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ORIGINAL ARTICLE

# Long-term safety and efficacy of laparoscopically placed mesh for apical prolapse

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## Abstract

**Introduction and hypothesis** Concerns regarding the use of vaginal mesh for prolapse have led to questions about the safety and efficacy of abdominally placed mesh. Mesh procedures for treating apical prolapse have become popular, either a laparoscopic hysteropexy (LSH) for uterine prolapse or a sacrocolpopexy (LSC) for vaginal vault prolapse. Robust long-term safety and efficacy data for these procedures are essential.

**Methods** All patients who had LSH or LSC since 2010 were invited back for face-to-face review and examination. Case notes were reviewed for surgical morbidities and patients were questioned about short- and long-term complications. The Patient Global Impression of Improvement (PGI-I) scale was used to assess prolapse, bladder and bowel symptoms postoperatively.

**Results** One hundred twelve patients were included in the review, 93 of whom were examined. The median time since surgery was 6 years (range 1–9 years); 2.7% cases had an intraoperative complication, two conversions to laparotomy and one bladder injury. Overall, 17.3% patients sought medical review postoperatively, with 10.7% having problems with their skin incisions. With regard to mesh safety, there was one case of bowel obstruction requiring resection following LSH and two vaginal mesh exposures following LSC; 97% had stage 1 or less apical prolapse at long-term follow-up and 79.6% reported symptoms of prolapse to be 'much better' or 'very much better' on the PGI-I scale.

**Conclusions** This study shows excellent long-term results from LSC and LSH with comprehensive follow-up, demonstrating a very low and acceptable level of intraoperative, short- and long-term complications.

**Keywords** Apical prolapse · Laparoscopic · Mesh · Sacrocolpopexy · Sacrohysteropexy · Safety

## Introduction

Apical prolapse encompasses uterine and vaginal vault prolapse, defined as descent of the uterus or vaginal vault (post hysterectomy) [1]. It is a common presenting complaint in the gynaecology clinic and appropriate long-term management is paramount. When conservative measures fail and patients ask for surgery, all surgical options should be considered.

Uterine-sparing surgery for prolapse has become more popular and good medium-term outcomes have been shown following laparoscopic sacrohysteropexy (LSH). LSH has benefits in terms of both medium-term outcomes and intraoperative complications compared to hysterectomy [2]. A large review showed a good subjective cure rate and low rates of repeat apical surgery [3].

The true prevalence of post-hysterectomy vault prolapse is unknown, but it is quoted as 0.2% to 43% [4]. Sacrocolpopexy is associated with lower awareness of prolapse, recurrence, need for repeat surgery and postoperative stress urinary incontinence compared to a variety of vaginal interventions [5]. Laparoscopic sacrocolpopexy (LSC) is equally as effective as abdominal sacrocolpopexy (ASC) giving 90% anatomical cure [6] but the minimal access technique reduces blood loss and length of stay [7].

Recent concerns regarding the use of vaginal mesh for prolapse have led to questions about the safety and efficacy

Contribution
Gemma Nightingale and Christian Phillips have equally contributed to the planning, execution and write up of this project.

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of abdominally placed mesh. Surgical morbidity, as well as medium- and long-term deleterious sequelae from vaginal mesh, appear higher than initially thought. The main long-term complications for vaginal mesh have proven to be mesh exposure or pain [8, 9].

When placed abdominally for apical prolapse, mesh exposure can be either into the vagina or into an abdominal viscus. The rate of mesh erosion in ASC is quoted as 2–11% with the risk of serious complication being 2% [10]. Vaginal mesh exposure following LSC was found to be 0.7% in one study [11] and 2% in another [12]. Long-term follow-up of laparoscopic sacrohysteropexy (LSH) found a 1.8% complication rate and no cases of mesh exposure [3].

Since 10 July 2018, in the UK, all transvaginal meshes for prolapse and tapes for stress urinary incontinence have been placed on "pause" and surgery using them cannot be performed. Transabdominal placement of mesh [LSC/LSH or ventral mesh rectopexy (VMR)] is permitted but is categorized as procedures under "high vigilance" with strict guidance on governance around the surgery. In the current climate, it is imperative that long-term data on it's safety and efficacy are collected and shared. To gain a true understanding of immediate, short- and long-term complications and outcomes, we invited all patients with abdominal mesh for prolapse back for review.

## Materials and methods

Laparoscopic sacrocolpoexy was introduced to our Trust in 2010, with laparoscopic hysteropexy introduced in 2010. As part of the hospital's "introduction of new procedure policy" all patients are consented for short-, medium- and long-term follow-up for service evaluation. As such, all patients undergoing LSC, LSH and VMR were always consented for long-term service evaluation. Ethical approval was sought but deemed not necessary by the hospital departments for 'Clinical Governance' and 'Research and Innovation'.

Cases between 2010 and the end of 2017 were identified using electronic theatre schedules, handwritten theatre booking diaries and the British Society of Urogynaecology (BSUG) database.

The surgical techniques employed have remained largely unchanged. For LSC, the extent of dissection was determined by the site and severity of prolapse, along with the degree of scarring in the affected compartments. The level of dissection was not standardized for fears that unnecessary extensive dissection could compromise subsequent bladder, bowel and sexual function. The type of mesh used for LSC was altered early on in the series in 2011 to Artysan (Ethicon, Somerville, NJ, USA) following two erosions seen with a heavier mesh. The mesh was attached to the anterior longitudinal ligament over the vertebral body of L5 using helical metal tackers (ProTack 5 mm, Tyco Healthcare, Mansfield, MA, USA) and to the vagina with 10-12 2-0 Vicryl sutures (Polyglactin, Ethicon, Somerville, NJ, USA). For LSH, a Prolene mesh (undyed polypropylene knitted non-absorbable mesh 15 cm × 15 cm, Ethicon, Somerville, NJ, USA) was used and cut to into an 'inverted Y' shape by the surgeon. Ethibond (Ethibond Excel, Polyethylene terephthalate, Ethicon, Somerville, NJ, USA) was used to attach the mesh to the cervical body as described by the Oxford group [13] and then tacked to L5 in the same way as for LSC. The peritoneum was always closed to cover the mesh for both procedures. No patients had a concomitant vaginal repair or continence procedure.

All patients were contacted by letter and invited to the hospital for review and examination. Case notes were collated and reviewed. Patients who accepted the invitation were seen and reviewed by either one of the authors. Enquiries were made about any postoperative problems, additional visits to their general practitioner (GP), any further surgery and any longer term complications. Patients were asked about abdominal or vaginal pain, dyspareunia and any urinary or bowel symptoms. The Patient Global Impression of Improvement (PGI-I) scale was used as a validated tool [10, 14] to assess symptoms of prolapse, bladder and bowel dysfunction.

Abdominal and vaginal examinations were performed to elicit any pain, determine the Pelvic Organ Prolapse Quantification (POP-Q) score [1] and check for mesh exposure. Patients were examined in a semi-recumbent lithotomy position and asked to perform a Valsalva manoeuvre or give a forceful cough.

The primary outcome measure for this service evaluation was patient safety, measured by the incidence of complications, either intra- or postoperatively. Complications were deemed to include visceral injury, need for blood transfusion, intensive care admission, return to theatre, reoperation for mesh exposure and long-term pain or dyspareunia. Secondary outcome measures included the duration of stay, requirement to see a Healthcare Professional postoperatively (outside of planned follow-up), need for repeat prolapse surgery, recurrence of prolapse (classed as stage 2 or greater on POP-Q) and patient PGI-I.

## Results

One hundred fifty-two patients were identified as having abdominally placed mesh for apical prolapse since 2010. Figure 1 outlines the patients identified for follow-up. Seven patients died since their procedure but all causes of death were unrelated to surgery.

The median time since surgery was 6 years (range 1–9 years). The median length of stay was 1 night (range 1–5 nights). There were eight patients (7.3%) requiring > 2 night's stay; three had ASC, two LSC cases were converted to open,

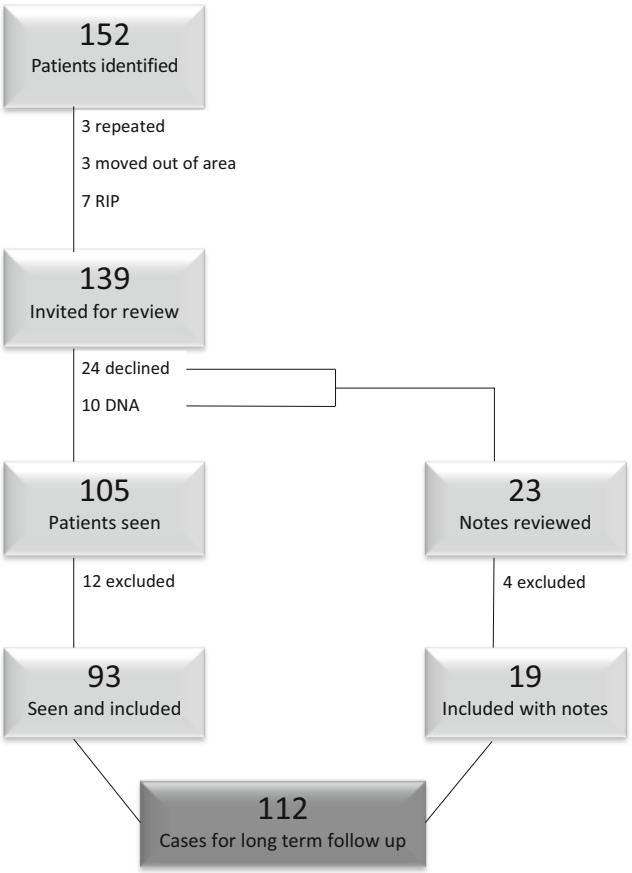



**Fig. 1** Flow diagram of patients identified and those included in the service evaluation

two patients had respiratory conditions requiring input prior to discharge and one had an intra-abdominal bleed.

Eighty-eight patients (79%) had a LSC, and of these 22 (25%) had a ventral mesh rectopexy (VMR) performed concurrently by a colorectal surgeon. Twenty-three patients (21%) had a LSH, with three of these (15%) having a VMR at the same time. Three patients had a planned ASC and two had an open subtotal hysterectomy and sacrocervicopexy.

## Safety

Complications were categorized into intraoperative, immediate, short or long term.

### Intraoperative

Two cases were started laparoscopically and converted to an open procedure. One case was converted because of adhesions and the other to complete the VMR because of scarred tissue planes in the rectovaginal space. One patient had an intraoperative bladder injury which was recognized and repaired by a Urologist. A catheter was left in situ for two weeks and there were no longer term consequences. No cases had considerable intraoperative blood loss, all documented as 10–50 ml.

The overall intraoperative complication rate was 2.7% although conversion to laparotomy is a recognized risk.

### Immediate

One patient required a blood transfusion postoperatively for a conservatively managed abdominal haematoma. Another patient required re-suturing of a port site (under local anaesthesia) for superficial bleeding requiring haemostasis. This gives an immediate complication rate of 1.8%. One patient spent a single night in the high dependency unit, but this was preplanned because of a pre-existing respiratory condition.

### Short term

There was only one readmission (0.9%) for a bleeding port site which settled with a compression dressing. Fourteen patients (12.5%) were seen as ward attenders, eight with wound problems, three with constipation, one with pain and two for removal of a catheter following urinary retention. Five patients attended their GP for review, four regarding concerns about their wound and one with constipation. Overall, 17.3% patients sought medical review postoperatively, with 10.7% having problems with their skin incisions.

### Long term

There was one case of bowel obstruction three years after a LSH. A segment of gangrenous small bowel (not perforated) was identified adherent to the mesh which required resection and primary anastomosis. The patient made a full recovery with no long-term sequalae. Two cases (1.8%) of vaginal mesh exposure were identified, five months and nine months post-laparoscopic sacrocolpopexy. Both cases had transvaginal excision of the exposed mesh performed as a day case with no further problems. Both cases of mesh exposure occurred early on in the learning curve using a heavier polypropylene mesh.

Three patients (3.2%) reported mild abdominal pain at follow-up but abdominal examination was unremarkable. Vaginal discomfort was reported by three patients and a further four patients reported superficial dyspareunia. Only one patient was no longer sexually active because of vaginal discomfort.

## Efficacy

Four patients had early recurrence of apical prolapse following LSC (3.6%). Repeat laparoscopy showed the mesh had stretched in two women and detached from the vaginal vault in the remaining two cases. In the cases where the mesh had

stretched, the mesh was plicated via laparoscopy as a day case procedure with no longer term sequelae. In the two cases of detachment from the vault, one patient had a sacrospinous vault fixation (SSVF); the other had a SSVF with further recurrence and then a repeat LSC. Both patients had suffered severe constipation which caused extreme straining, leading to the recurrence.

Of the patients seen back for long-term follow-up, 14 (15.1%) had subsequent pelvic floor repairs (12 anterior colporrhaphy, 2 posterior colporrhaphy). Stress urinary incontinence (SUI) was reported by 31 patients (33.3%) although only 11 (11.8%) of these were de novo following surgery. Nine patients (9.7%) went on to have a TVT® (Gynecare TVT Retopubic System, Ethicon, USA) placed.

All patients attending follow-up accepted an examination and no vaginal mesh exposures were identified. The only two mesh exposures were those noted early on in the learning curve that were treated as day cases. All patients tolerated a speculum examination and vaginal examination without undue discomfort.

The majority of patients had stage 1 or less prolapse in any compartment; 98% apical, 96% posterior compartment and 66% anterior compartment. The median value for point C on POP-Q was −9. When comparing point C with the total vaginal length (TVL), 91 patients (98%) had C ≤ -(TVL/2). Table 1 shows the percentage of patients with each stage of prolapse by compartment both preoperatively and at long-term follow-up. Graph 1 shows the percentage of patients with stage 1 or less prolapse preoperatively and at long-term follow-up.

Seventy-four patients (79.6%) reported their symptoms of prolapse were 'much better' or 'very much better' on the PGI-I scale since surgery. Of those who had urinary and bowel symptoms prior to surgery, 47.3% and 38.8% respectively were 'very much better' or 'much better' postoperatively. Nineteen patients did not have any bladder symptoms preoperatively and 44 did not have any bowel symptoms. For this reason, the PGI-I has been shown as a percentage of people with prolapse, bladder or bowel symptoms preoperatively, shown in Graph 2.

For the 12 patients who reported 'no change' or a worsening in their symptoms, surgical details and examination findings are shown in Table 2.

Results from patients with follow-up of 60 months (5 years) or more were sub-analysed. Sixty-one patients were included in this "long-term" category, with a median follow-up of 82 months (6.8 years); 96.7% patients in this group had stage 1 or less apical prolapse at follow-up. All the patients in our series who had subsequent vaginal repairs are in this subgroup. That equates to 19.7% having a subsequent anterior colporrhaphy and 3.3% a posterior colporrhaphy; 68.9% had no significant cystocele (grade 1 or less) and 96.7% had no significant recto-enterocele on follow-up examination. Within this group, 80.3% still felt their symptoms were 'much better' or 'very much better' on PGI-I.

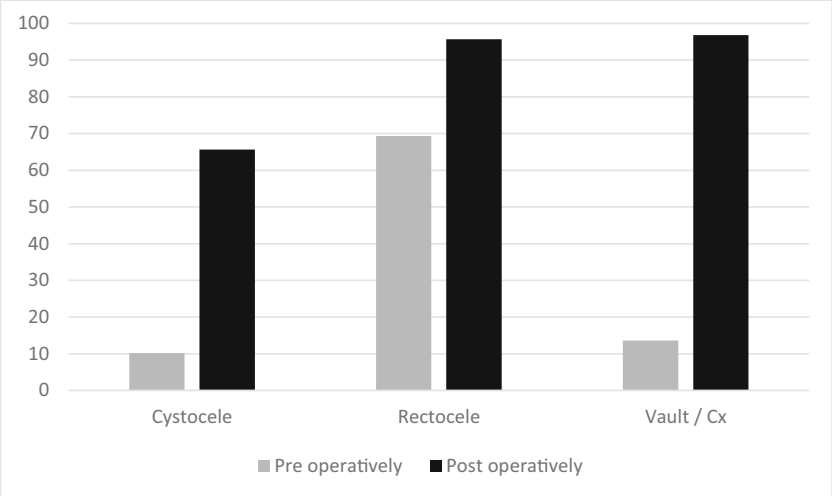
## Discussion

Although there have been other papers assessing the long-term safety of laparoscopic apical support surgery, this is the largest long-term review of patients treated by laparascopic sacrocolpopexy/hysteropexy in whom all patients were invited back for a face-to-face review and examination. We present both safety and efficacy data. Jefferis et al. reported their 10-year experience of LSH which included more patients, but their paper was a case note review alone and patients were not invited back for examination; thus, failures and complications may have been under-reported [3]. Similarly, Baines et al. reported long-term follow-up of LSC with large numbers but again patients were not invited back for clinical examination and interview [11]. The median follow-up in our series is longer than in other published work [12, 15].

This study demonstrates a low intraoperative complication rate. The only intraoperative complication involving injury to a viscera was the single bladder injury. Excluding the

**Table 1** Percentage of patients with stage 0–4 prolapse by compartment, preoperatively and at follow-up

| Stage of prolapse | Cystocele | | Rectocele | | Apical compartment | |
|---|---|---|---|---|---|---|
| | % of patients pre operatively $n = 88$ | % of patients at follow-up $n = 93$ | % of patients preoperatively $n = 88$ | % of patients at follow-up $n = 93$ | % of patients preoperatively $n = 88$ | % of patients at follow-up $n = 93$ |
| 0 | 4.5 | 37.6 | 39.8 | 74.2 | 4.5 | 91.4 |
| 1 | 5.7 | 28.0 | 29.5 | 21.5 | 9.1 | 6.5 |
| 2 | 44.3 | 26.9 | 15.9 | 4.3 | 38.6 | 1.1 |
| 3 | 40.9 | 6.5 | 10.2 | 0 | 31.8 | 1.1 |
| 4 | 4.5 | 1.1 | 4.5 | 0 | 15.9 | 0 |

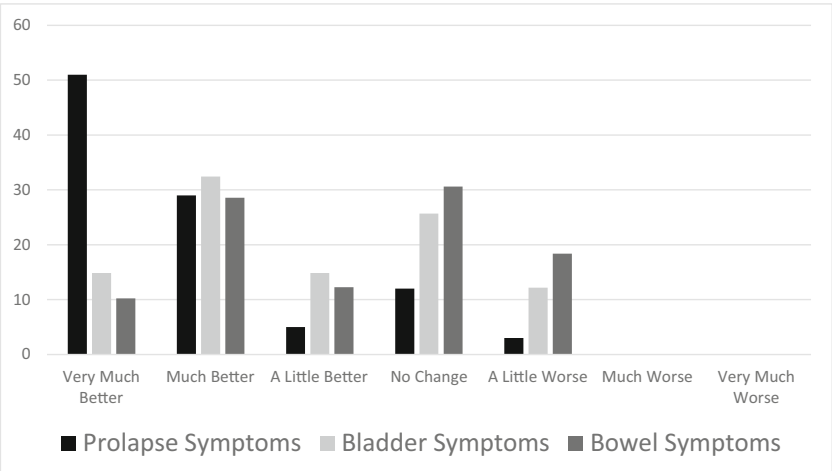



**Graph 1** Percentage of patients with stage 1 or less prolapse pre- and postoperatively, by compartment. Preoperatively $n = 88$; postoperatively $n = 93$

conversion to laparotomy, this gives an intraoperative complication rate of < 1%. There were no cases of bowel injury or major blood loss which confirms that laparoscopy and abdominally placed mesh for prolapse is a safe operation. The complication rates in our series are lower than in other published studies [11, 16]. This may be because all early cases in the series were performed jointly with a colorectal colleague; thus, the lower complication rate may be a reflection of having two experienced surgeons working together. For LSC, the degree of anterior and posterior dissection was individualized to each patient depending on the degree of prolapse in each compartment. On occasions, the dissection may not have been as extensive as the surgeon would have desired because of limitations imposed by scarring from previous surgery. To reduce the risk of iatrogenic bladder or bowel injury the level of dissection may therefore have been compromised. It is the opinion of the author team that a low intraoperative complication rate, but higher recurrent rate is preferable than a higher intraoperative complication rate that may preclude mesh placement if bowel (or possibly bladder) injury occurs. The authors recognize a low iatrgenic injury rate but a higher rate of vaginal repairs than in other series [12, 13, 19]. Two cases which started laparoscopically were converted to an open procedure giving a rate of 1.9%. These were converted for technical reasons where the surgeons decided that a laparotomy would allow a better outcome rather than a complication. Our results are consistent but lower than those found by Gantra et al., who, in their large systematic review of laparoscopic prolapse procedures, found a conversion rate of 2.7% [17]. This again may be due to the learning curve or complex cases being performed with cooperation between the urogynaecology and colorectal consultants.

Our mesh exposure rate of 2.6% is consistent with previous rates quoted in the literature which range from 0.7 to 2.9% depending on the paper [11, 12, 15, 18]. It is interesting to highlight that there were no asymptomatic mesh exposures at (median 6-year) follow-up as this has been a concern in papers that did not include face-to-face review [11].

The only significant long-term mesh complication in our series was the small bowel resection which occurred following a bowel obstruction from a segment of small bowel adherent to the mesh after LSH. This case was early in the learning




**Graph 2** PGI-I scores for prolapse, bladder and bowel symptoms at long-term follow-up. Shown as percentage of patients with symptoms preoperatively

**Table 2** Surgical details, examination findings and outcomes for patients reporting 'no change' or 'a little worse' on the PGI-I scale. [PFE = pelvic floor exercises, AR = anterior repair (colporrhaphy)]

| PGI-I | Initial surgery | Findings on examination Baden-Walker degree of prolapse | | | Outcome |
|---|---|---|---|---|---|
| | | Cystocele | Recto-enterocele | Uterus/vault | |
| No change | LSC 2011 | 1 | 0 | 0 | PFE |
| | LSC (converted to open) 2011 | 0 | 2 | 0 | PFE |
| | LSC 2012 | 1 | 0 | 0 | Pessary inserted |
| | LSC 2013, AR 2015 | 3 | 1 | 2 | PFE |
| | LSH 2014 | 3 | 0 | 0 | Listed for AR |
| | LSH 2014 | 1 | 0 | 0 | Pessary inserted |
| | LSC 2014 | 2 | 0 | 0 | PFE |
| | LSH 2014 | 2 | 0 | 0 | PFE |
| | LSC 2015 (mesh detachment followed by SSVF) | 4 | 2 | 3 | Pessary inserted |
| | LSC 2018 (bladder injury) | 3 | 0 | 0 | Listed for AR |
| A little worse | LSC 2011 | 1 | 1 | 3 | Pessary inserted |
| | LSC 2016 (mesh detachment, SSVF, repeat LSC 2018 complicated by abdominal haematoma) | 2 | 0 | 1 | PFE |

curve of the surgeon and the technique of covering the entirety of the mesh had been improved in the later cases.

The subjective cure rate in our series was 79.6%. This is comparable to other studies which quote a subjective cure rate ranging from 79 to 96% depending on the scale used in some studies [3, 11, 12, 15, 16, 18]. The subjective cure rate in the group with ≥ 5-year follow-up was also high at 80%, which is similar to the long-term results following abdominal sacrocolpopexy [19].

Table 1 outlines the details of the 12.9% patients who reported either no change in their symptoms of prolapse or worsening of their symptoms. Of those reporting worse symptoms or no change in symptoms, only three women had apical prolapse of stage 1 or more; one had multicompartment prolapse. Five patients had anterior or posterior compartment prolapse causing their symptoms. Considering that no patients in our series had concomitant pelvic floor repairs, the overall subjective cure rate for apical prolapse is positive, although the authors acknowledge in this is a very small minority (12.9%) of patients, and the sacrocolpopexy failed to fully address their global prolapse. Only 15% patients had a subsequent pelvic floor repair, which supports the strategy for interval surgery over concomitant laparoscopic and vaginal procedures. If the subsequent vaginal repairs are classified as 'recurrences' of that particular compartment, then the proportion of patients with stage 1 or less prolapse in the anterior compartment would be lower at 53% and 94% for the posterior compartment. The authors acknowledge that there is debate about whether concomitant prophylactic surgery for incontinence should be performed at the same time as sacrocolpopexy; this is beyond the scope of this paper. However, our data appears to support waiting and performing interval surgery for incontinence if the patient still has/develops "de novo" incontinence following apical surgery [20]. Only 9.7% patients had a surgical procedure for SUI postoperatively when 17.8% were symptomatic prior to surgery.

We did note the number of patients seeking medical attention for wound infections or problems was higher than expected. This may be a reflection of how the data were collected as many of the patients were dealt with in primary care, this would not normally have been reported to the surgeon and would have been excluded from retrospective case note reviews [3, 11]. Since this service evaluation, patients are receiving an additional dose of antibiotic prophylaxis and wound care is emphasized at discharge. This will be re-examined at a later date.

## Strengths and weaknesses

The strengths of our study include the inclusivity of all patients being invited back for long-term follow-up face to face, the long duration of median follow-up (6 years) and the large number of patients included. Sixty-five per cent of patients seen face-to-face had their surgery < 5 years ago. All patients were reviewed by one of the authors guaranteeing consistency in the questioning, examination and documentation of POP-Q. No concomitant prolapse surgery was performed on our patients meaning that follow-up results and reoperation rates are accurate for LSC/LSH alone. Many other papers involve

multiple surgeries, which will alter the true long-term outcome of LSC/LSH.

A weakness of our study is the heterogenicity of procedures included. A mixture of hysteropexy and sacrocolpopexy (± ventral mesh rectopexy) was assessed. As the primary outcome was the safety of mesh the authors think this is relevant and appropriate. Another weakness is the heterogeneity in preoperative assessment in relation to both symptoms and staging of prolapse, which prevents direct comparison of pre- and postoperative symptom scores and staging of prolapse. However, the PGI-I was used, which is a recognized validated tool to assess subjective outcomes. Postoperative POP-Q classification was performed on all patients to assess objective cure, and an assessment of stage of preoperative prolapse was made from either Baden-Walker or POP-Q classification. This technique is well recognized and has been adopted in large randomized studies in the past [21]. Only 83% patients included in this review were actually seen face to face, but this still includes 93 patients, which is larger than other long-term follow-up studies [19].

In conclusion, this study shows excellent long-term results from LSC and LSH with robust follow-up, demonstrating a very low and acceptable level of intraoperative (< 1%) and short-term complications. Our study confirms the long-term safety of abdominally placed mesh with low levels of mesh exposure (2.6%) or long-term pain. The efficacy of apical support with mesh is commendable with 98% objective cure rate and 80% subjective cure rate at long-term follow-up.

## Compliance with ethical standards

**Conflict of interest** None.

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