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ORIGINAL ARTICLE

High risk of complications with a single incision pelvic floor repair kit: results of a retrospective case series

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Abstract
Introduction and hypothesis The aim of this study was to retrospectively assess the extent and severity of the post-operative complications associated with the Pinnacle Pelvic Floor Repair Kit.
Methods This is a descriptive analysis of 23 consecutive women who had a prolapse repair with either an anterior (n=19) or posterior (n=4) Pinnacle kit. The clinical records of all these patients were available for analysis. Pre-operative data and intra-operative complications were noted. All post-operative complications and repeat surgical interventions were recorded. In addition to pelvic floor symptoms, we looked specifically for pelvic pain and mesh contraction, exposure, extrusion or erosion. Complications were classified according to the joint IUGA/ICS system.
Results Seventy percent (n=16) of our cohort experienced at least one complication. All, except one, were following an anterior Pinnacle. 10 patients (43 %) had a tender vaginal mesh prominence, including a contraction band anteriorly or at the vaginal apex. Six (26 %) complained of associated buttock, groin or vaginal pain, while the tenderness was only detected during vaginal examination in 4 (16 %) patients. Three (13 %) patients required vaginal mesh excision for severe pain and one required a second procedure. Three patients (13 %) had vaginal mesh exposure and 8 (35 %) developed de novo stress incontinence. Two patients (8 %) developed symptomatic recurrent prolapse, one following mesh excision owing to large mesh exposure. Another patient had an anterior compartment prolapse above and below a tender contracted anterior vaginal mesh.
Conclusions The Pinnacle kit was associated with a high incidence of post-operative complications in this small series.

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Introduction

Following their introduction into pelvic floor surgery, the mesh kit systems were rapidly adopted by a number of pelvic floor reconstructive surgeons. This was largely driven by the perceived benefit in the outcomes of the prolapse repair. As greater numbers of these products were used, data began to emerge on a high incidence of complications compared with native tissue repair or even abdominal sacrocolpopexy. Many surgeons have had to reflect on the indications for using a vaginal mesh in pelvic organ prolapse surgery. A major catalyst in this process was the release of the USA Food and Drug Administration document citing concerns regarding the high incidence of adverse events associated with these products [1].

Many pelvic floor surgeons will agree that achieving a perfect anatomical and functional result from a prolapse operation remains a challenge. The motivation to use mesh is in many circumstances based on a desire to improve the post-operative quality of life in these women. The supporting data improved results when using mesh is contraindicated. Some studies have shown a benefit and others have demonstrated that it makes no difference. For example, one randomised controlled trial comparing anterior colporrhaphy with a trocar-based mesh kit demonstrated improved anatomical and quality of life outcomes at 1 year in women who have the mesh kit [2]. On the other hand, a smaller randomised controlled trial showed similar anatomical and functional outcomes, whether mesh was used or not, and higher re-operation rates in the mesh group [3]. Despite these concerns, many urogynaecologists believe that there remains a place for prosthetic mesh materials in prolapse surgery.

Since Julian [4] first reported the use of mesh in prolapse surgery, there has been significant evolution, not only in the range of available products, but also in the marketing strategies of the manufacturers and their influence on the surgeons using these devices. The initial use of self-fashioned flat mesh was followed by the launch of the anterior and posterior trocar-based kit systems, techniques that are reproducible and tension-free. The anterior trocar-based systems are associated with excellent arcus-to-arcus support, but they do not provide adequate apical suspension. Support of the vaginal apex necessitates the placement of a posterior trocar kit, suspending the vagina to the sacrospinous ligament. The other disdavantage of the trocar systems is the risk of bladder and bowel injury during the blind passage of the trocars. This led to the development of a third generation of kits involving a single vaginal incision that avoids the risks of trocar passage. These products provide apical attachment of the mesh to the sacrospinous ligament through a single anterior or posterior vaginal incision.

Work by Chen, Ashton-Miller and Delancey [5] has demonstrated the importance of adequate apical support when repairing a cystocele. They also describe the influence of a paravaginal defect in the aetiology of a cystocele. The concept, therefore, of a mesh kit system that provides good apical support by suspending the apex to the sacrospinous ligament, while providing paravaginal mesh attachment, makes anatomical sense. A number of anterior apical single incision mesh kits are available. These include: the Elevate (American Medical Systems), the Ascend (Caldera Medical), the Pinnacle (Boston Scientific), the Uphold (Boston Scientific) and the Nuvia (CR Bard) kits. Data for most of these devices are currently limited. A number of studies have reported on the clinical outcomes of the Elevate kit [6, 7]. Moore et al. [7] demonstrated anatomical cure rates in excess of 90 % in a prospective cohort of 60 women. None of the patients in that series required operative re-intervention. Except for one cadaver-based study [8], there are no published clinical studies reporting on the clinical outcomes of the Pinnacle device.

Following the improved anatomical success rates with trocar-based mesh kits and the potential advantages of a system with good apical and paravaginal support, our unit adopted the Pinnacle Pelvic Floor Repair kit as our system of preference in women who we considered suitable for a mesh procedure. After performing a number of these procedures, we noted an unusually high number of post-operative complications in our small cohort. The aim of this study was therefore to retrospectively assess the extent and severity of the postoperative complications associated with the Pinnacle Pelvic Floor Repair Kit.

Materials and methods

This is a retrospective descriptive analysis of women who had a prolapse repair with the Pinnacle kit. We performed either an anterior or posterior Pinnacle procedure in 23 women between May 2010 and June 2011 and the clinical records of all these patients were available for analysis. We recorded pre-operative symptoms, including the presence of a vaginal bulge, stress incontinence, urgency and urgency incontinence, voiding dysfunction and defecatory difficulty. We also recorded whether the women were sexually active or not and if they had any pre-operative dyspareunia. We noted any pre-operative symptoms of pelvic pain or any other pain syndrome. Prolapse was graded using the Baden Walker Classification system [9] in this subset of women. From the operative record we noted the operation time and whether there was a urinary tract or bowel injury. In the immediate post-operative period, we recorded any voiding dysfunction and the duration of catheterisation. In the post-operative period, we recorded all complications and repeat surgical interventions. In addition to pelvic floor symptoms, we looked specifically for pelvic pain, mesh contraction and mesh exposure, extrusion or erosion.

All the complications were classified according to the joint International Urogynaecology Association and International Continence Society system for the classification of complications related directly to the insertion of meshes [10]. The International Continence Society and International Urogynaecology Association have jointly established a standardised classification system for complications arising directly from the insertion of synthetic and biological material in female pelvic floor surgery. This classification system is known as the Category, Time and Site (CTS) classification system. The category (C) is assigned to the complication using the principal that the least severe complication would involve the prosthesis remaining within the anatomical site into which it was inserted, while the more severe complications would involve an increasing migration or protrusion into surrounding anatomical structures, opening into surrounding organs and systemic compromise. The time (T) for the complication is assigned according to when it is clinically diagnosed. T1 depicts complications diagnosed intra-operatively and up to 48 h post-operatively. T2 is assigned to complications diagnosed from 48 h to 6 months post-operatively. T3 is assigned to complications diagnosed after 6 months. The site (S) is assigned according to the site in which the complication has been noted. The site categories range from 1 to 5, where 1 is assigned to complications in the vagina along the suture line and 5 is assigned to intra-abdominal complications.

We also recorded de novo incontinence and recurrence of prolapse. Ethics approval was obtained from the University of Cape Town Human Research Ethics Committee (HREC 128/2012) for a retrospective review of data, analysis and publication.

The procedures were performed by two high-volume pelvic floor reconstructive surgeons. One was a fellowship-trained urogynaecologist and the other had more than 30 years' experience in pelvic organ prolapse surgery. One of the surgeons

had attended a formal training workshop in Nimes, France, on the Pinnacle procedure. This involved a number of didactic lectures and live video-linked surgical demonstrations of two cases. There was no cadaver training. This had been transferred to the other surgeon prior to performing the procedure. Since both surgeons were experienced in pelvic floor dissection and were comfortable with the pelvic floor anatomy, they felt competent to continue with no additional training or mentorship. Both surgeons had significant experience in pelvic floor surgery, with both having performed more than 100 proedures with the Capio Suture Capture device. The experience with mesh and mesh kits amounted to more than 70 cases for one surgeon and 30 cases for the other. Pre-operatively, detailed informed consent was taken from our patients. This included an explanation of the risks versus the benefits of using transvaginal mesh. Patients were told that although the device was new, both surgeons were experienced in the vaginal placement of mesh.

The indications for the use of mesh in our unit at the time at which we introduced the Pinnacle included recurrent anterior or posterior prolapse, a cystocele equal to or greater than grade 2, a posterior prolapse associated with significant uterine or vault prolapse and a large enterocele. Minimally invasive sacrocolpopexy was not available in our unit at that time.

With regard to the operative technique, the anterior Pinnacle was performed as follows. The patient was catheterised. The anterior compartment was infiltrated with a solution of vasopressin, bupivicaine and normal saline. Depending on the size of the prolapse, between 80 and 150 ml was used. Care was taken to ensure an adequate depth of infiltration. This was followed by a full thickness paravaginal dissection towards the obturator fascia and sacrospinous ligaments. Once the ligament could be palpated, using blunt digital dissection, it was cleared of the overlying connective tissue, about 3–4 cm from the ischial spine. The area medial to the obturator fossa and along the arcus tendineus fascia pelvis (ATFP) was also cleared by digital dissection. If the uterus was still present, the medial part of the dissection was taken apically to expose at least 3–4 cm of the anterior cervix. If the uterus was absent, the inside of the vaginal vault was dissected free in a similar way. During the dissection, if there was any suspicion of inadvertent cystotomy, a cystoscopy was performed. The Pinnace kit comprises the mesh and a Capio suture capture device. The mesh (Fig. 1) consists of a central rounded rectangular portion that lies over the bladder and a long apical tongue-shaped section. Between these two portions there are four mesh arms, two on each side. A loop of suture is attached at the end of each arm and this is continuous with a plastic tube that ends in a small bullet-shaped needle that is inserted onto the Capio device (Fig. 2). Prior to insertion of the mesh, we always found that it was necessary to cut off the apical tongue-shaped portion of the mesh (Fig. 3). This left us with a rounded rectangular mesh

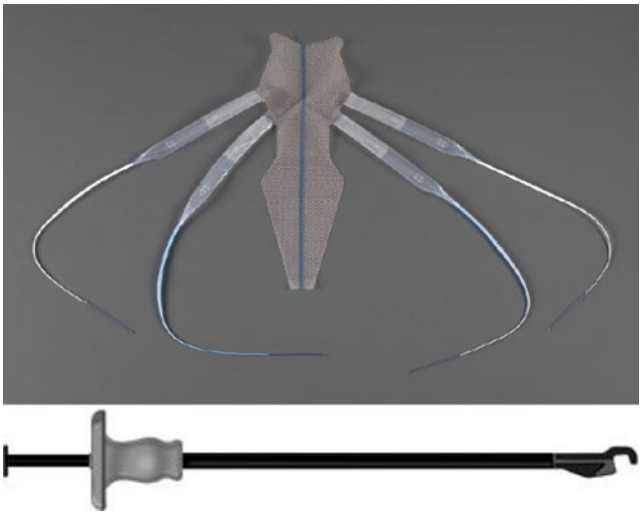

Fig. 1 Anterior Pinnacle kit with mesh and Capio device

with two mesh arms on each side, a pair that will be inserted into the sacrospinous ligament and a pair for attachment to the ATFP. The apical arms were usually attached first. Care was taken to ensure that the attachment was at least 2 cm from the ischial spine towards the sacrum, ideally in the lower third of the ligament. According to the manufacturer, the aim of distal arm placement was to achieve an attachment to the ATFP, approximately 2 cm anterior to the ischial spine. Following placement of the four arms, the apex of the mesh was attached to either the cervix or the vaginal vault using a monofilamentous delayed absorbable suture. The distal portion of the mesh was attached to the underlying bladder fascia using a superficially placed braided absorbable suture. The mesh arms were then adjusted, taking care not to leave any tension on any portion of the mesh or the mesh arms, and the excess parts were removed. The excess vaginal skin was not excised and closure was performed using an absorbable multifilament suture.

Fig. 2 Configuration of the arm attachment to the mesh body in the anterior Pinnacle

Fig. 3 Anterior Pinnacle after excision of the redundant mesh

The posterior Pinnacle kit is similar to the anterior device, but it only has two apical arms. Following 60 to 100 ml of infiltration, a posterior midline full thickness incision is made. This is followed by dissection towards the sacrospinous ligament and any overlying connective tissue is cleared off in the same manner as with the placement of the anterior Pinnacle. The vault or the cervix are also managed similarly. The two mesh arms are secured at least 2 cm from the ischial spine and the distal portion of the mesh is attached to the rectal fascia using two absorbable multifilament sutures. Care is again taken when adjusting the mesh arms that no tension is placed on any portion of the device. The vaginal skin is then closed with an absorbable multifilament suture. For both the anterior and posterior devices, a vaginal pack was inserted and this was removed 2 days post-operatively.

If a concomitant mid-urethral tape was inserted, this was done through a separate incision after the Pinnacle had been inserted.

Results

This analysis describes the immediate and short-term post-operative outcomes in 23 consecutive women undergoing a prolapse repair using the Pinnacle mesh kit. Our analysis includes 19 anterior and 4 posterior procedures. The average age of the women in this retrospective case series is 65 years (range 50–83). Table 1 summarises the pre-operative symptoms of our cohort. The pre-operative degree of prolapse is depicted in Tables 2 and 3. Four patients had a concomitant midurethral tape. Seven patients that had an anterior Pinnacle repair underwent a concomitant posterior fascial plication. Twenty patients had primary prolapse repair surgery using the Pinnacle pelvic floor repair kit, while 3 had recurrent prolapse surgery.

Table 1 Pre-operative data

	Yes	No	Not recorded in notes
Bulge symptom	23	0	
Stress incontinence	9	13	1
Urinary urgency	13	10	0
Urgency incontinence	9	14	
Sexually active	7	13	3
Dyspareunia	3	3	17
Previous hysterectomy	11	12	
Previous prolapse surgery	5	18	
Post-menopausal	20	3	
Smokes	6	17	
Pelvic or vaginal pain	1	11	11

Table 2 Anterior Pinnacle: pre-operative characteristics

Degree of prolapse (Baden–Walker classification)	Anterior (n=19)	Apical (n=12)
Grade 1	0	5
Grade 2	3	4
Grade 3	15	1
Grade 4	1	2

The median surgical time was 70 min (range 35 to 220 min). Seventy percent (n=16) of the women in our cohort experienced at least one complication (Tables 4, 5). All, except one, were following an anterior Pinnacle. A high proportion of these patients had varying degrees of post-operative pain. Ten patients (43 %) had a tender vaginal mesh prominence and this included either a contraction band anteriorly or at the vaginal apex. Of these 10 women, 6 (26 %) complained of associated buttock, groin or vaginal pain, while the tenderness was only detected during vaginal examination in the other 4 patients (16 %). Three patients (13 %) required extensive vaginal mesh excision for severe pain and 1 woman required a second procedure.

Three patients (13 %) had vaginal mesh exposure that was diagnosed between 10 and 21 days post-operatively. One exposure resolved on oestrogen cream therapy and the other two required excision. One patient had a small (<1 cm) mesh extrusion diagnosed at 6 weeks, which was successfully excised at 24 weeks as it was associated with a tender prominent vaginal mesh arm.

Three patients (13 %) developed post-operative voiding dysfunction that necessitated prolonged catheterisation,

Table 3 Posterior Pinnacle - preoperative characteristics

Degree of prolapse (Baden–Walker classification)	Posterior (n=4)	Apical (n=3)
Grade 1	0	2
Grade 2	0	1
Grade 3	4	0
Grade 4	0	0

Table 4 Summary of complications in individual patients

	Description of complication (ICS/IUGA)	Code1	Code2	Code3	Description of complications: other
1	Prolonged difficult surgery with estimated blood loss >1,000 ml. Large (>2-cm) midline anterior vaginal mesh exposure day 21 post-operatively, associated with post-operative vaginal infection. Infection treated, mesh excised 24 weeks post-operatively. Voiding dysfunction requiring prolonged catheterisation (28 days). Associated with *E. coli* urinary tract infection.	7AT1S1	3CT2S1	4BT2S2	Symptomatic recurrent mid-compartment prolapse seen at 30 weeks. Declined sacrocolpopexy.
2	Small midline posterior vaginal mesh exposure associated with post-operative vaginal infection day 11 post-operatively. Treated with antibiotics and vaginal oestrogen cream. Mesh exposure resolved at 6 weeks. Voiding dysfunction requiring prolonged catheterisation (13 days). Associated with *E. coli* urinary tract infection.	2CT2S1	4BT2S2		
3	Mesh exposure seen day 10 post-operatively—associated with vaginal infection. Treated with antibiotics and topical oestrogen. Mesh excised 12 weeks post-operatively. Prolonged catheterisation (90 days) due to voiding dysfunction post-operatively. Delayed trial of void owing to co-incidental cervical spine fracture during the catheterisation period.	3CT2S1	4BT2S2		
4	Small (<1-cm) mesh extrusion noticed at 6 weeks. Bilateral tender prominent vaginal mesh arms. Mesh excised 24 weeks postoperatively. Lost to follow-up—metastatic breast carcinoma.	3AaT2S1	3BbT2S2		De novo stress and urge urinary incontinence at 6 weeks. Treated with oxybutynin. Urge urinary incontinence resolved, but stress urinary incontinence persisted. Trans-obturator tape placed, but stress leakage continued. Booked for retropubic tape. Lost to follow-up.
5	Tender prominent vaginal mesh ridge palpated anteriorly at 10 weeks. No pain reported. Not sexually active.	1BbT3S2			
6	Tender prominent mesh ridge palpated at the vaginal apex at 6 weeks. Associated with buttocks pain near coccyx. No dyspareunia.	1BeT2S2			
7	Tender prominent vaginal mesh ridge palpated anteriorly at 8 weeks, still present at 20 weeks. Associated pelvic and groin pain. No dyspareunia.	1BeT3S2			De novo urge urinary incontinence—responded to oxybutynin.
8	Tender prominent mesh ridge palpated at the vaginal apex at 6 weeks. No pain reported. Not sexually active.	1BbT2S2			De novo stress urinary incontinence reported at 6 weeks. Resolved by 24-week follow-up.
9	Tender prominent vaginal apical mesh arms palpated at 6 weeks, still present at 24 weeks. No pain reported. Not sexually active.	1BbT2S2			
10	Recurrent symptomatic (vaginal bulge) grade 3 cystocele 20 months post operatively. Cystocele rolled over and under the prominent non-tender vaginal mesh contraction.	1AaT4S2			Symptomatic recurrent grade 3 cystocele seen 20 months post-operatively. Booked for laparoscopic hysterectomy and sacrocolpopexy.
11	Tender prominent vaginal vault mesh ridge palpated at 6 weeks—associated with vaginal pain. Not sexually active. Mesh partially excised 40 weeks post-operatively. Ongoing intermittent suprapubic and vulval pain. Referred to pain clinic.	1BeT2S2			De novo urge and stress urinary incontinence 6 weeks. Transobturator tension-free vaginal tape placed 20 weeks post-operatively. Developed voiding dysfunction. Tape initially unsuccessfully cut 4 weeks later. Tape successfully cut 24 weeks after initial placement.
12	Small breach in bladder mucosa superior to left ureteric orifice, not full thickness, ureters clear—catheterised for 10 days. Tenderness in region of left ischial spine adjacent to left vaginal apical mesh arm at 6 weeks—associated with spontaneous left iliac fossa pain. Not sexually active.	4AT1S2	1BeT2S2		De novo stress urinary incontinence, declined surgery.

Table 4 (continued)

	Description of complication (ICS/IUGA)	Code1	Code2	Code3	Description of complications: other
13	Full thickness bladder injury noticed intra-operatively, ureters clear, repaired vaginally—catheterised for 10 days. Tender prominent anterior/apical vaginal mesh ridge at 6 weeks—associated with spontaneous perineal pain and dyspareunia. Required mesh excision twice.	4AT1S2	1BeT2S2		
14	De novo stress incontinence				De novo stress urinary incontinence at 6 weeks. Declined midurethral tape as symptoms not bothersome.
15	De novo stress incontinence				De novo stress urinary incontinence at 32 weeks. Retropubic tension-free vaginal tape placed with resolution of symptoms.
16	De novo stress incontinence				De novo stress urinary incontinence at 6 weeks. Trans-obturator tension-free vaginal tape placed with resolution of symptoms.

ranging from 13 to 90 days. Two of these patients required a suprapubic catheter and the third patient was treated with a transurethral catheter. None of these patients had a concomitant midurethral tape at the primary surgery. One had had a posterior Pinnacle with concomitant enterocele repair.

Two patients (8 %) have developed a symptomatic recurrent prolapse. The prolapse recurrence in the one patient developed following a mesh excision due to a large mesh exposure. The other patient had recurrent anterior compartment prolapse above and below a tender, contracted anterior vaginal mesh.

Discussion

In this retrospective case series we report a high number of post-operative complications following the insertion of the Pinnacle single-incision pelvic floor repair kit. In the present controversial climate surrounding mesh use, this is a very important clinical study. Every patient and surgeon embarking on a surgical intervention for pelvic organ prolapse has to appreciate the potential for an adverse event, manifesting either intra- or post-operatively. It is now apparent, however, that complications associated with mesh kits are not only more common, but they are often more severe, difficult to manage and more likely to be life-altering.

Table 5 Summary of complications

Complication	*n* (%)
Cystotomy	1 (4)
Rectal/bowel Injury	0
Ureteric injury	0
Mesh exposure/erosion/extrusion	4 (17)
Voiding dysfunction	3 (13)
De novo stress incontinence	8 (35)
Recurrent prolapse	2 (8)
Buttock, groin, vaginal pain/tenderness	10 (43)
Repeat surgical intervention in operating room (Dindo 3b)	8 (35)

A study looking at the complications and re-operation rates of surgical repair for vaginal apical prolapse [11] reported that mesh kits were associated with an almost two-fold increase in repeat surgical intervention compared with native tissue repair. This was due to a significantly higher rate of surgical complications. The range of surgical complications is broad and this has been reported in a number of trials [12–16]. This includes vaginal mesh exposure and erosion into a viscous. There may also be a higher incidence of de novo pelvic floor symptoms following mesh kit insertion, including stress incontinence [17] and prolapse in another compartment [18].

We detected a high incidence of post-operative mesh contraction in our cohort, with 10 of our patients (43 %) reporting pain and/or tenderness over the mesh on vaginal examination. Six of these women (26 %) reported pain radiating to the vagina, buttock or back. This is significantly higher than the rate reported in other studies and with other devices. In a systematic review [11] on mesh kits used for apical prolapse, the incidence of pain was 2.5 % with a range of 0–23 %. The majority of the mesh kits in that study were posterior trocar-based systems. In their randomised controlled trial comparing an anterior trocar-based mesh kit with anterior colporrhaphy, Altman et al. also reported a lower incidence of post-procedure pain [2]. Of all the complications associated with mesh kit insertion, the most difficult to manage are post-operative pelvic pain and dyspareunia. Despite treatment, many women are left with residual symptoms. A study of 60 women with a vaginal mesh complication found that about one third were still symptomatic following surgical management [19].

It could be argued that the high number of complications in our cohort might be related to poor surgical technique, inappropriate patient selection or problems with the design of this mesh system. Both surgeons performing the operations in this study were experienced in pelvic floor reconstructive procedures. When inserting the Pinnacle kit, the mesh is placed using the Capio device. This has been our standard approach to native tissue sacrospinous ligament fixation since 2006 and both operators were familiar with the device and the dissection required to access the sacrospinous ligament. It is important to note, however, that this cohort represents a series of women at the beginning of our learning curve and the potential difficulties are highlighted by patient 1 in Table 4. We also appreciate that the number of women developing mesh erosion, exposure or extrusion in our cohort was higher than the rate reported in other studies [20]. We had one cystotomy, which is an accepted risk of pelvic organ prolapse surgery, but this does pose a number of questions relating to surgical technique.

It is important to consider that the design of this mesh may also be a contributing factor to the problems experienced in our cohort. Providing adequate apical support remains an important aspect of surgery for both anterior and middle compartment prolapse and this is addressed when using modern mesh kit systems, including the Pinnacle, Elevate and Nuvia. These mesh kits have an additional distal arm that is secured inferiorly to provide level 2 support. In the Nuvia and Elevate mesh kits, this second mesh arm is approximately 4 to 5 cm from the proximal apical arm on the mesh body and this facilitates placement in the obturator internus fascia. Clinical data on the Elevate [6, 7] have not demonstrated a higher risk of developing a complication than with other devices. The distal arm on the Pinnacle mesh, however, is immediately adjacent to the apical arm and the principle of placement includes attaching this part of the mesh along the ATFP approximately 2 cm anterior to the ischial spine. We believe that this may be the cause of the increased pain associated with the Pinnacle mesh, since its position may create a tight mesh bridge over the ischial spine that could potentially produce a "pinching effect" on the pudendal nerve.

The company marketing the Pinnacle has recently launched a newer, similar device. The mesh is identical and the mesh arms are also applied to the sacrospinous ligament using the Capio device. This "Uphold" kit only has two apical arms and a much smaller mesh body. Two studies reporting on this device have demonstrated excellent outcomes [21, 22] with a low rate of complications. We believe that this further corroborates our hypothesis that it is the second distal mesh arm in the Pinnacle kit that induced the high incidence of pain in our cohort.

The quality of training of surgeons in the use of mesh kit devices is an important issue. One of the surgeons involved in this study went to a 1-day training course on the use of the Pinnacle. The practical component of this training was minimal. We would suggest that the training following the introduction of mesh devices should involve cadaver exposure as a minimum followed by mentoring by an operator experienced in the specific device.

A large number of women in our cohort had not had previous pelvic floor surgery and we appreciate the fact that the use of mesh in primary prolapse surgery is controversial. However, we believe that an apical anterior mesh kit plays a role in women with a large anterior prolapse and particularly in those with a significant apical component.

The Pinnacle was approved by the Food and Drug Administration (FDA) in January 2009. This approval was granted via Section 510(K) following demonstration of equivalence to other marketed predicate devices. All of the other mesh kits were approved in this way. The introduction of a mesh kit via the FDA 510(K) required no human or animal studies and this has prompted widespread criticism. This issue is brought further into question by the fact that the Pinnacle kit has been withdrawn from the market, probably because of a higher incidence of adverse events following its use in human subjects.

This is the first clinical study reporting on the Pinnacle pelvic floor repair kit. To our knowledge the only other study was a cadaver-based report [8] on the anatomical fixation points of this device where Cayrac et al. found significant variations in the distance from the point of fixation to important structures including the pudendal nerve and ischial spine. This raises important questions concerning the reproducibility of device placement. The other important issue that needs urgent attention is the fact that devices of this nature are brought onto the market before the publication of any clinical data.

Thirty-five percent of the women in our series developed de novo stress incontinence, which is higher than the rate reported in other studies [17]. The reasons for this remain unclear, but this may be caused by excessive bladder neck elevation resulting in a disrupted sphincter mechanism.

We admit that this study has a number of significant weaknesses. Sexual function is an important outcome variable in prolapse surgery research. It is regrettable that the reporting and documentation of pre- and post-operative dyspareunia was inconsistent in our series and this may have compromised our conclusions. The high incidence of pain, both at rest and on vaginal examination, however, suggests that this specific device may have been associated with poorer sexual function outcomes than both native tissue surgery and other mesh kit devices. De novo stress incontinence contributed significantly to our complication rate. This is a recognized complication of both native tissue and mesh kit surgery. It is difficult to assess if this was higher in our cohort since we do not have a comparator.

Another weakness in our study is the inconsistency of the follow-up. At the time of the study, it was our practice to routinely follow patients up 6 weeks postoperatively. Some

of the patients in the study presented with complications before the 6-week follow-up visit. The timing of further follow up visits and the duration of follow-up was decided on an individual basis and was based on any ongoing clinical issues. Only 2 patients were followed up beyond 1 year.

Quality of life (QOL) is the most important outcome variable in pelvic floor surgery and it is regrettable that we did not have pre-and post-operative QOL questionnaires in our cohort. This would not only have strengthened the findings of our study, but it would have enabled us to more reliably measure the impact of the complications on our patients. In our study we used the Baden–Walker as opposed to the standardized ICS-POPQ prolapse quantification system for our pre- and post-operative prolapse measurements. This represents another obvious weakness in our data, since the POPQ system is more precise and the pre- and post-surgery scores are infinitely more comparable using this system.

Retrospective, uncontrolled data based on a small case series in a single institution should always be assimilated with caution and we fully appreciate the significant weaknesses in this report. However, this paper is the first clinical report on the Pinnacle device and this series highlights a number of significant concerns regarding the use of this mesh kit. Alternative devices are now available and we believe that clinicians wishing to use an apical single incision kit should consider options other than the Pinnacle kit.

Conflict of interests None.

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