain during intercourse, and the effect on quality of life due to sexual problems was similar in the randomised groups.

### **Complications**

Two women (3%) experienced short-term complications: one returned to theatre for postoperative bleeding and one woman required suprapubic catheterisation for urinary retention. In all, 6/66 (9%) women required stitch removal, and 2/32 (6.3%) required removal of some mesh (one before 6 months and one before two years). At two years, 5/51 (10%) had vaginal pain or discomfort which was not related to intercourse.

## **DISCUSSION**

This study describes the follow-up of 66 women two years after prolapse surgery in a factorial randomised controlled trial of mesh versus no mesh, and PDS sutures versus Vicryl sutures. This is the only trial which evaluates two different types of sutures.

### **Main message**

Although there was no evidence of a statistically significant difference between the randomised groups on the POP-SS or the prevalence of residual prolapse symptoms at follow up, women who received Vicryl sutures reported significantly better overall quality of life due to prolapse symptoms at two years (mean difference 2.05, 95% CI 0.19 to 3.91, Table II).

The evidence from three RCTs included in a Cochrane review suggested that the use of an absorbable polyglactin mesh (Vicryl) may reduce the objective recurrence of prolapse compared with anterior repair alone (Maher et al., 2010). However, patient reported outcomes, QoL, patient satisfaction and the re-operation rate for recurrence of prolapse were not reported in any of these trials, and follow up was limited to one year. Our study included both patient reported outcomes and a longer term follow up.

Meschia et al (Meschia et al., 2007) showed no difference in postoperative urinary outcomes (both stress urinary incontinence and overactive bladder) when fascial

plication was compared to Pelvicol overlay (porcine dermis graft). Similarly, no difference was noted in the post operative urgency and detrusor overactivity between the Prolene mesh (synthetic non-absorbable) and Pelvicol group in one trial (Cervigni et al., 2005). Although there was no difference in the prevalence of urinary incontinence at two years between the randomised groups in our study, women randomised to the Vicryl suture group had better results on the ICI urinary score and quality of life due to urinary symptoms at two years (Table IV). There were no differences in the other dimensions of health (constipation, faecal urgency, faecal incontinence, difficulty and pain during intercourse, or satisfaction with surgery) but the sample size was small. We are not aware of any other prolapse surgery trial that has reported the effect of mesh or sutures on subsequent urinary, bowel and sexual symptoms.

Our reoperation of 6% is comparable to that found in the much larger systematic review of the use of Vicryl mesh in prolapse surgery (9%, Jia et al). Similarly our mesh erosion rate of 6% with absorbable synthetic meshes is comparable to the 6% reported by Jia et al.

### **Critical assessment**

The strength of our study is the length of follow up of participants in a prospective randomised controlled trial, and the reporting of a range of pelvic floor dysfunction symptoms by the women themselves. The prolapse and urinary symptoms (but not bowel or sexual function) were assessed using validated scales (Hagen et al., 2009; Avery et al., 2004).

A further strength is the number of gynaecologists who contributed participants. There were no learning curve issues as the technique of mesh inlay was a simple addition to the standard repair procedure. The study had high acceptability and implementation rates amongst both specialist and general gynaecologists, indicating that a larger trial could expect good buy-in, thus increasing its generalisability and feasibility.

Because it was a feasibility study, it was not powered to detect differences between the groups. Although some statistically significant differences were found, their reliability is uncertain and remains to be confirmed in a larger trial. While we did not examine the women again at two years to assess objective recurrence of prolapse, we feel that this is of less importance than the subjective report from the women

themselves, or the need for further management (particularly pessaries and surgery) which arises as a result of symptomatic recurrence.

We were unable to analyse the data according to type of repair (anterior, posterior or both; or primary or secondary surgery) because the sample size was too small, although we realise the clinical importance of doing so. We were unable to report differences in the de novo dyspareunia rate, as we did not record the baseline dyspareunia rate but we were able to compare women who were actually sexually active at follow up according to their randomised allocation.

The apparent differences between the suture types need confirmation and explanation. In fact, in our study, some trends relating to suture type (quality of life due to prolapse and urinary incontinence) reached statistical significance in favour of Vicryl sutures, contrary to our hypothesis. However, the clinical significance of the apparent benefits from Vicryl suture are difficult to evaluate and need to be confirmed in future research.

## **Conclusions**

The current study demonstrated the feasibility of obtaining meaningful patient reported outcomes related to prolapse, urinary, bowel and sexual function after prolapse surgery in the context of a randomised controlled trial. The ostensible advantages of Vicryl over PDS sutures were unexpected, contrary to our hypothesis, and need to be confirmed in future research. One such study is now under way, the multicentre RCT (PROSPECT), which is funded by the UK NIHR NETSCC HTA programme.

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## **Declaration of Interest**

None

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## **Supplemental digital content**

The following supplementary contents are available in the online version of this article:

Appendix S1. Preoperative questionnaire

Appendix S2. Surgeons questionnaire

Appendix S3. Third day postoperative questionnaire

Appendix S4. Two year questionnaire

## REFERENCES

Allahdin S, Glazener C, Bain C. 2008. A randomised controlled trial evaluating the use of polyglactin mesh, polydioxanone and polyglactin sutures for pelvic organ prolapse surgery. *J Obstet Gynaecol* 28:427-431.

Avery K, Donovan J, Peters TJ, Shaw C, Gotoh M, Abrams P. 2004. ICIQ: a brief and robust measure for evaluating the symptoms and impact of urinary incontinence. *Neurourol Urodyn* 23:322-330.

Beck RP, McCormick S, Nordstrom L. 1991. A 25-year experience with 519 anterior colporrhaphy procedures. *Obstet. Gynecol* 6:1011-1018.

Cervigni M, Natale F, Weir J, Galante L, Panei M, Agostini M, et al.. 2005. Prospective randomized trial of two new materials for the correction of anterior compartment prolapse: Pelvicol and Prolene Soft (Abstract). *Neurourology and Urodynamics* 24:585-6

Chu CC, Williams DF. 1984. Effects of physical configuration and chemical structure of suture materials on bacterial adhesion. A possible link to wound infection. *Am J Surg* 147:197-204.

De Ridder, F. Claerhout, P. Verleyen, S. Boulanger, and J. Deprest. 2004. Porcine dermis xenograft as reinforcement for cystocele stage III repair a prospective randomized controlled trial (Abstract). *Neurourol Urodyn.* 23: 435-436.

Diez-Itza I, Aizpitarte I, Becerro A. 2007. Risk factors for the recurrence of pelvic organ prolapse after vaginal surgery: a review at 5 years after surgery. *Int Urogynecol J Pelvic Floor Dysfunct* 18:1317-1324.

Dunn, D. L. 2005. "Wound Closure Manual." from [http://www.jnigateway.com/public/USENG/Ethicon\\_WCM\\_Feb2004](http://www.jnigateway.com/public/USENG/Ethicon_WCM_Feb2004).

Ellerkmann RM, Cundiff GW, Melick CF, Nihira MA, Leffler K, Bent AE. 2001. Correlation of symptoms with location and severity of pelvic organ prolapse. *Am J Obstet Gynecol* 185:1332-7.

Hagen S, Glazener C, Sinclair L, Stark D, Bugge C. 2009. Psychometric properties of the pelvic organ prolapse symptom score. *BJOG* 116:25-31.

Jia X, Glazener C, Mowatt G, MacLennan G, Bain C, Fraser C, et al.2008. Efficacy and safety of using mesh or grafts in surgery for anterior and/or posterior vaginal wall prolapse: systematic review and meta-analysis. BJOG 115:1350-1361.

Karlovsky ME, Kushner L, Badlani GH.2005. Synthetic biomaterials for pelvic floor reconstruction. Curr Urol Rep 6:376-384.

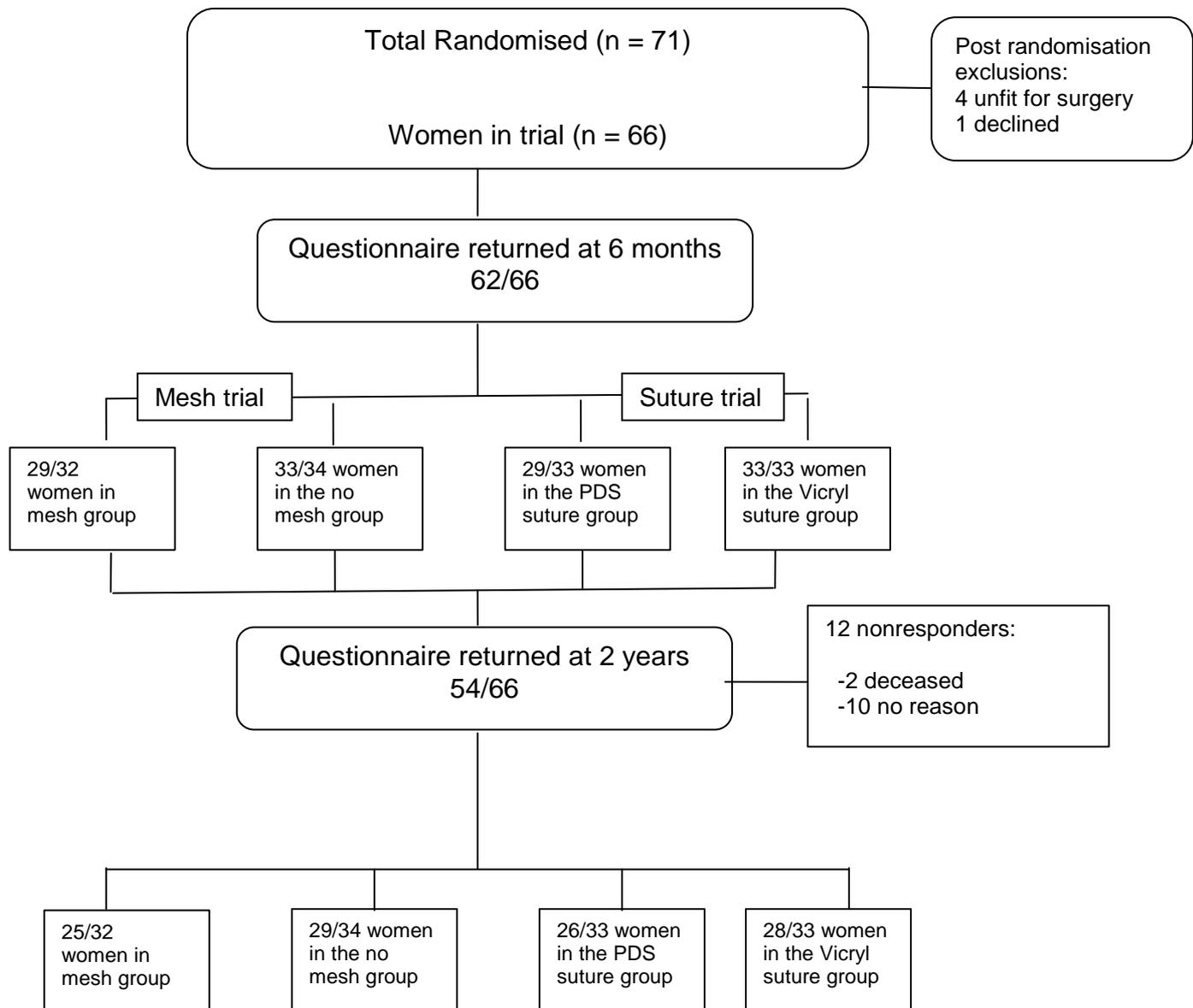
Maher C, Feiner B, Baessler K, Glazener CMA. 2010. Surgical management of pelvic organ prolapse in women. Cochrane Database of Systematic Reviews, Issue 4. Art. No.: CD004014. DOI: 10.1002/14651858.

Meschia M, Pifarotti P, Bernasconi F, Magatti F, Riva D, Kojancic E.2007. Porcine skin collagen implants to prevent anterior vaginal wall prolapse recurrence: A multicentre, randomized study. Journal of Urology, **177**:192-5.

Olsen AL, Smith VJ, Bergstrom JO, Colling JC, Clark AL.1997. Epidemiology of surgically managed pelvic organ prolapse and urinary incontinence. Obstet.Gynecol 89:501-506.

Srikrishna S, Robinson D, Cardozo L, Cartwright R. 2008. Experiences and expectations of women with urogenital prolapse: a quantitative and qualitative exploration. BJOG 115:1362-1368.

**Figure 1 Study Flow chart showing flow of participants through the study and 2 years follow up.**



**Table 1 Baseline characteristics by randomised allocation**

	Mesh Trial		Suture Trial	
	Mesh (n=32)	No mesh (n=34)	Polydioxanone (n=33)	Polyglactin (n=33)
Age >= 60 years	18 (56.3%)	20 (58.8%)	19 (57.6%)	19 (57.6%)
Parity				
Para 1 or less	15 (46.9%)	17 (50%)	14 (42.4%)	18 (54.5%)
Para 2 or more	17 (53.1%)	16 (47.1%)	19 (57.6%)	14 (42.4%)
Post-menopausal	28 (87.5%)	28 (82.4%)	28 (84.8%)	28 (84.8%)
Smoking	1 (3.1%)	3 (8.8%)	3 (9.1%)	1 (3%)
HRT	5 (15.6%)	2 (5.9%)	2 (6.1%)	5 (15.2%)
COPD	7 (21.9%)	7 (20.6%)	7 (21.2%)	7 (21.2%)
PFMT	9 (28.1%)	9 (26.5%)	8 (24.2%)	10 (30.3%)
Primary operation	27 (84.4%)	30 (88.2%)	28 (84.8%)	29 (87.9%)
Secondary operation	5 (15.6%)	4 (11.8%)	5 (15.2%)	4 (12.1%)
Preoperative ring use	8 (25%)	4 (11.8%)	4 (12.1%)	8 (24.2%)
Type of prolapse				
Cystocele	16 (50%)	12 (35.3%)	16 (48.5%)	12 (36.4%)
Rectocele	7 (21.9%)	6 (17.6%)	5 (15.2%)	8 (24.2%)
Both (19)	8 (25%)	11 (32.4%)	9 (27.3%)	10 (30.3%)
Paravaginal repair	2 (6.3%)	0 (0%)	1 (3%)	1 (3%)
Concomitant operations				
Hysterectomy	6 (18.8%)	8 (23.5%)	9 (27.3%)	5 (15.2%)
Cervical amputation	8 (25%)	10 (29.4%)	8 (24.2%)	10 (30.3%)
Continence operation	7 (21.9%)	6 (17.6%)	5 (15.2%)	8 (24.2%)
Other	0 (0%)	2 (5.9%)	0 (0%)	2 (6.1%)

COPD chronic obstructive airway disease, HRT hormone replacement therapy, PFMT pelvic floor muscle training, Polydioxanone = PDS, Polyglactin = Vicryl

**Table II Effects of surgery on prolapse symptom (POP-SS) and Quality of Life (QoL) scores at baseline and 2 years after surgery**

	Mesh Trial			Suture Trial		
	With Mesh	No mesh	Adjusted mean difference <sup>a</sup> (95% CI)	With PDS	With Vicryl	Adjusted mean difference <sup>a</sup> (95% CI)
Baseline Mean(SD)n	14.0(7.0) 32	13.0(6.3)34		14.1(7.1)33	13.0(6.2) 33	
2 Years Mean(SD)n	4.3(4.2)25	4.3(6.3)29	0.21 (-3.14 to 2.73)	5.5(6.3) 26	3.2(4.2)28	2.24(-0.70 to 5.17)
<b>Quality of Life due to prolapse symptoms<sup>c</sup></b>						
Baseline Mean(SD)n	5.1(3.3)30	4.5(3.8)33		4.7(3.5)31	4.8(3.7)32	
2 Years Mean(SD)n	1.5(3.0)23	1.8(3.5)29	-0.23(-2.08 to 1.63)	2.5(4.1)24	0.9(2.1)28	2.05 (0.19 to 3.91) <i>p</i> -value<0.05

<sup>a</sup>The adjusted mean differences and their confidence intervals were calculated using an ANCOVA model.

<sup>b</sup>POP-SS = Pelvic Organ Prolapse – Symptom Score, (0= none of seven prolapse symptoms were present at any time to 28= when all seven symptoms were present all the time)

<sup>c</sup> Effect of prolapse symptoms on quality of life (0='not at all' to 10='a great deal').

**Table III** Number of women satisfied with surgery and number who would recommend surgery to a friend at 2 years after surgery

	Mesh Trial			Suture Trial		
	With Mesh	No Mesh	<i>p</i> -value <sup>a</sup>	With PDS	With Vicryl	<i>p</i> -value <sup>a</sup>
Satisfied <sup>b</sup> at 2 years n/N	20/23	21/25	1.000	17/22	24/26	0.289
Recommend at 2 years n/N	21/24	20/24	1.000	16/22	25/26	0.060

<sup>a</sup> Fisher's exact test.

n= number of women satisfied or recommended surgery to a friend, N = number of women who responded.

Satisfaction was assessed on a five point Likert scale [very satisfied, fairly satisfied, fairly dissatisfied, very dissatisfied and not sure].

<sup>b</sup> Satisfied defined as very or fairly satisfied

**Table IV** Effects of surgery on urine symptoms and Quality of Life (QoL) scores at baseline and 2 years after surgery

	Mesh trial		Adjusted mean difference <sup>a</sup> (95% CI)	Suture Trial		Adjusted mean difference <sup>a</sup> Effect size (95% CI)
	With Mesh	No mesh		With PDS	With Vicryl	
<b>Urinary Symptoms: ICI Score<sup>b</sup></b>						
Baseline Mean (SD)n	8.1(5.8)32	7.1(6.6)33		6.9(6.0)33	8.3(6.5)32	
2years Mean (SD)n	4.2(3.9)25	4.6(5.5)29	-1.05 (-3.60 to 1.52)	5.5(5.9)26	3.5(3.3)28	2.56 (0.02 to 5.11) p-value<0.05
<b>Quality of Life due to urinary symptoms<sup>c</sup></b>						
Baseline Mean (SD)n	3.6(3.6)32	3.4(3.7)34		3.1(3.4)33	3.9(4.0)33	
2years Mean (SD)n	1.3(2.6)25	1.5(2.8)29	-0.38 (-1.80 to 1.04)	2.1(3.5)26	0.8(1.4)28	1.45 (0.03 to 2.86) p-value<0.05

<sup>a</sup> The adjusted mean differences and their confidence intervals were calculated through an ANCOVA model.

<sup>b</sup> ICI-Q score(International Consultation on Continence Short-Form Urinary Incontinence questionnaire): 0=no symptoms, 21=maximum frequency, quantity of incontinence and effect on quality of life

<sup>c</sup> Effect of urinary symptoms on quality of life (0='not at all' to 10='a great deal').

**Table V Bowels symptoms and their effect on quality of life at baseline and 2 years after surgery**

	Mesh Trial		Odds Ratio <sup>a</sup> (95% CI)	Suture Trial		Odds Ratio <sup>a</sup> (95% CI)
	With Mesh	No Mesh		With PDS	With Vicryl	
<b>Constipation<sup>c</sup></b>						
Baseline n/N	16/32	14/33		18/33	12/32	
2 years n/N	6/24	9/28	0.70 (0.21 to 2.38)	7/24	8/28	1.05 (0.32 to 3.54)
<b>Faecal urgency<sup>c</sup></b>						
Baseline n/N	10/31	7/33		9/33	8/31	
2 years n/N	5/24	5/27	1.13 (0.28 to 4.55)	5/23	5/28	1.26 (0.31 to 5.08)
<b>Faecal incontinence<sup>c</sup></b>						
Baseline n/N(%)	8/31	5/33		8/33	5/31	
2 years n/N	5/24	6/27	0.92 (0.24 to 3.53)	5/23	6/28	1.03 (0.237to 3.95)
<b>Quality of Life due to bowel symptoms<sup>d</sup></b>						
	Adjusted mean difference <sup>b</sup> (95% CI)			Adjusted mean difference <sup>b</sup> (95% CI)		
Baseline Mean(SD)n	2.1(2.2)32	1.7(2.2)32		2.1(2.4)33	1.7(2.3)32	
2 years Mean(SD)n	2.0(2.9)23	1.1(2.1)28	0.6 (-0.77 to 1.98)	2.2(3.2)23	0.9(1.5)28	1.08 (-0.29 to 2.45)

n= number of women with bowel symptoms, N = number of women who responded

<sup>a</sup>The adjusted odds ratios and their confidence intervals were calculated using a logistic regression model

<sup>b</sup>The adjusted mean differences and their confidence intervals were calculated using an ANCOVA model.

<sup>c</sup> Definitions: Constipation [sometimes, most of the time or all the time]; faecal urgency [sometimes, most of the time or all the time]; faecal incontinence [occasionally, sometimes, most of the time or all the time].

<sup>d</sup> Effect of any bowel symptoms on quality of life (0='not at all' to 10='a great deal').

**Table VI** Number of sexually active women with difficulty with intercourse or pain with intercourse at two years after prolapse surgery, and effect of prolapse on quality of life due to sexual problems.

	Mesh trial			Suture Trial		
	With Mesh	No Mesh	<i>p</i> -value <sup>a</sup>	With PDS	With Vicryl	<i>p</i> -value <sup>a</sup>
<b>Difficulty with intercourse</b>						
2 Years n/N	3/9	6/13	0.873	3/11	6/11	0.386
<b>Pain with intercourse</b>						
2 Years n/N	3/9	3/12	1	2/11	4/10	1
<b>Sexual quality of life scores at baseline and 2 years after prolapse surgery</b>						
	With Mesh	No mesh	<i>p</i> -value <sup>b</sup>	With PDS	With Vicryl	<i>p</i> -value <sup>b</sup>
Baseline-Median [IQR](n)	6.0[2.0 to 7.0](15)	5.0[2.0 to 8.5](20)		6.0[3.0 to 10.0](18)	3.0[2.0 to 7.0](17)	
2 Years Median [IQR] (n)	0[0 to 1.0](9)	0[0 to 4.0](14)	0.671	0[0 to 4.00](11)	0[0 to 3.0](12)	0.863

Only 21 women were sexually active after surgery

n = Number of women reporting difficulty or pain with intercourse, and effect of prolapse on quality of life due to sexual symptoms (0='not at all' to 10='a great deal'), N = number of women who responded.

IQR = interquartile range

<sup>a</sup> Fisher's exact test

<sup>b</sup> Mann-Whitney-Wilcoxon test