

Vaginal Mesh Kits for Prolapse 2010: Update in Technology and Techniques to Minimize Complications

Robert D. Moore, DO, FACOG, FACS; G. Willy Davila, MD, FACOG

Treatment of women with pelvic floor prolapse has advanced in recent years. The discussion below focuses on vaginal mesh procedures, advances in technology, which patients can benefit from this technology, and what the surgeon needs to know for successful repair.

Approximately 6 years ago, vaginal mesh kits were introduced to the market in an attempt to obtain the benefits of a more durable repair as well as to simplify and standardize the technique of mesh placement vaginally. The Apogee/Perigee (AMS) and Prolift (Gynecare) systems were the first 2 kits released for treatment of vaginal prolapse in all compartments including anterior, posterior and apical (Figures 1 and 2). Other companies have released similar kits, but all have used the same basic concept of passing needles/trocars through incisions made in the groin and buttocks to assist in the placement and anchoring of the vaginal mesh graft through the levator muscles

(or sacrospinous ligaments) in the anterior or posterior compartment.

PROVEN EFFICACY

Studies have confirmed higher cure rates with vaginal mesh kits than standard repairs, and many have shown an improvement in sexual function.¹⁻³ However, concerns in the community over reported complications (such as vaginal mesh exposures, erosions into viscera, vaginal pain, and dyspareunia⁴) led to an FDA notification regarding the safety of these approaches in late 2008. Here we review the status and role of vaginal mesh kits in prolapse repair, as well as recent modifications that have been made in an attempt to decrease complications while still benefiting from the increased cure rates seen with the use of mesh in vaginal prolapse repair.

MAXIMIZING BENEFIT... WHILE MINIMIZING COMPLICATIONS

When used properly, in the right patient population, mesh seems to have a definite role in the treatment of pelvic organ prolapse. We cannot ignore the high failure rates seen with traditional repairs, nor can we exchange higher cure rates with grafts that result in high rates of complications. Interestingly, despite the recent reports of complications, there have also been an increasing number of studies published supporting mesh use.⁵ A Cochrane review published in 2008 evaluating level I evidence concluded that the use of mesh in the anterior compartment is supported.⁶ Evidence for the use of mesh in the posterior compartment is not as definitive; however, prospective studies have evaluated its

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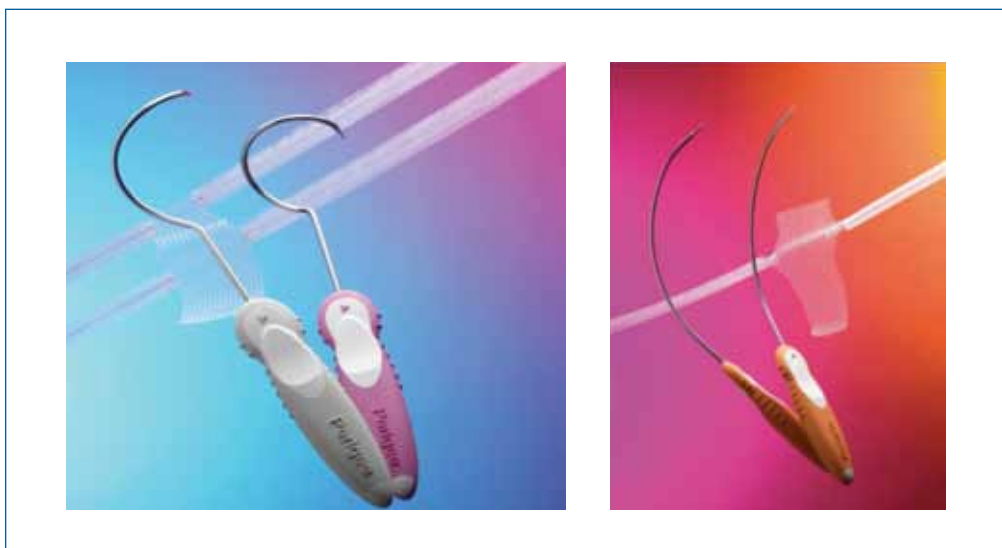


FIGURE 1. Perigee/Apogee Systems by AMS.

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There is no exact science regarding which patients would most benefit from a graft in their pelvic floor repair. A conservative approach to graft placement will help minimize complications.

safety and anatomic durability.^{5,7} Since the development and launch of the early mesh kits, much has been learned about how to reduce complications. Techniques have improved, and technology has advanced. The following summarizes some of these improvements.

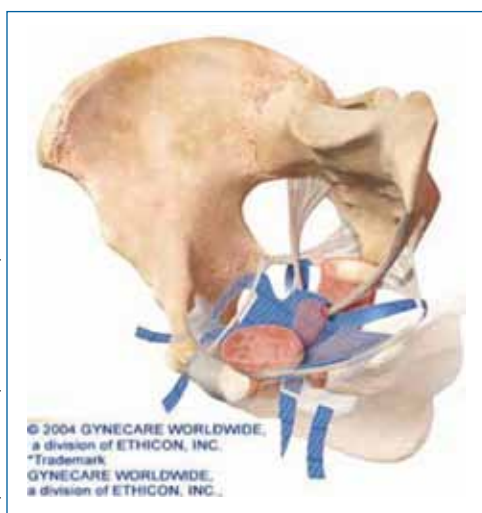
Patient Selection

Patient selection may be the most difficult factor to determine; however, it may also be the most important. To date, there is no exact science regarding which patients would most benefit from a graft in their

pelvic floor repair. A conservative approach to graft placement will help minimize complications. As we gather more data, the role of graft placement may expand; Table 1 reviews our current recommendations. Vaginal mesh use in younger sexually active patients with mild prolapse should be avoided until we have more data in this population. Additionally, relative contraindications should be considered in patients with uncontrolled diabetes, on high doses of chronic steroids, or severely immunocompromised. The use of a biologic graft may be considered in this subset of patients, especially in the posterior compartment.⁸

Surgical Experience and Technique

Surgeon experience and surgical technique are other critical components required to minimize complications. Although the use of “kits” has simplified the process and made the technique more standardized, these procedures should be considered advanced, to be completed by surgeons with advanced training and/or experience in pelvic floor surgery. Many of the complications that have occurred may have been due to inexperienced surgeons without adequate training, experience, or in-depth knowledge of pelvic anatomy. As subspecialty certification in the field goes forward, this should help define the requirements for surgeons to obtain privileges to complete advanced pelvic floor surgery.



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FIGURE 2. Prolift System by Gynecare Worldwide.

TABLE 1. Patient Considerations for Mesh Kit Use

- Recurrent prolapse (previous failure)
- Older patient with progressing prolapse
- Advanced prolapse (stage III or IV)
- Postmenopausal
- Decreasing estrogen status
- Poor tissue quality
- Chronic increases in abdominal pressure (eg, obese, chronic cough)

With experience have come improvements in surgical technique. We have found that the use of a hydrodissection solution (up to 40 to 60 cc in each compartment) helps to find the right tissue plane for a full-thickness, avascular dissection, which helps minimize bleeding and place the graft in the proper tissue plane. Decreased bleeding has led to decrease in post-op hematomas, a possible cause of mesh exposures and/or infections when they rarely occur. Additionally, placing the graft deeper helps minimize risks of dyspareunia and vaginal discomfort that can be caused by the graft being too superficial. Other techniques that have been recognized to reduce complications are listed in Table 2.

Advancements in Technology to Address and Minimize Complications

Another critical component that has helped dramatically reduce complications of mesh use vaginally is advancement in technology.

Lighter Mesh

Type I macroporous polypropylene mesh has long been recognized as the best-tolerated material to be used for vaginal prolapse surgery. Many of the complications reported to the FDA were with mesh materials that were not type I meshes and thus resulted in high rates of exposures, infections, abscesses, and rejection of the graft. Procedures such as Prolift and Apogee/Perigee have always utilized type I mesh, and complications such as these are very rare, but lesser effects such as vaginal mesh exposures have been still been troublesome to both patient and surgeon.

Exposures are not a major complication and typically can be handled easily with exci-

TABLE 2. Minimizing Risks of Complications

- Keep incisions as small as possible
- Type I soft, macroporous mesh
- Minimize mesh load
- No "T" incisions with hysterectomy
- Hydrodissection with full thickness dissection
- No tension on mesh or mesh arms
- Excise minimal vaginal epithelium
- Pre-op and post-op vaginal estrogen
- Lay mesh flat

sion of the exposed portion of graft alone. However, exposures are still a complication that many surgeons fear, even if they are usually self-limiting. This type of complication has been minimized with thicker dissection techniques, as well as improvements in mesh technology, such as decreasing the density and weight of the mesh while maintaining type I properties.

IntePro Lite, the mesh that is in the new Elevate Prolapse Repair System by AMS, is 50% lighter and less dense than the original mesh used in Apogee/Perigee and the Gyne-mesh used in Prolift. Significant improvements in healing quality have been seen with this lighter mesh, without sacrificing cure rates. Mesh exposure rates have decreased 50% with this lighter mesh.⁹ Issues such as

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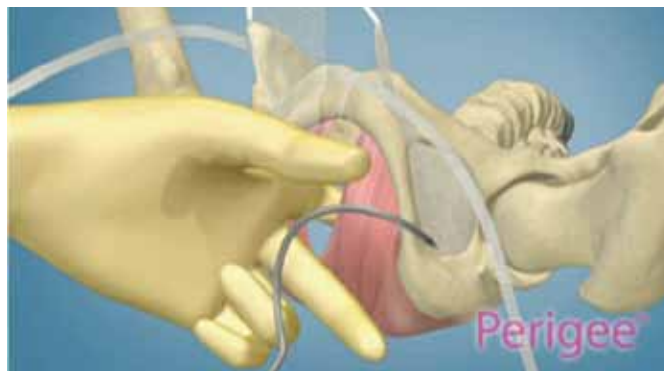


FIGURE 3. External needle passes required by the original Perigee procedure from AMS, now eliminated with the Elevate approach.

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the patient or her partner being able to feel the mesh under the vaginal skin have essentially been eliminated with this new technology. The potential for a decrease in vaginal discomfort and/or dyspareunia with the use of a lighter mesh is currently being studied. Concerns have been raised that mesh contraction or shrinkage can result in vaginal pain, and the use of a lighter weight mesh implanted without tension should potentially reduce this risk as well.¹⁰

New Systems Eliminating External Needle Passes

Complications from the blind needle passes through the groins and buttocks, such as life-threatening bleeding, have been reported with the anterior deep needle pass of Prolift; bladder and bowel injuries have also been seen with other systems utilizing the original approach of external needle passes (Figure 3).¹¹ Most of the pain associated with these

types of procedures can be attributed to the mesh arms being too tight, whether they are anchored through the levator muscles or penetrating through the back of the sacrospinous ligament.

Patients who present with pain vaginally, with or without intercourse, following the original procedures typically have a palpable band of one of the mesh arms penetrating the pelvic sidewall, and/or the mesh has bunched up across the midline of the vagina in the anterior compartment because the arms are placed too close together. This particular situation is not caused by “mesh shrinkage” but is due to surgical error. Additionally, systems such as Perigee and Anterior Prolift did not provide any level I or apical support with the cystocele repair; therefore, patients were at risk for vault failure or would require a dissection of the posterior compartment for concomitant vault suspension.

The new Elevate system by AMS (Figure 4) has addressed these issues by eliminating all external needle passes and thereby decreasing the risks of placement of the system, as well as eliminating lateral mesh arms penetrating through the levator muscles for anchoring. The system utilizes only one vaginal incision (for either the anterior or posterior system) and involves placement of 2 apical arms anchored to the sacrospinous ligaments with very small self-fixating tips to provide apical support through either the anterior or posterior compartment. To date, the tips provide the least invasive approach to achieve an attachment to the sacrospinous ligaments and provide excellent fixa-

New Single Incision Approach

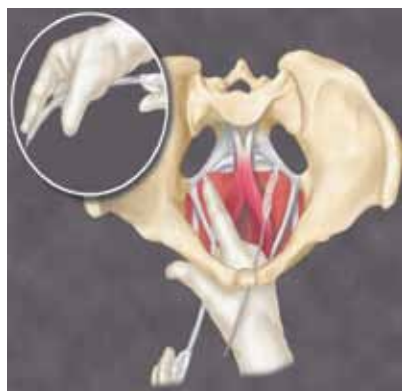
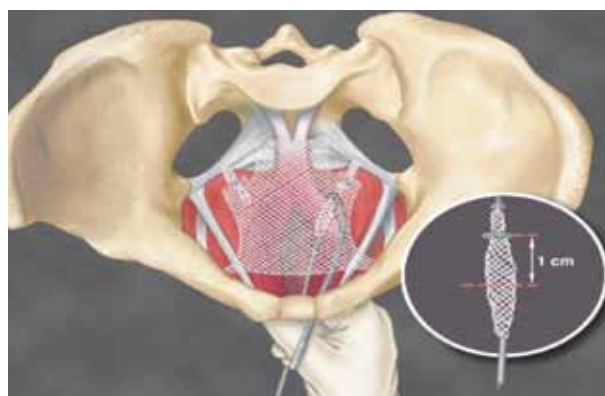
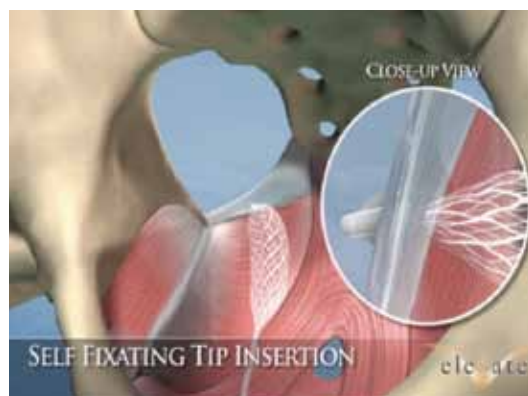


FIGURE 4. Anterior Elevate System, AMS. Single incision system for treatment of cystocele and concomitant vault prolapse eliminating all external needle passes. Placement of apical arms into sacrospinous ligaments with self-fixating tips and subsequent placement of graft up over the arms and adjusting into place.



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tion. The apical portion of the body of the graft is then fed over the arms and can be adjusted to fit the vaginal length and provide vault support via either compartment.

The sacrospinous ligaments have always provided an excellent point of fixation for vault support. However, more invasive approaches involving passing a suture carrier around the ligament or passing a mesh arm through the back of the ligament carry a high risk of pudendal nerve injury or entrapment. Attachment with the small fixating tip of the Elevate system gives the benefit of excellent vault support, while decreasing risk of neuropathy significantly. Early studies have shown excellent cure rates with minimal risk of leg or buttock pain.⁶ Additionally, with no mesh arms penetrating the pelvic sidewalls laterally, the issue of these arms causing tight bands has been eliminated, and therefore the risk of dyspareunia decreases significantly. The benefit of this system is both level I and II support via either compartment, utilizing a single incision and no external needle passes, which addresses and eliminates many complications that have been an issue with the current systems.

CONCLUSION

Pelvic floor prolapse is a significant quality-of-life issue for many women. Over the past 10 years, more focus has been given to the treatment of this condition as the fields of urogynecology, female urology, and reconstructive pelvic surgery have continued to grow. Traditional repairs have an unacceptably high rate of failure and are not immune from many of the same complications for which vaginal repair with grafts are commonly criticized. When used by an experienced and advanced pelvic surgeon with an in-depth knowledge of female pelvic anatomy, in the proper clinical situation with appropriate patient selection, the benefits of graft use do seem to outweigh potential risks. Improvements in technology, such as lighter weight meshes and procedures that eliminate external needle passes, will also help continue to reduce complications.

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