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Original Article

Mesh repair of vaginal wall prolapse

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ABSTRACT

Background: Over the last decade, mesh augmented surgical repair is being increasingly used in pelvic organ prolapse. Perigee and Apogee are comprehensive, single-use needle suspension kits that provide a standardized delivery method for mesh or graft-augmented repairs. This study has been carried out to study the safety and efficacy of the Perigee and Apogee mesh repair systems.

Methods: 10 cases of posterior vaginal wall prolapse with or without Apical prolapse underwent Apogee mesh repair surgery and 10 cases of anterior vaginal wall prolapse underwent Perigee mesh repair surgery. Depending on the findings either Apogee or Perigee or both were used. Patients were followed up for complications of the surgery if any, and for the relief of the symptoms related to prolapse and associated symptoms of bowel/bladder dysfunction. Objective cure rate was prolapse < stage 1 as per the POPQ system. Data collected was statistically analyzed.

Results: The objective and subjective cure rates were 100%. Postoperative complications were minor. No patient developed de novo urinary urge symptoms, stress urinary incontinence or UTI postoperatively. There were no operative complications like bladder injuries, hematoma and rectal injuries. The mean blood loss was 180 ml and the mean duration of surgery during the Apogee and Perigee mesh repair was 51.5 ± 2.99 min and 60.9 ± 4.65 min respectively.

Conclusion: In the present study there was a significant improvement in the degree of prolapse after the mesh repair surgeries and the results were consistent even at 12 months follow up.

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Introduction

Pelvic organ prolapse (POP) is a bulge or protrusion of pelvic organs and their associated vaginal segments into or through the vagina.¹ It occurs when the upper vagina bulges into or outside the vagina and is a common and distressing condition which occurs when there is a weakness in the supporting structures of the pelvic floor allowing the pelvic viscera to descend.

Pelvic floor repair involving anterior and/or posterior colporrhaphy has been the established treatment for pelvic organ prolapse over the last century, but carries a high rate of recurrence.²

Graft materials have been employed in repairing defects or hernias throughout the body. Their purpose is to either completely replace the weak tissue by spanning across that tissue or to provide a scaffold for fibroblast infiltration. The patient's own connective tissue may grow into the graft, and

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if the graft is degradable, replace the graft as a supportive structure.

Graft materials include autologous tissues like cadaveric allografts and fascia, dermis and other connective tissues, xenografts from animal sources, and various synthetic materials. Julian first reported on the use of synthetic mesh for cystocele repair in 1996.³

Over the last decade, mesh augmented surgical repair is being increasingly used, mainly for secondary procedures.

Recently a number of prolapse repair mesh devices have been designed by different companies and extensively marketed as a minimally invasive approach for pelvic floor repair.

Each of these prolapse repair mesh devices utilizes woven monofilament low-weight macroporous polypropylene meshes with extension arms to permanently reinforce the pubocervical and the rectovaginal fascia. Insertion techniques are very similar and involve the use of especially shaped insertion needles to anchor the mesh arms. The needle passage lies close to vessels, nerves and organs of the pelvis and pelvic side wall, with slight differences between devices as to which structures are closest to the needle tracks.

Perigee and Apogee are comprehensive, single-use needle suspension kits that provide a standardized delivery method for mesh or graft-augmented repairs. Perigee uses the trans-obturator technique for the treatment of anterior prolapse; Apogee uses a posterior vaginal and perianal approach for the treatment of vault and posterior prolapse. These kits represent the “next generation” in vaginal prolapse repair because they allow for safe, consistent, comprehensive treatment and offer tension-free mesh or graft augmentation options to accommodate individual patient pathologies. They allow pelvic organ prolapse to be repaired in a minimally invasive manner with a short procedure time and a rapid postoperative recovery.

This study has been carried out to study the safety and efficacy of the Perigee and Apogee mesh repair systems in the anterior and posterior vaginal wall prolapse respectively.

Materials and methods

10 cases of posterior vaginal wall prolapse with or without Apical prolapse underwent Apogee mesh repair surgery and 10 cases of anterior vaginal wall prolapse underwent Perigee mesh repair surgery. Depending on the findings either Apogee or Perigee or both were used.

The study population comprised of patients with anterior vaginal wall prolapse or posterior vaginal wall prolapse with or without Apical prolapse or both (including Post hysterectomy status) reporting to Gynaecology OPD meeting the inclusion and exclusion criteria.

The study was carried out from 01 September 2010 to 30 August 2012. (Period of observation till 30 December 2012). The patients underwent surgery for their respective defects and were followed up after that for their prolapse assessment. The last patient underwent surgery in January 2012. The average follow up was 14 months (range 12–16 months).

All patients with complaints of mass descending per vaginum were examined in the OPD to confirm the findings of prolapse. Prolapse assessment was done as per the POPQ (Pelvic Organ Prolapse Quantification) system.

In 1996, the International Continence Society defined a system of Pelvic Organ Prolapse Quantification (POPQ).⁴ Demonstrating high intra and inter-examiner reliability, the POPQ system is a major advance in studying prolapse. It allows researchers to report findings in a standardized, easily reproducible fashion. This system contains a series of site-specific measurements of a patient's pelvic organ support. Prolapse in each segment is measured relative to the hymen, which is a fixed anatomic landmark that can be identified consistently. Six points are located with reference to the plane of the hymen: two on the anterior vaginal wall (points Aa and Ba), two in the apical vagina (points C and D), and two on the posterior vaginal wall (points Ap and Bp). All POPQ points, except total vaginal length (TVL), are measured during patient Valsalva and should reflect maximum protrusion. Depending on the findings the prolapse is staged as follows:

Stage 0	No prolapse is demonstrated. Points Aa, Ap, Ba, Bp are all at -3 cm, and point C is between total vaginal length (TVL) and (TVL -2 cm).
Stage I	The most distal portion of the prolapse is >1 cm above the level of the hymen.
Stage II	The most distal portion of the prolapse is <1 cm proximal or distal to the plane of the hymen.
Stage III	The most distal portion of the prolapse is <1 cm below the plane of the hymen but no further than 2 cm less than the total vaginal length.
Stage IV	Complete to nearly complete eversion of the vagina. The most distal portion of the prolapse protrudes to $> +$ (TVL -2) cm.

Inclusion criteria for Perigee or Apogee were patients with symptomatic anterior or posterior vaginal wall prolapse respectively with stage 3 or more as per the POPQ systems.

Exclusion criteria for Apogee and Perigee were patients with pelvic organ prolapse less than stage II (POPQ) or patients with history of prior graft-augmented repair and patients with systemic or local conditions that would preclude surgery or affect healing such as coagulation disorders, infections, compromised immune response, vaginal bleeding, uncontrolled diabetes, restricted leg motion (inability to conform to the lithotomy position), history of pelvic cancer in previous six months, history of radiation to the pelvic area.

Baseline investigation was done. Clearance from anaesthesiologist was obtained and suitable patients were selected for surgery using Apogee and Perigee vaginal mesh repair systems. All selected patients consented for the surgery.

Depending on the findings of the case either Apogee mesh system (Figs. 1 and 2) or Perigee mesh system (Figs. 3 and 4) or both repair systems were used. Concomitant procedures were performed as per requirement in each case.

Antibiotics (Injection Cefotaxime, Flagyl, Amikacin) were given for 07 days in total. Patients were discharged on post-operative day 7.

Data was collected preoperatively, postoperatively before discharge on day 7, at 1 month, 3 months, 6 months, and 12

Fig. 1 – Apogee mesh with its two fixating arms.

months respectively. Physical examination of the surgical site was conducted at each visit and complications were recorded as to the compartment, days to onset, intervention for resolution, and vaginal wall exposure site. Prolapse stage was assessed pre operatively and at each visit post operatively.

Blood loss at the time of surgery was assessed by assessment of blood loss during surgery with the help of amount of blood soaked on various types of swabs used in surgeries,⁵ measuring the preoperative haemoglobin, immediate post-operative haemoglobin, assessment of vital parameters in the immediate postoperative period.

Patients were followed up for complications of the surgery if any and other observational data like procedure duration, estimated blood loss and for the relief of the symptoms related to prolapse and associated symptoms of bowel/bladder dysfunction. Objective cure rate was prolapse $\leq$ stage 1as per the POPQ system. Data collected was statistically analyzed.

Results

Table 1 depicts the patient demographics, previous prolapse surgery and the associated procedures performed at the time of mesh repair.

Fig. 2 – Placement of Apogee mesh arms by hooking it onto the Apogee needle after insertion of the needle.

Fig. 3 – Perigee mesh with 4 arms.

One patient who underwent Apogee mesh repair with laparoscopic left salpingo-oophorectomy had a previous total abdominal hysterectomy (TAH). One patient who underwent only Perigee mesh repair also had a previous total abdominal hysterectomy (TAH). Three patients (27.3%) who underwent both Apogee and Perigee mesh repair had previously undergone TAH. One patient (09.1%) who underwent both Apogee and Perigee mesh repair had a previous history of vaginal hysterectomy followed by abdominal sacrocolpopexy for vault prolapse. One unmarried patient who underwent both Apogee and Perigee mesh repairs was a case of Marfans syndrome who presented to us with recurrent UV prolapse with history of two failed abdominal sling surgeries. Stress urinary incontinence was present in one patient and a transobturator tape was placed at the time of surgery to cure stress urinary incontinence. Concomitant procedures at time of surgery included vaginal hysterectomy in 04 (36.4%) patients, laparoscopic salpingo-oophorectomy in 02 (18.2%) patients and transobturator tape application for stress urinary incontinence in 01 (9.1%) patient. 09 patients (81.8%) underwent both Apogee and Perigee mesh repair and the uterus was preserved in one patient who was a case of Marfans syndrome as she was desirous of future fertility. Seven patients (63.7%) were sexually active prior to surgery.

All patients in the study were having Grade III/IV (POPQ) anterior vaginal wall or posterior vaginal wall prolapse or both except one patient who had procidentia with Grade IV/IV anterior and posterior vaginal wall prolapse (POPQ). After the

Fig. 4 – Placement of the Perigee mesh with all 4 arms.

Table 1 – Patient demographics, previous prolapse surgery and the associated procedures performed at the time of mesh repair.

	Perigee	Apogee	Both
Number of patients	01	01	09
Mean age, years (range)	46	40	42.1 (32–63)
Mean parity (range)	05	03	2.7 (0–5)
Mean BMI (range)	24.23	30.44	21.78 (18.67–25.29)
Smokers, n (%)	Nil	Nil	Nil
Postmenopause, n (%)	Nil	Nil	03 (27.3%)
Previous surgery for prolapse/TAH/VH, n (%)	01 (TAH)	01 (TAH)	03TAH (27.3%) 01 VH and abdominal sacrocolpopexy (09.1%) 01 Composite sling surgery (09.1%)
Associated procedures, n (%)	Nil	01	06 (54.6%)
(a) Concurrent vaginal hysterectomy	Nil	Nil	04 (36.4%)
(b) TOT	Nil	Nil	01 (09.1%)
(c) Others	Nil	Laparoscopic left oophorectomy	Laparoscopic right oophorectomy
Anaesthesia	01(SA)	01(GA)	04SA, 03CSE, 02GA

respective mesh repair the prolapse was reduced to Grade I/IV (POPQ).

The Objective cure rate in present study was 100% (Cure rate was defined as site-specific prolapse $\leq$ Grade I/IV POPQ system). All patients who underwent either Apogee or Perigee mesh repair or both were followed for their prolapse assessment at 01, 03, 06, 12 months. No patient had any increase in the prolapse. All were found to have $\leq$ grade I/IV prolapse as per the POPQ system. The subjective cure rate was also 100% in both groups. There was no change in the mean vaginal length in both Apogee and Perigee groups respectively when compared preoperatively and postoperatively upto their follow up of 12 months.

No patients developed de novo urinary urge symptoms postoperatively. None suffered from stress urinary incontinence or urinary tract infection postoperatively. There were no operative complications like bladder injuries, hematoma and rectal injuries.

No patient suffered from blood loss of over 500 ml. The mean blood loss in cases which underwent only Apogee and Perigee repair (combined) was 180 ml. In cases where patients had concurrent procedures there was extra blood loss but still none suffered from blood loss more than 500 ml.

Postoperative complications were minor and included fever on the day of surgery, groin pain, buttock pain and constipation in 01 patient each. Fever was managed with antipyretics. One patient who underwent laparoscopic oophorectomy with Apogee and Perigee mesh repair had complaints of lower abdominal pain for 02 days which was treated with Diclofenac rectal suppositories. Another patient suffered from groin pain in the region of the adductor longus tendon and periurethrally on the same side and presented at one week

postoperatively with this pain. She was treated conservatively with tablet Diclofenac, muscle relaxants, and rest, and the pain spontaneously was resolved by second postoperative week.

None of these patients required a postoperative blood transfusion. There were no postoperative bleeds or hematomas and none had to be taken back to the operation theatre for bleeding or pain. There were no bladder injuries due to needle passage at the time of mesh placement. The average hospital stay was 8 days. Foleys catheter was removed on postoperative day two for patients who underwent Perigee repair and on postoperative day 1 for patients who underwent Apogee repair. After removal of the urinary catheter a voiding trial was attempted. None of the patients' had postoperative urinary retention.

No patient had any local or systemic infection. Before surgery 07 (63.7%) patients were sexually active and none complained of dyspareunia at the follow up visits. No patient experienced vaginal mesh extrusion, mesh erosion. There were no postoperative infections of the mesh and no mesh had to be removed secondary to infection or pain. None had to be taken back to the operating room for revision of the mesh or release of the lateral mesh arms due to pain.

In the Apogee group the preoperative POPQ status of the patients was compared with the postoperative POPQ status. The preoperative values of points Ap, Bp, C, TVL (total vaginal length) were 2.30 ± 0.675 cm, 3.00 ± 0.00 cm, 4.40 ± 0.966 , 7.90 ± 1.101 cm (mean $\pm$ SD) respectively. In the postoperative period the Ap, Bp, C, TVL value were -2.20 ± 0.350 cm, -2.350 ± 0.412 cm, -5.10 ± 0.738 cm, and 7.90 ± 1.101 cm (mean $\pm$ SD) respectively.

In the Perigee group the preoperative POPQ status of the patients was compared with the postoperative POPQ status. The preoperative values of points Aa, Ba, C, TVL (total vaginal length) were 1.90 ± 0.568 cm, 2.50 ± 0.527 cm, 4.20 ± 1.398 , 7.90 ± 0.994 cm (mean $\pm$ SD) respectively. Mean Aa, Ba, C, TVL value in the postoperative period were -2.25 ± 0.354 cm, -2.30 ± 0.3496 cm, -5.10 ± 0.738 cm, 7.9 ± 0.994 cm respectively.

All parameters were compared and P value was calculated using paired T test in both Apogee and Perigee group. The P value for points Ap, Bp, Aa, Ba and C was highly significant. This shows that there was significant improvement in the prolapse in both the groups and the total vaginal length remained almost the same even after the repair in both the groups.

The mean duration of surgery during the Apogee mesh repair was 51.5 ± 2.99 min and the mean duration of surgery during the Perigee mesh repair was 60.9 ± 4.65 min.

Discussion

In total, the Apogee and Perigee devices were used in 11 patients: 01 patient underwent only Apogee mesh repair, 01 patient underwent only Perigee mesh repair and 09 patients underwent combined Apogee and Perigee mesh repair. The choice of device used was primarily according to the stage of prolapse in each compartment after assessment as per the POPQ system.

All patients attended their first follow up visit at 4 weeks. The cure rate at 01, 03, 06 and 12 months was 100% with patients showing stage I POPQ. None out of the 11 patients underwent further surgery neither re-presented with symptomatic prolapse in another compartment within a period of 12 months after the initial operation.

The objective cure rate was 100% and subjectively no patients in the series suffered from persistence/recurrence, or appearance of new symptoms (100% subjective cure rate).

The objective as well as subjective cure rate in the present study was 100% and the results are comparable with many other studies reported in literature as depicted in Table 2.

In the present study the mean surgical time for Apogee and Perigee repair was 51.5 ± 2.99 min and 60.9 ± 4.65 min (mean $\pm$ SD) respectively. The results are comparable with many studies reported in the literature. The mean duration of surgeries in other studies is as depicted in Table 3.

In the present study none of the patients had dyspareunia after the mesh repair. The results are well comparable to many other studies reported in the literature.

Biller et al (2007) reported de novo dyspareunia occurred only in 9 cases out of 108⁷. Lukban, et al (2008) reported an incidence of 1.0% for dyspareunia⁸ and Gauruder- Burmester, et al (2007) reported no peri- or intraoperative complications.¹⁰

Davila, et al (2006) in a retrospective multicentre study of 299 patients reported that the device-related complications, including pain, were demonstrated in <1% of patients.¹⁶

In the present study none of the patients' had mesh erosion or mesh exposure till their follow up of 12 months after the mesh repair. Our results are well comparable and are even better than many other studies reported in the literature.

Balakrishnan S et al (2006) reported mesh erosion in nine cases out of 35.⁶ Biller, et al (2007) demonstrated durability and high objective and subjective cure rates with minimal complications and no graft erosions.⁷

Table 3 – Surgical time taken for Apogee and Perigee repair in various studies.

Study	Type of mesh system	Mean procedure time
Lukban et al (2008) ⁹	Apogee	46.95 $\pm$ 21.62 min
Gauruder et al (2007) ¹⁰	Apogee	35 $\pm$ 4.5 min
Mahdy et al (2008) ¹³	Perigee	72(65–80) min
Moore et al (2008) ¹⁵	Perigee	86 $\pm$ 44.1 min
Present study	Apogee	51.5 $\pm$ 2.99 min
Present study	Perigee	60.9 $\pm$ 4.65 min

Meschia M, et al (2007) reported that the mesh exposure was seen in only one case out of 2.¹⁷ Sarsotti C, et al (2007) in a study on 47 patients with apical prolapse used Apogee system and reported mesh erosion in five cases.¹¹

Mahdy et al (2008) in a retrospective study on 32 patients reported that the incidence of graft erosion was 3.8%.¹³

In the present study there were no operative complications like bladder injuries, hematoma and rectal injuries and no major postoperative complications. On follow up no patient complained of dyspareunia, mesh erosion or any urinary symptoms.

The present study results compare well or are much better than many other studies reported in the literature as has been described in the above paragraphs.

In 2008, the US Food and Drug Administration (FDA) issued a warning regarding the use of mesh for prolapse and incontinence repair,¹⁸ repeating that warning in 2011, although narrowing it to vaginal mesh used to correct pelvic organ prolapse (not for anti-incontinence procedures or when used abdominally).¹⁹ These warnings stemmed from concerns over mesh erosion through the vagina, pain, infection, bleeding, dyspareunia, organ perforation, and urinary problems. While many of these complications are common to all pelvic floor repairs, mesh erosion and some types of organ perforation are surely unique to mesh and the trocars used for its placement. In the present study we never came across any such complications.

Table 2 – Cure rates with Apogee and Perigee in various studies.

Study	Number of cases	Objective cure rate (Apogee) at 01 year	Objective cure rate (Perigee) at 01 year
Balakrishnan, et al (2006) ⁶	35	97%	–
Biller, et al (2007) ⁷	108	96.2%	–
Lukban, et al (2008) ⁸	200	100%	–
Lukban, et al (2008) ⁹	174	90.1%	–
Gauruder- Burmester, et al (2007) ¹⁰	48	100%	100%
Sarsotti C, et al (2007) ¹¹	47	98%	–
Abdel-fattah (2008) ¹²	70	95%	95%
Mahdy et al (2008) ¹³	32	–	96.1%
Li-chung et al (2011) ¹⁴	91	100%	100%
Present study	20	100% (10)	100% (10)

Conclusion

In the present study there was a significant improvement in the degree of prolapse after the mesh repair surgeries and the results were consistent even at 12 months follow up. There was marked improvement in the quality of life after the surgery. The Apogee and Perigee mesh repair devices are associated with excellent short and long term cure rates and low morbidity rates. In experienced hands these kits are very safe and effective. However, some of their uncommon complications are serious and can be life threatening and need highly specialised management. We, therefore, recommend that these procedures should only be performed by specialists with detailed knowledge, training and in well-equipped tertiary hospitals.

Randomised trials comparing these mesh repair kits to the established repair procedures are needed before these procedures can be used in routine clinical practice.

The limitation of the current study is limited number of patients due to high cost of the Apogee and Perigee mesh

repair kits and medium term follow up and we do recommend further prospective studies with long term follow up.

Conflicts of interest

All authors have none to declare.

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