Original Article

Trans-vaginal total pelvic floor repair using customized prolene mesh: A safe and cost-effective approach for high-grade pelvic organ prolapse

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ABSTRACT

Aims: To assess safety, efficacy, and cost-effectiveness of trans-vaginal total pelvic floor repair with customized prolene mesh in patients with high-grade pelvic organ prolapse.

Materials and Methods: A total of 32 patients, who underwent trans-vaginal total pelvic floor repair using a customized prolene mesh from January 2007 to June 2010 for grade III and IV pelvic organ prolapse, were analyzed retrospectively. Prolapse was graded using Pelvic Organ Prolapse Quantification system of International Continence Society. Patients were evaluated for symptoms associated with prolapse pre- and postoperatively.

Results: Of the 32 patients, 18 were grade IV uterine prolapse, 10 were grade III uterine prolapse, and 4 were grade IV vault prolapse. Twenty-eight patients underwent vaginal hysterectomy at the time of repair. All the patients had associated anterior and posterior prolapse of varying degree. Follow-up ranged from 6 to 42 months. All patients had symptomatic relief after surgery. There were no intraoperative rectal or bladder injuries. Early complications were perineal pain (30), *de novo* urgency (4), vaginal discharge (3), vaginal wall hematoma (2), and failure to void (2). Two patients had vaginal erosion of mesh.

Conclusions: Trans-vaginal total pelvic floor repair using a customized prolene mesh is safe and effective treatment for comprehensive repair of high-grade pelvic organ prolapse. The use of this custom-made prolene mesh makes the procedure very cost-effective and affordable. The reduction in cost is about 25–30 times with the use of this mesh when compared with commercially available variety.

Key words: Customized prolene mesh, prolapse, trans vaginal tape

INTRODUCTION

Pelvic organ prolapse and the symptoms associated with the condition are increasingly recognized as the major health problem. Pelvic organ prolapse is seen in about 50% of multiparous women especially after vaginal deliveries and menopause.[1] The urinary and lower gastrointestinal symptoms plus the hampered sexual function affects a woman's quality of life and daily activities.[2] There are several risk factors associated with pelvic organ prolapse, the most consistently noted are increasing age, vaginal delivery, and obesity.[3,4] The estimated lifetime risk of a woman undergoing surgery for genital prolapse is about 11% and about 20% undergoing concomitant anti-incontinence procedures due to associated stress incontinence.[5]

Besides providing restoration of normal anatomy, preservation of sexual function, and alleviation of clinical symptoms, the repair technique should have long-term efficacy as a goal and should be justified for its cost as well.[6] Significant advances have been made in the field of trans-vaginal pelvic reconstructive surgery over the years.[7] Many authors have reported their experience with the use of various commercially available, minimally

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invasive, synthetic biomaterial graft kits and various placement techniques have also been described for trans-vaginal pelvic reconstruction.[8-12]

Most of these commercially available kits have a limitation in terms of their high cost which can be a hindrance, especially in Indian setup. In this study, we report anatomical and functional outcome of our technique of trans-vaginal total pelvic floor repair using customized prolene mesh.

MATERIALS AND METHODS

A total of 32 patients, who underwent trans-vaginal total pelvic floor repair for grade III and IV pelvic organ prolapse from January 2007 to June 2010, were included in this retrospective study. Prolapse was graded using Pelvic Organ Prolapse Quantification system of International Continence Society.[13] Patients were evaluated for urinary, bowel, and coital symptoms associated with prolapse pre- and postoperatively using a nonvalidated questionnaire prepared for such patients visiting our uro-gynecology clinic. Uroflowmetry with postvoid residue estimation was done in all patients, and urodynamic evaluation was done only in patients with severe urgency or high postvoid residue. Repair was done by placing customized prolene mesh, Prolus Mesh [Lotus surgical private limited, LM-450-1] using four-point fixation technique. Intra- and postoperative complications were recorded. Follow-up period ranges from 6 to 42 months.

Surgical technique

All patients underwent general physical and focused pelvic examination during the first visit to the clinic, to assess the health of vaginal mucosa and grade of prolapse. In patients with unhealthy vaginal mucosa or ulceration, estrogen cream with betadine vaginal pessaries were prescribed for 4–6 weeks and periodic reassessments were done.

After admission, all patients received mechanical bowel preparation using polyethylene glycol and betadine vaginal suppository the night before surgery. Prophylactic antibiotics (cefoparazone + sulbactum 1 g intravenous) were administered at the time of induction of anesthesia (general or regional).

Patient was placed in dorsal lithotomy position with proper padding of all pressure points. Examination under anesthesia is done to assess the local tissues and uterine size. Ring retractor is placed, patient is catheterized, and weighted vaginal speculum is applied on posterior vaginal wall for exposure. In patients undergoing hysterectomy, the cervix is pulled down with the help of Allis tissue forceps [Figure 4a]. Diluted 2% xylocaine with adrenaline solution is injected for hydrodissection of tissues to raise the vaginal flaps [Figure 4b]. An elliptical full-thickness incision is made around the cervix in patients undergoing vaginal hysterectomy. An anterior midline longitudinal incision is made from the cervical incision up to 1 cm proximal to external meatus and then extending it to the posterior vaginal wall in the midline. In patients with vaginal vault prolapse, a vertical midline incision is made extending from anterior to posterior vaginal wall. Full-thickness vaginal flaps are raised and vaginal hysterectomy is performed with the standard technique. The bladder along with peri-vesical fascia is cleared off the vaginal flaps from medial to lateral, and dissection is carried out deeply till the endopelvic fascia is reached on both sides of bladder. Posteriorly, the dissection is carried out separating the rectum infero-medially and laterally to the ischiorectal fossa and superiorly up to ischial spine and sacrospinous ligaments on both sides. In presence of enterocoele, the sac is dissected, opened, reduced, and the peritoneum is closed with purse-string absorbable suture. While doing this, caution is taken not to dissect too laterally or take lateral sutures to avoid injuring ureters. The cut and ligated uterosacral ligaments are sutured together in the midline.

A 30 × 30 cm prolene mesh is fashioned as shown in Figure 1 with its measurements. The mesh is placed in the vaginal incision. One centimeter transverse incisions are made suprapubically about 2.5 cm lateral to midline on either side just above the symphysis pubis. Vicryl 2-0 sutures are brought out through the vaginal incision into the suprapubic incisions separately with the help of two pronged suture passer needle after perforating the endopelvic fascia sharply with the help of scissor [Figure 2a and 4c]. The sutures are then tied to the anterior limbs of prolene mesh separately on both sides. While passing the needle, utmost care is taken to be abutting to the posterior surface of pubic bone to avoid injuring the bladder. Intraoperative cystoscopy is done to rule out any injury to antero-lateral bladder wall. The anterior limbs of the mesh on both sides of midline are left in the subcutaneous plane

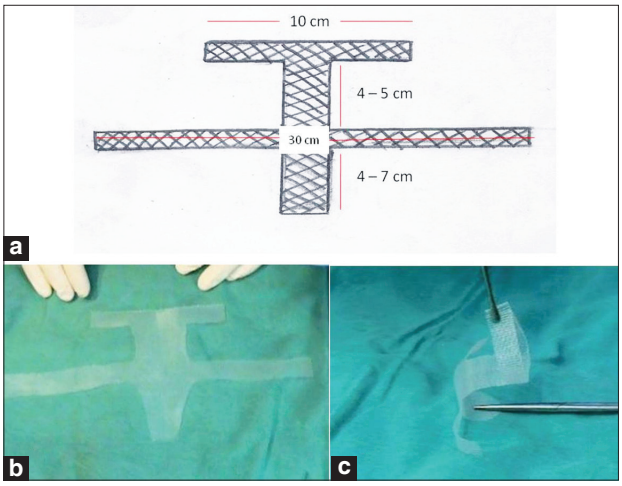

Figure 1: (a) Customized prolene mesh, diagrammatic representation with measurements, (b) Customized mesh before placement, (c) Mesh as it will be positioned inside

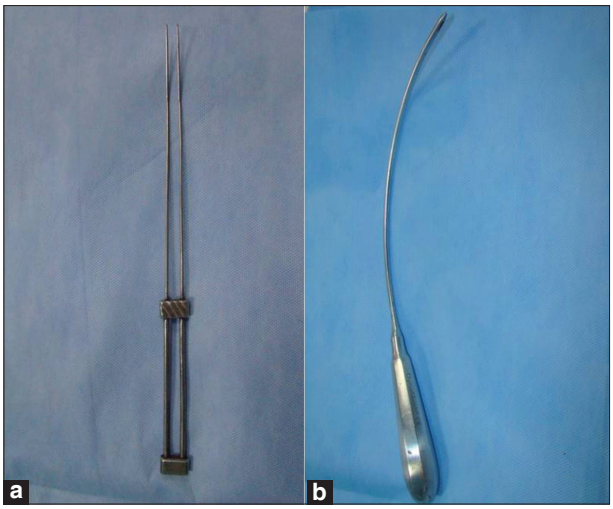

Figure 2: (a) Suture passer needles, anterior two pronged, (b) posterior curved,

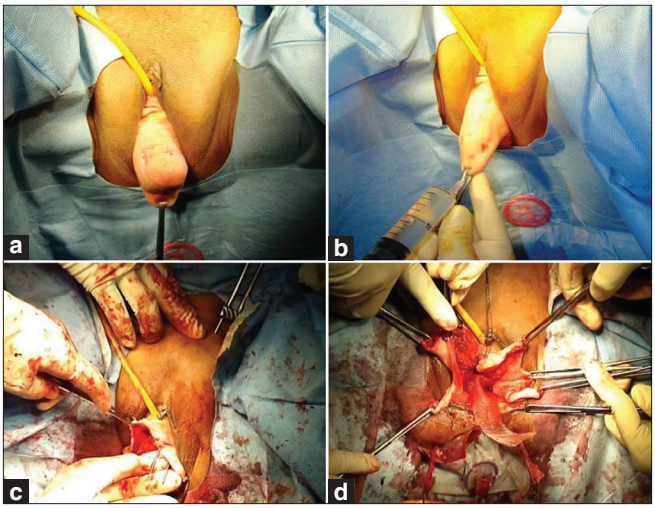

Figure 4: (a) Operative procedure, high-grade prolapse, (b) Saline dissection of vaginal flaps, (c) Anterior suture placement, (d) Placement of posterior limbs of mesh

without any tension with the vicryl sutures tied loosely. Bilateral 1 cm incisions are now made in the perineum 3 cm lateral and posterior to the anal opening. Long and curved Lina needle [Figure 2b] is inserted through the ischiorectal fossa on the right side perforating the levator ani muscle just infront of sacrospinous ligament medial to ischial spine and delivered into the vaginal incision. A prolene 1 suture is passed through vaginal incision and taken out from the perineal incision [Figure 4d]. The right posterior limb of the mesh is attached to the suture and brought out of the perineal incision. Similar procedure is performed on the left side. Anterior and posterior fascial plication is done before reinforcement with mesh. The lower part of the mesh is placed over plicated pararectal tissue fixed to the surrounding tissue with absorbable sutures. Care is taken that the mesh is not included in the perineorrhaphy. The vaginal flaps are minimally excised to preserve the previous depth and calibre of vagina. Vaginal

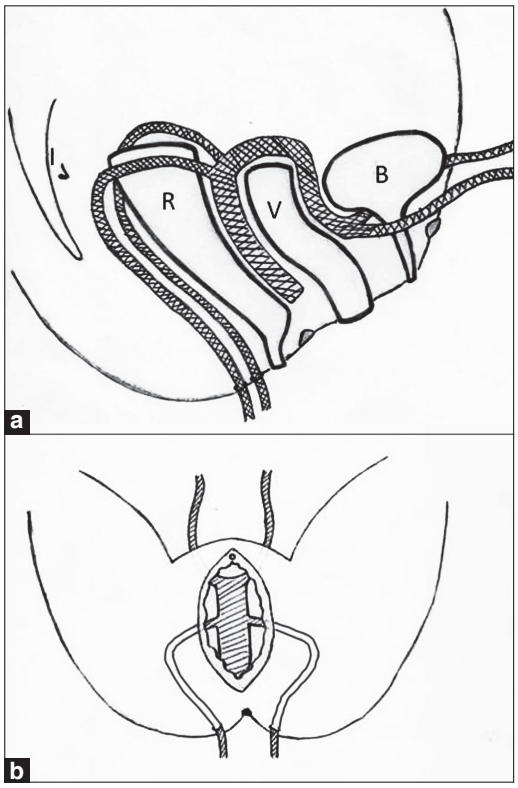

Figure 3: (a) Diagrammatic representation of mesh position, lateral view, (b) Anterior view, Bladder (B), Vagina (V), Rectum (R), ischial spone (I)

flaps are sutured together after achieving good hemostasis. The suprapubic and infra coccygeal limbs on each side are left in subcutaneous plane tied loosely without any tension and skin incisions are sutured. Betadine gauze pack is placed intravaginally for 24 h. The anterior part of mesh creates good anterior vaginal wall support to the bladder and urethra with both anterior limbs creating a sling at the level of bladder neck. The posterior part of mesh reinforces the recto-vaginal septum with formation of new utero-sacral ligaments for the support. The middle part of mesh supports the apical compartment [Figure 3a and 3b].

RESULTS

A total of 32 patients underwent total pelvic floor repair using the technique previously mentioned. The mean age of these patients was 54.91 years (40–71 years) and parity 3.62 (range 2–7). The follow-up ranged from 6 to 42 months. The demographic and clinical details of the patients are listed in Table 1. All the patients had varying degree of associated anterior and posterior compartment prolapse. There were 22 patients with grade IV uterine prolapse and 10 patients with grade III uterine prolapse. Total pelvic floor mesh repair was combined with hysterectomy in these 28 patients. Four patients with previous hysterectomy had grade IV vault prolapse. Two out of 32 patients had undergone vaginal surgery for prolapse previously. One had anterior colporrhaphy and one had posterior colporrhaphy.

Table 1: Patient demographics

Demographic details	No.
Patient's age in years	54.91 (40–71)
Parity	3.62 (2–7)
Postmenopausal status	26
Diabetes mellitus	8
Hypertension	10
Thyroid dysfunction	4
Previous vaginal surgery for prolapsed	2
Stage III prolapse	10
Stage IV prolapse	22
Concomitant hysterectomy	28
Previous hysterectomy with vault prolapsed	4

Both had recurrence of prolapsed at 18 and 24 months after first procedure.

All patients had mass protruding out of vagina as their primary complaint [Table 2]. Twenty-six patients out of 32 had urinary complaints, majority having stress urinary incontinence. Six patients had bowel symptoms, mostly constipation. Twenty-six patients were postmenopausal and only six patients were sexually active. Only two out of six sexually active patients complained of dyspareunia.

Postoperatively, all patients had subjective improvement in their symptoms. No patient complained of vaginal mass as none of them had recurrence of grade III or IV prolapse. All of them had improvement in their urinary and bowel symptoms also.

In the early postoperative period, 30 patients had perineal pain which improved with analgesics and none extending beyond 2 weeks [Table 3]. Two patients had vaginal wall hematoma which resolved on conservative treatment. Four patients having *de novo* urgency responded to anti-muscarinics and none were symptomatic at 3 months. Two patients had voiding difficulties after catheter removal and had to be temporarily recatheterized for 7 days. Estimated blood loss was about 150 ml. Two patients required blood transfusion postoperatively who had borderline anemia and no patient had blood loss exceeding 500 ml. There was no bladder or rectal injury intraoperatively.

There was no mesh erosion into bladder or rectum. Two patients had vaginal erosion of the mesh, one required partial excision of mesh with reapproximation of vaginal flaps, and other was treated conservatively. Two patients complained of mild stress urinary incontinence postoperatively and were treated conservatively.

DISCUSSION

The goal of surgical correction of pelvic support defect is to restore normal anatomy and function to all compartments without precipitating new defects.[6] Abdominal approach, i.e., abdominal sacrocolpopexy has been associated with success rates of 74–100%; however, it has morbidity, including wound problems (4.6%), hemorrhage (4.4%), ileus or small bowel obstruction (3.3%), exposure to general anesthesia, and a longer recovery period.[14,15] Trans-vaginal approach gives us the advantage to repair all compartment defects simultaneously through the same incision with less morbidity.

The superior success of grafts in abdominal hernia repair encouraged uro-gynaecologists to use them for correction of pelvic organ prolapse.[16] The introduction of synthetic and biological prostheses has been proposed to reduce recurrence rates while maintaining vaginal capacity and coital function.[8,17] Ever since the use of synthetic graft materials have come in practice for trans-vaginal pelvic floor reconstruction, various minimally invasive, mesh-based surgical kits have been introduced by the surgical companies to simplify the procedures. Over the years, various innovations and modifications have been introduced

Table 2: Symptoms

Patient's symptoms	No.
Mass protruding out of vagina	32
Urinary symptoms	26
Stress urinary incontinence	15
Incomplete voiding	6
Frequency	5
Urgency	4
Voiding by vaginal digitations	2
Bowel symptoms	6
Constipation	6
Defecation by vaginal digitations	3
Sexual dysfunction	2
Dyspareunia	2
Sexually Inactive	28

Table 3: Complications

Early complications	No
Perineal pain	30
De novo urgency	4
Vaginal discharge	3
Need for blood transfusion	2
Vaginal wall hematoma	2
Voiding difficulty	2
Late complications	
Vaginal erosion of mesh	2
Vaginal dryness	2
Stress urinary incontinence	2

in the design and material of the mesh for ease of usage and to minimize complications. The recommended material for mesh is type I monofilamentous, macroporous (size > 75 microns) polypropylene as it has less chances of erosion.

Like many other total vaginal mesh (TVM) devices,[18] our customized mesh is also based on trans-vaginal placement of tension-free polypropylene mesh with anterior limbs placed suprapubically at the level of bladder neck or mid-urethra and posterior limbs traversing through levator ani and then para-rectally taken out of the perineum.

In our study, all patients had subjective symptomatic relief and none of the patient had recurrence or required any prolapse surgery. The reported cure rate using Prolift mesh has been about 95% in various series.

The concomitant anti-incontinence procedure at the time of prolapse repair has been a subject of debate. After the repair of prolapse, various studies have reported *de novo* stress incontinence rates of 8–60%. CARE trial by Brubaker showed that the symptoms of SUI were significantly less prevalent (19.0% vs. 39.7%, $P < 0.0001$) and less bothersome (6.1% vs. 24.5%, $P < 0.0001$) in the patients randomized to prophylactic Burch colposuspension in comparison to sacrocolpopexy alone.[19] No other statistically significant differences in storage or voiding symptoms were recorded between the two arms (level 1b of evidence). In our study, the anterior limbs of mesh were placed as tension-free vaginal mesh supporting urethra at bladder neck level acting as a hammock. This explains low incidence of stress incontinence in our patients. All patients had improvement in their voiding and storage symptoms associated with prolapse. Nilsson and colleagues reported an excellent 5-year subjective and objective cure rate (84.7%) and a low failure rate (4.5%) using tension-free vaginal mesh for stress incontinence, with no increase in the failure rate seen over a 5-year follow-up period.[20] Complication rates are minimal in experienced hands, with a urinary retention rate of approximately 4% (but reported in some series to be up to 12%) and *de novo* urgency or urge incontinence occurring in about 5% of patients. In our study, two patients had immediate postoperative urinary retention needing temporary catheterization and three had *de novo* urgency which resolved on anti-muscarinic drugs. Two out of 32 patients had mild degree of stress incontinence. Varying degree of perineal pain felt by most of the patients required analgesics for initial few days but none beyond 2 weeks. Two cases of vaginal wall hematoma resolved on conservative treatment.

There was no intraoperative bladder or bowel injury in any of our patients. The commercially available kits use blind placement of trocar for mesh placement which may be associated with trocar-related injuries to the bladder and rectum. In our technique, the placement of needles is under vision with finger guidance minimizing the risk of visceral injuries.

There was no bladder or rectal erosion of mesh in our study. Two patients developed vaginal erosion of mesh. First case of erosion was from the initial few cases where we used to excise the vaginal wall. Second was a small exposure which could be treated successfully on conservative basis. Cosson and colleagues reported a multicentric study involving 687 patients.[21] The cure rate was 95%, with prolapse recurrence in the range of 0–11%. Vaginal erosions occurred in 0–13%. At 2008 AUA meeting, Lukban and colleagues reported a multicentric prospective trial using the Apogee mesh in 168 patients. At 6 months, the cure rate for posterior and apical wall defects were 92 and 94%, respectively. No intraoperative complication was experienced, but vaginal erosions occurred in 9%. Elmer *et al* reported a study of 261 patients with a follow-up of 1 year.[22] The anatomical cure rate was 79–86%. Bladder and rectal injuries were seen in 3% and vaginal erosions in 11%. Feiner *et al* reviewed eight studies and 1295 patients in which the Prolift mesh kit was used to treat apical prolapse.[23] With a mean follow-up of 30 weeks, the mean objective success rate was 87% (range 75–94) and the mean complication rate was 16%. Vaginal erosions occurred in 7%.

Sentilhes *et al* reported good outcomes of high-grade genital prolapse after hysterectomy using trans-obturator infra-coccygeal hammock of synthetic polypropylene mesh.[24] Badlani *et al* suggested simultaneous hysterectomy with vaginal prolapse repair using synthetic mesh[11] and Roover also showed better outcomes in patients undergoing hysterectomy when compared with patients with hysteropexy.[25] Maher *et al* demonstrated that for repair of vaginal vault prolapse, abdominal sacral colpopexy and vaginal sacrospinous colpopexy were equally effective but the abdominal approach was associated with longer operative time, longer convalescence period, and more cost, but less chances of prolapse recurrence when compared with vaginal approach.[26] Meschia *et al* compared the results of posterior intravaginal slingoplasty and sacrospinous fixation in the management of vault prolapse. They concluded that both procedures have equal efficacy in treating vault prolapse.[27]

Out of 24 patients, 19 were postmenopausal. Only two out of six sexually active patients reported dypareunia due to prolapse which improved after surgery. Patients were not very forthcoming about their sexual health-related symptoms. None of the patients had *de novo* dyspareunia. All six sexually active patients resumed sexual activity after 3 months of surgical procedure. Four out of six sexually active patients reported satisfactory vaginal intercourse without pain. Two patients complained of vaginal dryness which may partially be because of loss of cervical secretions after hysterectomy.

Three commercially available mesh kits for prolapse repair include Prolift (Gynaecare/Ethicon) for comprehensive repair, Avaulta (Bard) anterior and posterior repairs, and Apogee and Perigee (American Medical System) for apical posterior and anterior repairs. The largest experience has been with Prolift in medical literature for comprehensive repair. The major limitation of their use especially in our set up is cost.

The cost of mesh is $80 only, which is about 25–30 times less than the other commercially available kits such as Prolift ($2379), Apogee ($1393), Perigee ($1570), and TVT ($945).

Although our initial experience with the use of customized mesh repair has shown encouraging results, the power of this study is limited due to its retrospective nature and small number of patients included. This is a retrospective analysis of an early experience of only 32 patients with follow-up of up to 42 months. Another limitation of our study was the use of nonvalidated questionnaire, but no validated questionnaire was available in Hindi, so we used modified translation of the questionnaire as done by Sentilhes *et al*.[24] Pre- and postoperative sexual functions needs more detailed evaluation as most of our patients were sexually inactive and those who were active were very hesitant in discussing their sexual symptoms.

CONCLUSION

Pelvic organ prolapse is a common condition in elderly, multiparuos, postmenopausal women. Yet it is ignored because it is not life threatening and there is a lack of awareness among general population and medical practitioners. This is due to lack of effective, safe, affordable, and one-time procedure to address all aspects of prolapse simultaneously. We have presented a comprehensive, trans-vaginal approach using a customized prolene mesh to repair high-grade pelvic organ prolapse with a follow-up to 42 months and it has been a safe and cost-effective treatment option. Along with correction of prolapse, it is also useful in improving associated stress urinary incontinence. The reduction in cost of mesh makes the procedure more affordable. Although further studies in large patient population with longer follow-up are required for comprehensive evaluation before changing clinical practice, our initial experience with the customized prolene mesh in treating high-grade prolapse has shown promising results.

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