

HIGH INCIDENCE OF VAGINAL MESH EXTRUSION USING THE INTRAVAGINAL SLINGPLASTY SLING

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ABSTRACT

Purpose: The intravaginal slingplasty (IVS) is a tension-free vaginal tape variant that uses a multifilament polypropylene tape to support the mid urethra for the treatment of female stress urinary incontinence. Numerous cases of defective vaginal wound healing have been described in the international urogynecological literature. We describe our experience of vaginal mesh extrusion using the IVS sling.

Materials and Methods: A total of 35 patients underwent suburethral sling procedures for anatomical stress urinary incontinence using the IVS system from November 2002 to September 2003. A retrospective chart review was performed to retrieve data on safety and efficacy, complications and outcomes using this product.

Results: Six patients (17%) to date have presented with defective vaginal healing manifested by extrusion of the sling material. Mean time to presenting symptoms was 9 months (range 2 to 15). All patients required surgical removal of the sling material. No urethral erosions were noted.

Conclusions: Our experience suggests that the IVS sling system, which uses a multifilament polypropylene suburethral mesh, incurs an unacceptably high rate of defective vaginal wound healing and mesh extrusion.

KEY WORDS: urinary incontinence, stress; vagina, wound healing, surgical mesh

Stress urinary incontinence (SUI) is a quality of life issue for millions of women worldwide. The concept of a sling for the management of stress incontinence was first introduced in the early 1900s by using the gracilis muscle for this purpose.¹ Autologous grafts (fascia, muscle, tendons, etc) have provided high success rates. However, their use has been limited by harvest site morbidities including pain, hernia and longer recovery times. As such, there have been many modifications of the autologous sling to maintain high success rates while reducing the morbidities associated with this operation.¹ Petros² and Ulmsten and Petros³ are primarily responsible for a major paradigm shift including the use of synthetic tape, placement at the level of the mid urethra, tension-free support and fixation by friction.^{2,3} Synthetic slings have dramatically increased in popularity in the management of SUI and have been rapidly adopted by the urogynecological community. They obviate the need for harvesting autologous tissues and are associated with high success rates similar to those of nonsynthetic materials. However, they are associated with higher rates of vaginal/urethral erosions (0.2% to 22%).^{4,5}

Polypropylene tapes have emerged as the standard because of lower reported rates of erosion/extrusions (0% to 5%) compared with other forms of synthetic slings.⁶ There are numerous forms and designs of polypropylene tapes from various companies including the tension-free vaginal tape (TVT) manufactured by Johnson and Johnson, suprapubic arc (SPARC™) by American Medical Systems, Intra-Vaginal Slingplasty (IVS) by Tyco and Advantage™ by Boston Scientific. IVS uses a multifilament polypropylene tape to provide mid urethral support for the treatment of stress urinary

incontinence, as opposed to the monofilament nature of the polypropylene slings provided by the other companies. In this article we provide our experience with the use of the IVS sling, and report an unusually high rate of defective vaginal healing and vaginal mesh extrusion associated with this product.

MATERIALS AND METHODS

Between November 2002 and September 2003 a total of 35 patients underwent placement of a multifilament polypropylene sling using the Intra-Vaginal Slingplasty product for the management of stress urinary incontinence by 3 surgeons from a single institution (fig. 1). Institutional review board approval was obtained and patient charts were retrospectively reviewed. All patients underwent assessment including history and physical examination, Incontinence Quality of Life questionnaire, 24-hour incontinence and voiding diary, Marshall test, cystoscopy, and multichannel videourodynamic examinations before surgery.

All patients were treated with broad-spectrum prophylactic antibiotics preoperatively, intraoperative antibiotic irrigation and postoperative antibiotics. After prepping and draping the patient in the dorsal lithotomy position, a 2 cm incision was made over the mid urethra, and the plane between urethra and vagina developed sharply and bluntly. The IVS tunneller device was introduced through the vaginal incision and passed retropubically, exiting above the pubis. The tunneller was removed, leaving the stylet in place and the procedure was repeated on the opposite side. After cystoscopy confirmed no penetration of the bladder, the IVS polypropylene mesh tape was threaded into the eyelet of the stylets and the stylets were pulled through the suprapubic incisions. The tape tension was adjusted, excess tape was excised, and the vaginal and suprapubic incisions were closed with a running, locked 2-zero polyglactin suture and topical skin adhesive, respectively. Following surgery, regular fol-

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Study received institutional review board approval.

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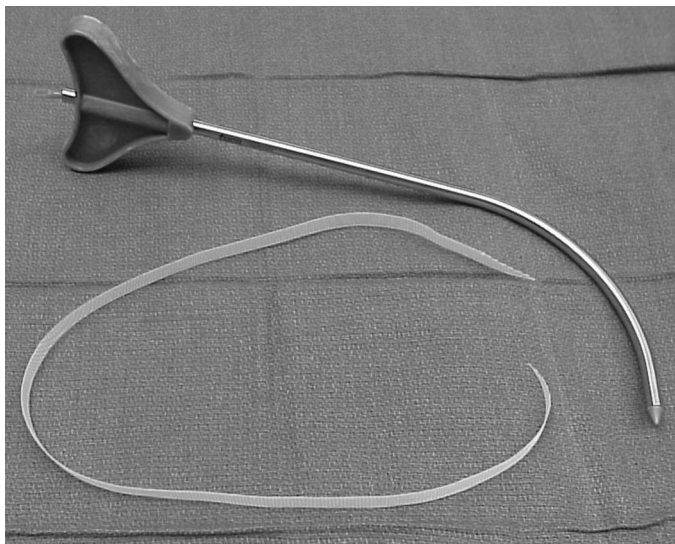


FIG. 1. IVS tunneller device and IVS tape

lowup examinations were performed at 2 weeks, 6 weeks and 12 months. Minimum followup was 18 months.

RESULTS

Of the 35 patients 6 (17%) who underwent placement of a Tyco IVS sling have demonstrated vaginal mesh extrusion of the multifilament polypropylene sling material (fig. 2). Average age in this cohort was 58 years (range 54 to 66). The presenting symptoms included intermittent serosanguineous vaginal discharge in 5 of 6 patients (83%), pelvic pain in 3 of 6 (50%) and dyspareunia in 3 of 6 (50%). All patients underwent pelvic examination and cystourethroscopy. All had extruded sling material visible in the anterior vagina and a tender, golf ball size pelvic mass developed in 1 patient. Mean time to presenting symptoms was 9 months (range 2 to 15). The first 2 patients were initially treated with antibiotics and analgesics. However, both patients required removal of the sling material due to persistent symptoms. Interestingly



FIG. 2. Vaginal extrusion of IVS mesh

1 patient presented 15 months after IVS insertion with vaginal pain and serosanguineous vaginal discharge. She was found to have a tender pelvic mass extending to the suprapubic incision site. Fever and increasing pelvic pain developed, and imaging revealed a pelvic abscess that required exploration, drainage and removal of the sling material.

All 6 patients ultimately required sling removal and all patients reported complete resolution of symptoms following removal of the IVS sling. Four patients remained continent following excisional surgery and 2 required placement of a secondary suburethral sling.

DISCUSSION

SUI due to urethral hypermobility and/or intrinsic sphincter deficiency adversely affects the quality of life of millions of women worldwide. In 1997 a panel summary examined the literature and body of evidence on the management of SUI, and concluded that surgical correction offers the most effective long-term cure and should be offered as initial therapy. Numerous techniques, materials and delivery systems have been developed over the years in the quest to find one with optimal efficacy and minimal morbidity. Von Giordano introduced the concept of slings in 1907 by using the gracilis muscle to create the sling.¹ Mcguire and Lytton popularized the use of autologous fascia in the late 1970s.⁷ Since then many different sling materials have been introduced which include autologous structures (rectus fascia, fascia lata, vaginal wall), allograft products (cadaveric fascia lata and dermal materials) and xenografts (porcine or bovine products). More recently, synthetic materials such as polytetrafluoroethylene, nylon, silicone, polyester and polypropylene mesh have emerged as alternatives.

Synthetic slings have gained popularity because of their advantage compared to autologous products in eliminating the need for harvesting and related complications. They offer freedom from autolysis and prion considerations, and the long-term cure and/or improvement rates can be greater than 90%.⁸ However, they have also been associated with greater rates of urethral erosion and vaginal extrusion.^{4,5} While urethral erosions are usually due to technical errors including excessive tension on the sling material against the urethra and/or unrecognized urethral injury, vaginal extrusions are usually due to subclinical infections or poor incorporation/integration of the sling material. The ProteGen system (Boston Scientific), a woven polyester based sling, has been associated with high rates of complications (50% vaginal extrusion and 20% urethral erosion), culminating in a recall by the Food and Drug Administration in 1999.⁹ Currently polypropylene has proved to be superior to other synthetic materials including polytetrafluoroethylene, polyester, or silicone in terms of better integration and lower complication rates.⁶

We reported on a series of patients who experienced vaginal extrusion and defective wound healing after placement of IVS, a suburethral sling that uses a multifilament polypropylene mesh for suburethral support. These patients required surgical removal of the sling material, 2 of whom after attempts at conservative treatment failed. An abscess developed in 1 patient along the course of the sling in the retro-pubic space. All had eventual resolution of symptoms after surgical excision.

IVS was introduced by Tyco as a minimally invasive approach for stress urinary incontinence during the 1990s.^{2,3} Like many of the newer sling systems, IVS was developed in the hopes of maintaining high cure rates while decreasing potential postoperative complications and length of hospital stay. The surgical principle includes neo-alignment of the mid urethra as well as tightening of the vaginal hammock.¹⁰ Like other synthetic slings, the mesh porosity should theoretically allow for invasion of fibroblasts and deposition of

collagen along the length of the tape to form a scar, which acts as a permanent artificial pubourethral ligament.¹⁰ The product was developed initially with nylon, but in 1999 Tyco began using polypropylene mesh to decrease infection rates and rejection.¹¹

The success rate of IVS has been similar to that of other available suburethral systems. Petros et al showed 81% cure rates at 4 years and the initial 2 patients who were treated in 1986 were continent 10 years postoperatively.¹⁰ Others have reported similar success rates.^{3,12} However, despite comparable efficacy, IVS appears to have higher rates of vaginal extrusion and mesh complications ranging from 6% to 15%.^{11–14} In a prospective, randomized, multicenter trial, Baessler et al reported that vaginal extrusions developed in 9% of patients with IVS compared to 0% of patients with TVT.¹¹ Glavind and Sander reported 14% vaginal extrusions using IVS vs 0% using TVT.¹³ In our series 6 of 35 patients (17%) experienced such complications.

The precise etiology of vaginal mesh extrusion associated with suburethral slings remains unclear. There is increasing evidence that inherent mesh characteristics, including material, filament structure, pore size, weave and elasticity, create the unique differences among the myriad of commercially available slings, and may engender these complications.^{9,15,16} The general surgical literature has long debated the association between multifilament sutures and wound complications. In a controlled, randomized study Osther et al showed that abdominal closures with multifilament sutures had a 16% incidence of wound infection vs 7% for monofilament sutures.¹⁷ Multifilament meshes used for suburethral slings may likewise predispose patients to such wound complications. Bafghi et al demonstrated a 7.4% infection rate of the multifilament IVS sling vs 0% with the monofilament TVT sling.¹⁸ Perhaps the smaller interstices between the IVS polypropylene multifilaments are apt to harbor bacteria, and impair tissue ingrowth and integration.¹⁹ This is in contrast to TVT, SPARC and Advantage, which are monofilament polypropylene and have loosely woven fibers with macropores greater than 80 microns that allow for collagen deposition and tissue incorporation.¹⁹

Another key difference among the various slings is elasticity. The IVS sling is nonelastic, does not require a covering sheath and, thus, is easy to re-tension. However, the TVT, SPARC and Advantage slings are elastic, require a covering sheath, and are more difficult to re-tension once the sheath is removed. Stiff, inelastic synthetic slings such as the IVS may not conform to the surrounding tissue as well as the more elastic slings, further interfering with tissue integration.¹⁵ Poor incorporation and decreased ingrowth of surrounding tissue may be the leading causes of higher rates of vaginal mesh extrusion associated with the IVS product. An animal model comparing properties of different meshes concluded that the IVS mesh engendered the greatest cellular response in terms of quantity of giant cells, histiocytes and fibrotic inflammatory reaction, and that excessive tissue fibrosis may have important biocompatibility implications.²⁰

In our series 3 surgeons (ALS, MG, SL) observed high rates of vaginal extrusion and poor wound healing using the Tyco IVS system. We do not believe that surgical technique was a factor in the genesis of the extrusions since the standard vaginal closure technique that we use for all transvaginal procedures—a running, locked 2-zero polyglactin suture—was used. This closure technique has not incurred this high rate of wound complications when using different sling materials. The patients in our series presented with vaginal discharge and spotting (83%), dyspareunia (50%), and pelvic pain (50%). Others have reported similar symptoms as well as irritative voiding symptoms, suprapubic pain, urinary infections and hematuria.¹⁵ A high degree of suspicion should be maintained in patients with these symptoms after sling operations. A thorough pelvic examination and cystoscopic

evaluation should be undertaken to rule out erosion complications. The underlying cause of the vaginal mesh exposure may be either vaginal wound dehiscence in which the surgically closed wound splits open in the immediate postoperative period, or vaginal extrusion in which the previously healed vaginal wall sustains a delayed breakdown on the basis of constant pressure from poorly incorporated mesh or from a mesh infection. In our series the mean interval for presentation of symptoms of extrusion was 9 months, a more prolonged period compared with other polypropylene meshes. Thus, it is unlikely that dehiscence had a role and more likely that poor incorporation and/or subclinical infection was contributory. Only 1 patient in the series had an obvious infection as manifested with fever, pain and pelvic abscess.

Treatment of all 6 patients in this study required surgical excision. Some authors advocate immediate surgical removal of the extruded sling material.¹⁶ Kobashi and Govier recently reported on the role of conservative management in mesh erosions.¹⁹ They observed 3 patients with 1 cm of exposed mesh in the anterior vagina and found that at 6 weeks there was re-epithelization of the mesh. They concluded that conservative management has a role in small erosions involving autografts, allografts or loosely woven mesh, and surgical treatment should be considered if there is no improvement by 3 months.¹⁹ Two patients in our series were initially treated conservatively, however both eventually required surgical excision.

CONCLUSIONS

Stress urinary incontinence has emerged as a highly prevalent medical condition and, as such, has created a large and competitive marketplace for New Age commercially available slings. The Tyco IVS sling is one of the many available sling options that has proved effective in curing or improving stress incontinence. However, a troubling incidence of vaginal mesh extrusion has been recognized. The multifilament composition of the mesh sling may predispose the IVS system to higher rates of such complications. Based on experience we believe that the high rate of defective vaginal wound healing and mesh extrusion associated with the Tyco IVS sling preclude its use for the treatment of stress urinary incontinence. In addition to its use for stress urinary incontinence, the Tyco IVS system has been promoted as an option for treating vaginal vault prolapse. In light of the wound healing issues observed in our series, it will be imperative to follow those patients carefully who undergo vaginal vault fixation for adverse effects in terms of apical and posterior vaginal mesh extrusion.

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