

Vaginal Wall Repair – Using Amniotic Membrane Graft

Abstract

Background: Standard colporrhaphy has been the main surgical procedure for vaginal wall prolapse for many years, with disappointing cure rates. Many investigators are now searching for alternative surgical techniques and materials to achieve better long term, postoperative results. Amniotic membrane is a natural human membrane tissue; when used as a vaginal graft, it will attract collagen, fibrinogen, and integrate with the local fascia providing a tough sheath, necessary for support and augmentation of the weak local fascia, to support the bladder, rectum, and vagina. It has been proven to demonstrate low antigenicity (incomplete HLA-A, B, C, and DR antigens), and hence will not be rejected by the recipient.

Objective: To test the clinical and surgical applicability of using a *biological fresh amniotic membrane graft* for the trans-vaginal repair of site-specific defects in anterior and posterior vaginal wall prolapse.

Method: A trapezoid shaped amniotic membrane graft (8 X12 cm) was applied to the anterior vaginal wall to correct the site-specific defect, by anchoring the graft to the Arcus Tendineous Fascia Pelvis, latterly at four points. While a superficial amniotic membrane graft (8 X 4cm) was placed on the posterior vaginal wall, between the rectum and the vagina, to correct the posterior wall defect. Excess graft material was excised. 21 patients had this procedure till now. All had spinal anesthesia, *3 had it with a vaginal hysterectomy, *6 had it with an anterior & posterior vaginal repair, *12 had it with a posterior vaginal repair.

Results: Patients with grade II or III vaginal defects were included in this study

- *Average age was 44.6 years.
- *Average parity was 4.2.
- *80% of patients had no complications, 20% had minor complications, relieved by medication.
- *No serious infections, rejections, and complications were noted till now (Max. period of study-180 days)
- *3 had mild de novo urgency.
- *1 had delayed vaginal healing.

Conclusion: In our study amniotic membrane graft was used for treating vaginal wall defects successfully with no serious complications. We feel that more studies are needed to better evaluate the efficacy and safety of this new surgical technique for vaginal wall repairs.

Keywords: Vaginal wall repair; Amniotic membrane graft; Vaginoplasty

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Introduction

The surgical repair of vaginal wall prolapse continues to remain one of the most difficult challenges in female pelvic floor reconstruction. The recurrence rate after standard colporrhaphy [1] ranges from 40-60 %. This high recurrence rate creates the necessity for developing new surgical techniques and better long-term solutions.

The majority of the anterior vaginal wall prolapse results from paravaginal defects 70% (lateral detachments from the ATFP) - mostly unilateral, on the right side, and at the level of the ischial spines; rather than midline defect. This new understanding of site specific vaginal defects has lead to changes in surgical techniques, to include, abdominal, laparoscopic, and vaginal repairs. Abdominal paravaginal repair requires a more invasive approach and a longer postoperative recovery, while laparoscopic

approaches are technically more difficult and challenging. Repair of vaginal wall prolapse by the vaginal route is usually simpler, and easier.

Surgeons have been investigating the use of synthetic and biological grafts in vaginal wall prolapse repairs. The use of an absorbable polyglactin 910 mesh (Vicryl) has shown little benefit in its use to correct vaginal wall prolapse (42%) [2] and the use of a synthetic permanent polypropylene mesh for vaginal repair shows a mesh erosion rate of 18% [3], de novo urgency rate of 20%, and dyspareunia 22% postoperatively. The mesh erosion rate or infection rate increased *four-fold* when the mesh was introduced vaginally as compared to the abdominal route in pelvic floor reconstruction cases [4].

Many pelvic surgeons, are now using biological grafts for vaginal prolapse surgery, such as cadaveric fascia lata [5,6],

cadaveric dermis, porcine small intestine, porcine dermis, or bovine pericardium, which are not used in the Middle East for cultural reasons. A new skin tissue generated matrix has given some hope, but is expensive. The use of *Amniotic Membrane* came to our personal attention as a possible biological graft material, since it is non-immunogenic, it will not be rejected, and as of protein nature, will be integrated and absorbed by the body after attracting fibrin and collagen, giving necessary support [7-9].

The first use of fetal amniotic membrane transplantation as a biological graft was reported by Davis in 1910, on burned and ulcerated skin, he observed lack of infection, minimal inflammation, decrease in pain and increase of re-epithelialization of traumatized skin. Others have used the amniotic membrane as a biological dressing for open wounds, burns, ulcers, as a graft in ophthalmic surgery, and as a neo-vaginal graft in Mc Indoe operation.

Human amniotic membrane is a tough membrane derived from the fetal membranes [10-12] and consist of 3 layers:

1. An inner single layer of amniotic epithelial tissue.
2. Thick basement membrane of collagen-rich mesenchyme 6 to 8 cells thick.
3. Vascular stroma loosely attached to the outer chorion, containing collagen types III, IV, V, and VII - fibronectin, laminin, fibroblasts, and growth factors.

Human amniotic membrane is believed to be non-immunogenic [13]. Antibodies or cell-mediated immune response to amniotic membrane have not been demonstrated, suggesting low antigenicity and hence the recipient will not reject it. Therefore, the use of systemic immunosuppressive drugs is not required. In contrast, chorion provokes neo-vascularization and a typical rejection phenomenon. However, repeated amniotic membrane transplantation from the same donor placenta, to heal a sterile, non-healing ulcer may create an immunologic reaction, possibly due to sensitization to unknown antigens. Therefore, it is recommended to use amniotic membrane from different donor placenta [14] in cases of repeated amniotic membrane transplantation.

To date, most clinical experiences with human amniotic membrane transplantation [15,16,17,18] have been with tissue preserved in glycerol solution or by cryo-preservation. Recent studies suggest that amniotic epithelial cells are not viable after preservation and it is unclear whether the growth factors survive cryo-preservation. Several surgeons have described the use of fresh human amniotic membrane for transplantation.

Aim of the work

Our objective is to describe a simple, inexpensive, and effective surgical technique for the trans-vaginal repair of an anterior and posterior vaginal wall prolapse, using a fresh amniotic membrane graft [19]. We believe that the majority of anterior vaginal wall defects require a para-vaginal repair, augmented by using a trapezoid shaped amniotic membrane graft (8X6X12cm), by anchoring the graft bilaterally, and tension free, to the arcus tendineous fascia pelvis (ATFP), at four or six points to provide complete support to the urethra, bladder and anterior vaginal

wall. While posteriorly, a fresh amniotic membrane graft (8x4cm), can be placed on the posterior vaginal wall, between the rectal fascia and the vagina, anchored distally at the uterosacral ligaments, and dorsally at the levator ani muscle. The excesses amniotic membrane graft is trimmed off, usually around 1-2 cm on each side [20].

The amniotic membrane graft is a natural human protein, attracting collagen formation, fibrinogen, and causing mild fibrosis, without being rejected, it will adhere to, and integrate with the local pubo-cervical fascia providing a fibrotic sheath, necessary for support and augmentation of the weak local fascia, and will be completely absorbed by the body.

Surgical Technique

The *Amniotic Membrane* is acquired from fresh specimen placenta, delivered by elective caesarean section with intact membrane, from our assisted reproduction unit. Donor women are subjected to HIV, Hepatitis B & C, Syphilis, Toxoplasmosis, Blood group & Rh, lab tests before delivery. The amniotic membrane needed is cut from the fresh placenta, rinsed with sterile saline solution to remove any debris, after separation of the chorion; and put in povidine iodine for 10 minutes then rinsed again. It can also be put in a solution of 80 mg. Gentamycine and 1 gr. Ampicilline for an additional 10 minutes, and then refashioned before use.

All patients were subjected to a questionnaire, detailed history, physical exam, urodynamics, and lab tests to evaluate all possible pelvic floor defects [21,22,23,24], and urinary incontinence, they signed a consent form, after explaining the procedure. Candidates for surgery are chosen if the anterior and posterior vaginal wall [25] prolapse are grade II or greater. Additional surgical procedures were performed if indicated.

The patient is placed in the dorsal lithotomy position, prepped and draped in the usual sterile fashion. The vaginal walls are injected with dilute xylocain-epinephrine solution, for homeostasis and pain relief. A midline incision is made through the anterior wall starting from the urethro-vesical junction to the vaginal apex near the cervix. The dissection is carefully performed to separate the vaginal epithelium from the underlying fascia; then continues latterly both sharp and blunt dissection to separate the bladder from the vagina, and reach the arcus tendineous fascia pelvis (ATFP), from the level of the urethro-vesical junction to the ischial spines. A finger is used to lightly clear the fascia lying over the ATFP.

A small round body needle on a needle holder, or an anurism needle (*) is used to pass 2 sutures of 0-PDS on each side into the ATFP. An index finger is used to identify the ischeal spine and the ATFP, the needle is then guided into position by sliding it next to the index finger; a thin retractor helps to provide better visualization. The first suture is placed through the ATFP, 2 cm superior to the ischial spines and picked up by a needle holder. The second suture is placed through the distal portion of the ATFP, close to the pubic bone, a third suture may be placed between the first and second suture. The same procedure is repeated on the opposite side so that a total of 4 sutures are placed. Beware of the obturator neurovascular bundle during the placement of the sutures near the ischial spine, especially if sutures are placed too anterior.

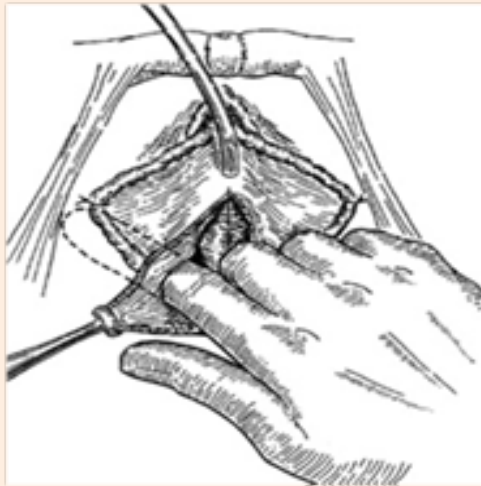


Figure 1: Finger dissection to reach White line (ATFP).

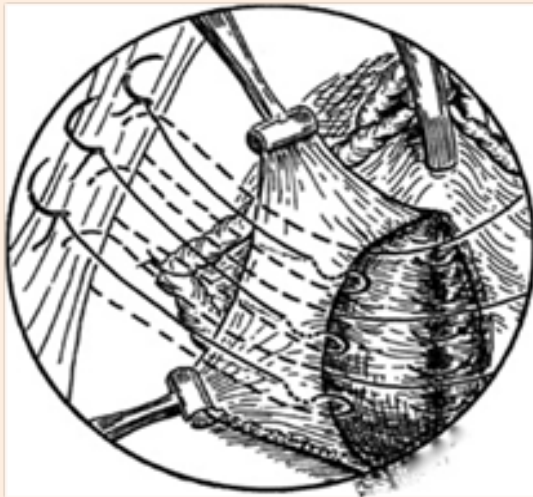


Figure 2: 3 para-vaginal sutures taken in ATFP.



Figure 3: Left side: Needle with corresponding Retractor (*) - Both Needles + Retractors



Figure 4: (**) An Anterior vaginal wall graft of fresh Amniotic Membrane refashioned for use.

The graft is then laid onto the anterior compartment with the mesenchymal surface [26] towards the bladder fascia, and is trimmed if too large. A double loop suture is fixed to the graft, 1cm from the edge, using the previous sutures in ATFP, taking also the pubo-cervical ligament lateral edges, first tying the sutures at the level of the ischial spines to ensure that the graft lies down flat and tension free, with the corners of the graft next to the ATFP on each side, then the sutures at the distal portion of the ATFP, are tied down. Care being taken not to stretch the graft too much as the membrane may break.

Finally, the graft is attached to the cervix at the peri-cervical ring, with delayed absorbable suture to provide additional support. The excess vaginal epithelium is trimmed off and the vaginal epithelium is closed in an interrupted suture fashion using absorbable suture.



Figure 5: (***) Posterior vaginal wall graft of fresh amniotic membrane refashioned for use.

Posteriorly (***), a longitudinal incision is made in the posterior vaginal wall extending deep to the vaginal fornix and the perineum is opened, the remnants of the recto vaginal septum are identified and sutured together, the graft (8X4) is then laid down superficially on the rectum and sutured by 2 sutures distally to the uterosacral ligaments; while dorsally the excess mesh is trimmed and then sutured to the levator ani muscles. The excess vagina is

trimmed, the vagina is sutured by a continuous suture, and the perineum reconstructed. Antibiotics and analgesics are given.

Results

- 21 patients had this procedure till now.
- All had spinal anesthesia,
- Average age was 46.6 years,
- Average parity was 4.2,
- 3 had it with a vaginal hysterectomy (anterior & posterior),
- 6 had an anterior & posterior vaginal repair,
- 12 had a posterior vaginal repair only

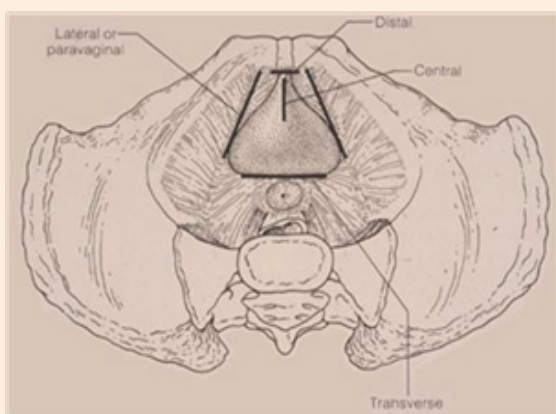


Figure 6: Site of anterior vaginal wall defects.

Site of anterior vaginal wall defects

- No infections or rejections were noted till now
- No bleeding or wound separation
- 3 patient had mild de novo urgency, relieved by anticholinergics
- 1 patient had delayed wound healing, relieved by antibiotics, and analgesics
- (Max. period of study 180 days)

Follow up

- All patients had a 30 day follow up
- 12 patients had a 60 day follow up
- 7 patients had a 90 day follow up
- 4 patients has a 180 day follow up

Patients were advised to come in after 30 days, 60 days, 90 days, 6 months and 12 months, for postoperative assessment, or if anything went wrong. As many of the patients came from out of town, they were not eager to come for their follow up appointment

Discussion

The high recurrence rate after a cystocele repair can result from various factors, like, incorrect diagnosis of site specific

defect, poor quality of vaginal fascia and muscular tissue, or an inherent connective tissue weakness. In cases of severe grade III or IV cystoceles, there is no good, usable supportive tissue fascia available for repair, especially in long standing cystocele. The advantage of the trans-vaginal, para-vaginal repair with graft augmentation is that the procedure provides support for all types of defects; lateral, transverse, and midline defects at the same time. Posteriorly; graft placement can also cure a large enterocele by blocking its descent.

We believe that the most important step in anterior graft placement is the anchoring of the graft to healthy supportive tissue, specifically to the ATRP, bilaterally at the four corners. If the ATRP proves to be weak and lax, a bigger sized graft may be used to be anchored to the sacro-spinous ligament distally and the obturator internus muscle dorsally. However this may prove difficult sometimes using our technique, a *Capio* suture anchoring device (Boston Scientific-USA), may prove to be a better tool for that purpose, if available.

A full sized trapezoid graft recreates and re-establishes adequate support for the urethra, bladder and entire anterior vaginal wall. The goal of this procedure is to completely rebuild and replace the fascia defect that exists. Good suspension from the vaginal apex along the entire vaginal wall, anterior and posterior to the vaginal opening is also mandatory, for long lasting success. This technique is not used for treatment of stress urinary incontinence; a sub-urethral sling procedure may be needed for that purpose [27].

Conclusion

Currently, the main operation for vaginal wall prolapse repair is still the standard anterior and posterior colpo-periniorrhaphy, reproductive and fetal tissues are a source of stem cells [28] and a new target for regenerative medicine [29].

Such treatments in gynaecology are still in the preclinical and clinical phases we feel that more studies are needed to better evaluate fetal graft materials, and other surgical techniques for vaginal wall repairs, with. Till now this technique has given us satisfactory results with no serious complications, and we are continuing this study to help us evaluate the effectiveness and safety of fresh amniotic membrane [30] graft augmentation in vaginal prolapse repairs.

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