International Journal of Gynecology and Obstetrics xxx (2016) xxx–xxx

Contents lists available at ScienceDirect

International Journal of Gynecology and Obstetrics

journal homepage: www.elsevier.com/locate/ijgo

www.figo.org

CLINICAL ARTICLE

# Early safety and efficacy outcomes of a novel technique of sacrocolpopexy for the treatment of apical prolapse

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ARTICLE INFO

*Article history:*
Received 25 September 2015
Received in revised form 12 May 2016
Accepted 18 July 2016

*Keywords:*
Apical prolapse
Bilateral abdominal sacrocolpopexy
Cervico-sacropexy (CESA)
Polyvinylidene fluoride mesh
Vagino-sacropexy (VASA)

ABSTRACT

*Objective:* To assess the safety and efficacy of a modified technique of bilateral abdominal sacrocolpopexy in which both uterosacral ligaments are replaced with polyvinylidene fluoride mesh to provide support to the cervix (cervico-sacropexy [CESA]) or vaginal vault (vagino-sacropexy [VASA]). *Methods:* A retrospective observational study was undertaken of women with posthysterectomy vault prolapse or recurrent apical prolapse following previous vaginal repair who underwent bilateral sacrocolpopexy between July 1, 2013, and December 31, 2014, in a tertiary referral unit in the UK. Before surgery and 3 months afterwards, prolapse was assessed using the Pelvic Organ Prolapse Quantification scale and functional outcomes were recorded using the International Consultation on Incontinence Questionnaire for vaginal symptoms and urinary incontinence. *Results:* Fifty women were included. At 3 months, 47 (94%) patients reported no bulge symptoms and the mean point C was −7.6. Complications comprised bladder injury in 1 (2%) and minor wound problems in 3 (6%) patients. No mesh erosion was reported. *Conclusion:* Bilateral abdominal sacrocolpopexy seems to be a safe and effective option for apical prolapse. Longer-term follow-up is needed to detect prolapse recurrence and mesh-related complications.





## 1. Introduction

The incidence of posthysterectomy prolapse varies from 0.2% to 45% [1]. Various treatment options are available, including the use of a vaginal pessary, pelvic floor physiotherapy, and surgery. Commonly performed surgery for vault prolapse includes sacrospinous fixation, transvaginal mesh insertion, and abdominal sacrocolpopexy.

Abdominal sacrocolpopexy was first described in 1957 by Lane [2] and has long been considered to be a gold-standard procedure for vaginal vault prolapse. The slightly higher surgery-related morbidity as compared with vaginal vault fixation procedures is offset by the durability of abdominal sacrocolpopexy [3], with reported long-term success rates of 68%–100% [4]. However, new-onset bowel dysfunction (obstructed defecation in 10%–50% of patients), voiding problems (overactive bladder or stress incontinence in 33%), and sexual dysfunction have been reported with traditional sacrocolpopexy [4]. Even though the reported incidence of mesh erosion into the vagina and viscera following sacrocolpopexy is low [4], the use of synthetic mesh in vivo has always been a concern.

Various modifications of sacrocolpopexy based on the route (open, laparoscopic, or robotic), type of mesh (alloplastic or synthetic), and site of mesh attachment (sacral promontory or lower) have been described in the literature, each claiming its unique advantages and success rates. Bilateral sacrocolpopexy using a predesigned mesh kit was first described by Jäger et al. [5]. The uterosacral ligaments are replaced with alloplastic tapes that reattach the cervix or vaginal vault to the second sacral vertebra. This attachment is more physiological than is attachment to the sacral promontory and provides an anatomically symmetrical suspension of the vault to the sacrum.

The superiority of synthetic mesh (type 1 polypropylene) over biological mesh (cadaveric fascia lata and porcine dermis) in terms of reduced failure rates of sacrocolpopexy has been proven [6]. In the present study, the DynaMesh-CESA or DynaMesh-VASA mesh system (FEG Textiltechnik mbH, Aachen, Germany) was used (Fig. 1). It is composed of three small pieces of mesh: a central rectangular piece for the cervix or vault, and two lateral pieces to be attached on the anterior surface of the second sacral vertebra (S2) on either side of the colon. The pieces are attached to each other using suture bridges to minimize the amount of synthetic material used (the volume of mesh used is approximately 10% of the volume of polypropylene mesh used for traditional sacrocolpopexy).

The mesh is made of monofilament polyvinylidene fluoride (PVDF) and is macroporous (pore size 6 mm). It is impregnated with iron for magnetic resonance imaging visibility. Sutures made from PVDF have

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http://dx.doi.org/10.1016/j.ijgo.2016.05.007
0020-7292/

Please cite this article as: Rajshekhar S, et al, Early safety and efficacy outcomes of a novel technique of sacrocolpopexy for the treatment of apical prolapse, Int J Gynecol Obstet (2016), http://dx.doi.org/10.1016/j.ijgo.2016.05.007

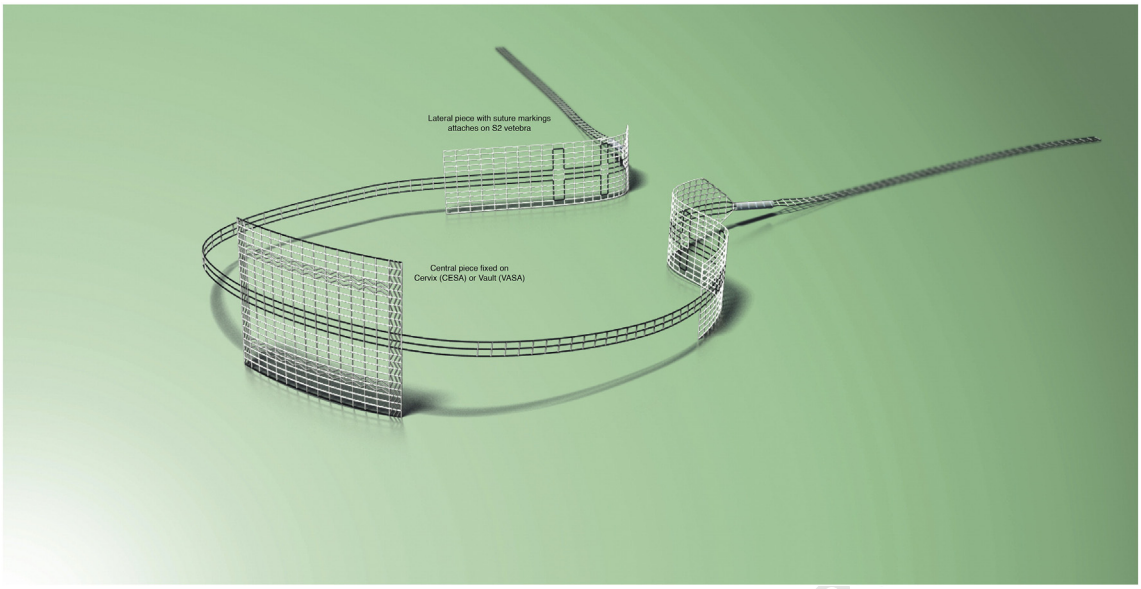


**Fig. 1.** Polyvinylidene fluoride mesh system for cervico-sacropexy and vagino-sacropexy (DynaMesh-CESA and DynaMesh-VASA; FEG Textiltechnik mbH, Aachen, Germany). Reproduced by permission of Dynamesh.

been widely used in cardiac, ophthalmic, and orthopedic surgery because of the material's high biocompatibility and reduced bacterial adherence [7]. The woven mesh has high shape stability and defined elasticity, which allows mobility of the pelvic floor while the mesh retains its shape when subjected to stresses placed on the pelvic floor [8].

The mesh is bespoke (having been designed for this particular sacrocolpopexy technique) and is therefore expensive, but it could be cost-effective if associated with less prolapse recurrence and fewer mesh-related problems in the future. Additionally, the mesh has to be sutured in place in a specific manner, ensuring standardization of the procedure, which in itself allows for a better understanding of the effects of a procedure across many units.

The aim of the present study was to review the safety and efficacy of bilateral sacrocolpopexy using DynaMesh-CESA or DynaMesh-VASA. The primary outcome measure was cure of prolapse at 3 months' follow-up; the secondary outcome measures were the complications of the procedure and the effects on bladder and bowel function.

## 2. Materials and methods

The present investigation was a retrospective observational study of women who underwent bilateral sacrocolpopexy between July 1, 2013, and December 31, 2014, at Norfolk and Norwich University Hospital, a large tertiary unit in the east of England. Patients with symptomatic posthysterectomy vault prolapse or with recurrent prolapse following previous vaginal repair were included. Patients unsuitable for an abdominal procedure were excluded. All women had either not responded to, or declined, alternative treatment options including use of a vaginal pessary, pelvic floor physiotherapy, and sacrospinous fixation. The patients were also informed regarding the modification of the traditional abdominal sacrocolpopexy procedure and the limited evidence regarding long-term outcomes of this procedure. Patients with posthysterectomy vault prolapse were offered vagino-sacropexy (VASA), and those with uterovaginal prolapse were offered subtotal hysterectomy and cervico-sacropexy (CESA) with or without bilateral salpingo-oophorectomy.

Before introducing the modified sacrocolpopexy procedure, approval was sought from the hospital new-procedure committee, who required close monitoring of clinical outcomes through a process of continuous audit. Ethics approval was not deemed necessary by the institutional research department because the present study was performed as part of the ongoing service evaluation required by the new-procedures committee. All patients gave consent—by signing the standard British Society of Urogynaecology consent form—for their details to be recorded on the society's database and used for audit and research.

Preoperative assessment in the urogynecology clinic included a standardized history of prolapse symptoms (vaginal lump or discomfort), urinary symptoms (urgency, frequency, urge or stress urinary incontinence, and voiding difficulty), bowel symptoms (difficulty with defecation, fecal urgency, and constipation), and sexual dysfunction secondary to prolapse. Objective assessment of the prolapse was performed during a Valsalva maneuver using a Sims speculum, with the patient in the left lateral position. The Pelvic Organ Prolapse Quantification scale was used to quantify the degree and type of prolapse at all sites. All patients with urinary symptoms underwent preoperative urodynamic testing. Before surgery, patients also completed the International Consultation on Incontinence Questionnaire for vaginal symptoms (ICIQ-VS) and for urinary incontinence (ICIQ-UI).

For the procedure, patients received one dose of prophylactic antibiotics. The procedure itself involves placement of the patient in a modified lithotomy position for easy abdominal and vaginal access. The abdomen is opened using a Pfannenstiel incision. In CESA, a subtotal hysterectomy is first performed, accompanied by bilateral salpingo-oophorectomy when appropriate. The uterosacral ligaments are identified at the cervix by elevating the uterus with a vaginal manipulator or the vaginal cuff with a probe in the vagina. In VASA, the peritoneum over the vault is opened to expose the vault. The peritoneum over the second sacral vertebra (S2) is opened with a vertical incision 1–2 cm long on either side of the rectosigmoid colon. Care is taken at this stage to identify the ureter on each side. The central piece of the mesh (Fig. 2) is sutured to the cervix or vagina, using four interrupted, nonabsorbable polyester sutures (Ethibond; Ethicon, Somerville, NJ, USA). A reusable curved hook with a handle (tunneler) is then introduced from the sacral peritoneal window under the peritoneum along the uterosacral ligament toward the cervix or vault. The tape arm is fed through the eye of the tunneler and brought back to the sacrum. Each arm is attached to the anterior longitudinal ligament over S2 (Fig. 3), using two interrupted Ethibond sutures. The peritoneum is closed to bury the mesh.

Operative details and data on perioperative complications were collected. All patients were reassessed 3 months after surgery in the outpatient clinic with the assessment measures used before surgery.

The data were collected using Excel 2007 (Microsoft Corporation, Redmond, WA, USA) and descriptive statistics were employed to



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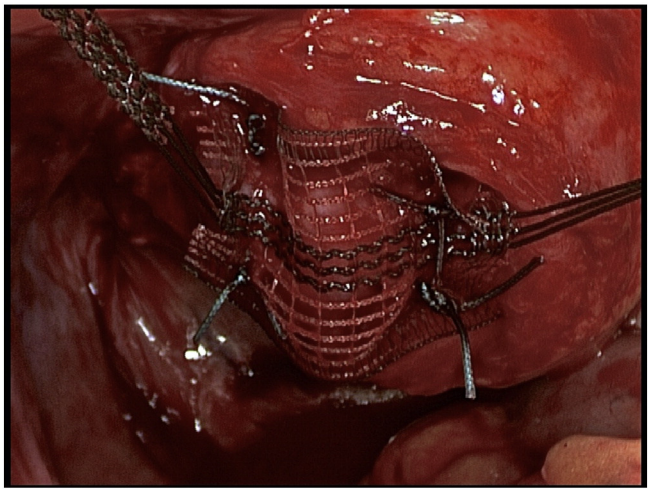

**Fig. 2.** Central portion of the mesh sutured to the vaginal vault.

present the data. Because of the nature of the present study, no other statistical analysis was necessary.

## 3. Results

Fifty women with a median age of 66 years were included in the study (Table 1). Thirty (60%) patients had a vault prolapse following abdominal hysterectomy. Twenty (40%) patients had undergone a previous prolapse procedure (vaginal hysterectomy with or without pelvic floor repair, and/or sacrospinous fixation). The sacrocolpopexy procedure was VASA in 38 patients and CESA in 12 patients. None of the patients had concomitant vaginal repair. Four patients with stress urinary incontinence confirmed by urodynamic testing underwent a tension-free vaginal tape procedure concomitantly.

VASA was not possible for three patients scheduled to undergo this procedure. Two of these patients had significant adhesions between the bowel and the left pelvic sidewall. It was difficult to mobilize the bowel safely, and one patient had a conventional sacrocolpopexy using polypropylene mesh and the second patient had only the right arm of VASA mesh attached to the vault. The third patient's bladder was adherent to the vault, and during an attempt to separate the bladder from the vault (with the assistance of an urologist), there was partial-thickness bladder injury. It was decided to abandon the procedure because of the risk of bladder mesh erosion. These patients were excluded from the study.

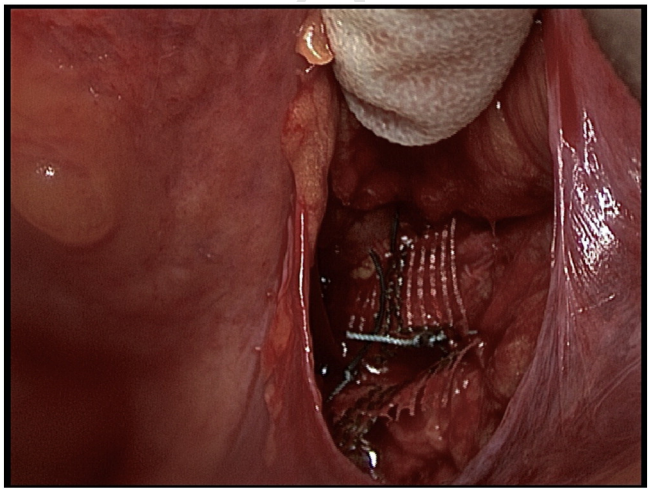

**Fig. 3.** Lateral arm of the mesh attached to the second sacral vertebra.

**Table 1**
Baseline characteristics (n = 50).

| Characteristic | Value [a] |
|---|---|
| Age, y | 66 (43–83)[b] |
| Body mass index [c] | 28 (23–32)[d] |
| Previous surgery | |
| Total abdominal hysterectomy | 28 (56) |
| Subtotal hysterectomy | 2 (4) |
| Vaginal hysterectomy | 15 (30) |
| Pelvic floor repair | 14 (28) |
| Sacrospinous fixation | 10 (20) |

[a] Values are given as number (percentage) unless indicated otherwise.
[b] Values are given as median (range).
[c] Calculated as weight in kilograms divided by the square of height in meters.
[d] Values are given as mean (range).

Intraoperative outcomes and complications among the 50 included patients are shown in Table 2. The mean duration of inpatient stay was 1.2 days (range 1–3). All patients had their catheter removed on day 1 following surgery and none of the patients had any voiding dysfunction or needed recatheterization.

Two (4%) patients had wound infection in the immediate postoperative period and were managed as outpatients using oral antibiotics. Both had an increased body mass index (29 and 30 [calculated as weight in kilograms divided by the square of height in meters]).

At 3 months after surgery, all but three patients reported an improvement in their bulge symptoms (Table 3). Four (8%) patients had a stage 1 prolapse (two cystoceles and two rectoceles) and one (2%) patient had a stage 2 cystocele on examination. Patients with a cystocele had mild symptoms, and only one needed a subsequent anterior repair. Interestingly, the two patients who had a low rectocele were both asymptomatic. In total, 21 (84%) of 25 patients with an overactive bladder before surgery were cured of their symptoms after prolapse correction. Four (16%) patients reported persistent symptoms and 1 (4%) patient needed referral to physiotherapy for bladder training. Stress incontinence improved after surgery in all except 1 (9%) of 11 patients. Four patients developed de novo stress incontinence, three of whom eventually required a tension-free vaginal tape to resolve their symptoms.

Although 13 (81%) of 16 patients reported an improvement of their bowel symptoms, 3 (19%) patients had persistent symptoms. Two patients reported de novo symptoms of constipation and straining to open their bowels. All patients were conservatively managed with laxatives and one patient needed a referral to the colorectal surgeons for further management. Of 11 patients who reported preoperative sexual dysfunction, 4 (36%) had resumed sexual activity at the 3-month follow-up visit and did not report any problems.

**Table 2**
Operative details and complications (n = 50).

| Outcome | Value [a] |
|---|---|
| Concomitant procedures | |
| Subtotal hysterectomy | 9 (18) |
| Salpingo-oophorectomy (unilateral or bilateral) | 14 (28) |
| Tension-free vaginal tape insertion | 4 (8) |
| Operative time, min | |
| Total operation [b] | 106 (60–171) |
| Sacrocolpopexy alone | 97 (60–147) |
| Complications | |
| Bladder injury | 1 (2) |
| Wound infection | 2 (4) |
| Readmission (within 4 wk) | |
| Wound dehiscence | 1 (2) |
| Obstructed defecation | 1 (2) |

[a] Values are given as number (percentage) and median (range).
[b] Includes concomitant procedures.



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**Table 3**
Symptoms before surgery and at 3-month follow-up (n = 50).[a]

| Outcome | Before surgery | After surgery | De novo symptoms after surgery |
|---|---|---|---|
| Prolapse [b] | | | |
| Stage 1 | 5 (10) | 4 (8) | – |
| Stage 2 | 23 (46) | 1 (2) | – |
| Stage 3–4 | 22 (44) | 0 | – |
| Point C | +2 (−1 to 4) | −7.6 (−6 to −8) | – |
| Bulge symptoms | 50 (100) | 3 (6) | 0 |
| Overactive bladder | 25 (50) | 4 (8) | 0 |
| Stress urinary incontinence | 11 (22) | 1 (2) | 4 (8) |
| Bowel dysfunction | 16 (32) | 3 (6) | 2 (4) |
| Sexual dysfunction | 11 (22) | 0 [c] | 0 |
| ICIQ-VS [d] | 25.3 (16–48) | 4.1 (2–10) | – |
| ICIQ-UI [e] | 9.5 (7–15) | 2.5 (1–5) | – |

Abbreviations: ICIQ-VS, International Consultation on Incontinence Questionnaire for vaginal symptoms; ICIQ-UI, International Consultation on Incontinence Questionnaire for urinary incontinence.

[a] Values are given as number (percentage) or mean (range).
[b] Quantified using the Pelvic Organ Prolapse Quantification scale.
[c] Only 4 patients had resumed sexual intercourse at 3 months' follow-up.
[d] Scale of 0–53.
[e] Scale of 0–21.

Objective improvements in prolapse symptoms and bladder function were demonstrated by changes in the ICIQ-VS and ICIQ-UI scores (Table 3).

## 4. Discussion

The present study evaluated both anatomical and functional outcomes of a novel technique of bilateral abdominal sacrocolpopexy for the treatment of apical prolapse. The procedure provided excellent vault support in 94% of patients who had no vaginal symptoms of prolapse, and suspended the vaginal vault to a mean point C of −7.6 on examination. Three patients had a cystocele at postoperative follow-up and only one of them needed a subsequent repair. Similar outcomes were noted in a previous study [5], which concluded that bilateral sacrocolpopexy is an effective treatment option for apical prolapse.

A review of the literature identified a few studies of other vaginal [9,10] or abdominal procedures [11–14] that involved reinforcement of the uterosacral ligaments to support the vault. However, procedures based on vaginal mesh are losing favor despite good success rates, because there has been a rising incidence of mesh erosions and pelvic pain.

In a small case study [11] of seven women undergoing laparoscopic uterosacral plication—which involves placing three purse string sutures incorporating the uterosacral ligaments, vagina, cervix, and the serosa of the rectosigmoid—no recurrence of prolapse was reported at 9 months and 17 months of follow-up. Maher et al. [12] used laparoscopic suture hysteropexy—involving plication and reattachment of the uterosacral ligaments to the cervix—in 43 women and reported an objective success rate of 79% at 12 months. Cutner et al. [13,14] described a laparoscopic technique of uterine suspension bilaterally to the sacral promontory using Mersilene (Ethicon, Somerville, NJ, USA) tape to recreate uterosacral ligaments. The first 10 patients reported 100% improvement in their symptoms, but 50% subsequently needed an anterior repair. The main difficulty in assessing any single procedure for prolapse repair is that it is often combined with other prolapse and/or anti-incontinence procedures. The route of repair, type of mesh, symptom questionnaire, definition of success, and duration of follow-up vary between studies. Existing data are mainly from small cohort studies with very few randomized trials.

The intraoperative complication rates in the present study were low. One (2%) patient had a bladder injury. Two (4%) patients had minor wound-related complications in the immediate postoperative period. These rates are comparable with those reported by Nygaard et al. [4], who recorded hemorrhage or blood transfusion in 4.4%, cystotomy in 3.1%, and wound infection in 4.6%. Significant bleeding can occur during dissection or mesh attachment at the sacral promontory (close to the bifurcation of the abdominal aorta and the left common iliac vein) or at the S3–S4 level from the midsacral plexus of veins [15]. With a clear understanding of the local anatomy and potential risks, the second sacral vertebra appears to be a safe area.

We have not seen any mesh erosion in the study population to date. Most studies have reported mesh erosion rates of 1%–8% with open or laparoscopic routes [4,16,17], mainly depending on the material of mesh used. Because small peritoneal windows are created to insert the mesh, it is easy to completely re-peritonealize the mesh in a tension-free fashion. This could possibly be associated with less long-term bowel or bladder mesh perforation and fewer adhesions than when the mesh is left uncovered.

Traditionally, the outcome of prolapse surgery is assessed by evaluating the anatomical improvement of prolapse. However, such surgery invariably has an effect on bladder, bowel, and sexual function. Varying the point of attachment of mesh from the sacral promontory to the second sacral vertebra ensures a more physiological axis of the vagina, and could lessen the visceral dysfunction associated with sacrocolpopexy. A substantial number of patients actually reported an improvement in their overactive bladder (84%), stress urinary incontinence (91%), and bowel symptoms (81%). Ludwig et al. [17] reported an improvement of urinary incontinence in 62% (16/26) and 33% (15/45) following CESA and VASA, respectively. Patients who had persistent urinary incontinence postoperatively were offered a transobturator tape, which resulted in an overall cure rate of 77% (CESA) and 71% (VASA) [18].

Only four patients with preoperative dyspareunia had resumed sexual activity by the 3-month follow-up in the present study, all of whom reported improved satisfaction and no pain. A recent study on sacrocolpopexy [19] has reported improved sexual function, which is important when considering this procedure in young, sexually active women.

Studies that compare laparoscopic with open sacrocolpopexy have shown less blood loss and shorter hospital stays, but a similar rate of return to normal activities and clinical equivalence in terms of treatment of prolapse [20]. The reported procedure has been performed laparoscopically in some centers [21]. However, the current operative time, short hospitalization, relatively quick recovery of patients without significant complications, and high satisfaction associated with this procedure could mean that a laparoscopic approach is not immediately necessary.

The main limitations of the present study are the small sample size and the short duration of follow-up. The patients are still being followed up with either clinic visits or telephone calls and postal questionnaires; the data are recorded on the British Society of Urogynaecology database.

In conclusion, a standardized procedure of bilateral abdominal sacrocolpopexy using a purpose-designed PVDF mesh system seems to be a safe and effective treatment option for apical prolapse in the short term. It is also associated with significant improvements in overactive bladder, stress incontinence, and bowel dysfunction. A continuous audit database is in place to record outcomes of this surgery.

## Conflict of interest

S.M. and E.M. have received travel bursaries from Kebomed (Cullompton, UK) and Cook Medical (Bloomington, IN, USA). S.R. has no conflicts of interest.

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