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Pubovaginal sling, the godfather of midurethral slings that remained so

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ABSTRACT

Forty years ago, autologous fascial slings became the gold standard in the treatment of genuine stress incontinence. In 1996, a synthetic material sling was introduced to the urogynecological literature known as tension-free vaginal tape. Some years later, another synthetic tape was introduced through a novel trajectory: transobturator. Due the conception of most polypropylene synthetic tapes, scores of devices, applicators and tape designs evolved. Now, with reports surfacing in the urologic literature on the adverse events of synthetic tapes and their potentially fatal complications, it is prudent to endeavor once more the place of autologous pubovaginal sling. This review addresses the evolution of pubovaginal slings and milestones of its journey to its current position in surgery of incontinence.

1. Introduction

Pubovaginal sling has been part of urologists' armamentarium for almost 4 decades. Midurethral slings have been recommended for all types of stress urinary incontinence as a first-line procedure[1-4]. Slings include a variety of autologous and synthetic materials, including fascia lata, rectus fascia[5,6], vaginal wall[7], cadaveric fascia[8], polytetrafluoroethylene[9], silicone[10], polypropylene[11], palmaris longus tendon[12], rectus muscle flap[13] and animal material such as porcine dermis and bovine fascia[14].

2. History

The first sub-urethral sling is traced to early 19th century. Giordano in 1907[15] used a pedicled gracilis muscle graft, detached from the thigh and translocated into the vagina. It was a retropubic sling surrounding the urethro-vesical junction, making what would be described today as a proximal sling. This procedure was later applied as a treatment for incontinent epispadias[16]. Three years later Goebell[17] performed a sling made of the pyramidalis muscles in 2 girls. He used the muscle separated from its fascia and postulated that it exerts an active muscular effect on the urethra. In 1914, Frangenheim used the same muscle together with its fascia[18], while Stoeckel suggested that the combined use of this muscle-fascia sling with a transvaginal plication of the bladder neck[19] gives better results. This procedure was termed as the Goebell-Frangenheim-Stoeckel operation.

Stoeckel argued that the material used for the sling was not crucial for the success of the procedure; it was rather a high urethral position and attachment of the sling to abdominal muscles that mattered[19]. In 1933, Price became the first to report use of autologous fascia lata. He passed it beneath the urethra in an antegrade approach. The ends of the fascia were secured to the rectus muscles[20].

In 1942, Aldridge[5] used rectus fascial slings in conjunction with vaginal surgery by mobilizing strips of

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rectus abdominis fascia, leaving the ends of the flap attached to the recti medially and tunneled the strips through the recti, about 4 cm above the pubic bone. The two ends were sutured together through a vaginal incision. Aldridge also identified the Peri-urethral fascia as a bloodless plane and observed that the rectus fascia was always accessible. In addition, he observed the abdominal relationship between the muscles and urethra, showing that, when there was an increase in abdominal pressure, the urethra was compressed at the same moment.

Few years later, Millin utilized strips of rectus fascia, looped under the urethra, and tied them over the top of the urethra. In 1948, Millin and Read[21] reported good results using long fascial strips to treat women with urinary incontinence secondary to urethral hypermobility. Jeffcoate[22] used the Aldridge technique on 40 women and reported an 86% cure rate.

But it was not until 1978 when rectus fascia pubovaginal sling (PVS) was revisited and modified. McGuire and Lytton[6] used a pedicled rectus fascial sling to achieve continence in 80% of patients with intrinsic sphincter deficiency (ISD). In 1991 Blaivas and Jacobs[23] modified the procedure further by using unattached rectus fascia, which decreased the tendency for sling over tightness, making urine retention more of an unlikely adverse event.

Since then, pubovaginal sling has been used as a primary treatment for stress urinary incontinence (SUI), whether due to urethral hypermobility or ISD[24,25]. This expanded use was supported by the premise that all patients with SUI have some degree of ISD and would benefit from urethral support[26].

In 1996, Ulmsten *et al.*[27] published their initial experience with a polypropylene tape (TVT) applied to 75 women with genuine SUI and followed them for 2 years, and they reported an 85% cure rate. TVT gained wide popularity over a short time because of its simplicity, decreased operative time, decreased recovery time, and good outcomes[28]. In 2001, Delorme introduced the first transobturator tape[29]. It adds the advantages of TVT lower incidence of bladder/urethral injury, as well as avoidance of the recurrent retropubic space. Fascia lata slings were re-visited by Carbone *et al.*[30], who modified the procedure by using titanium bone screws as bone anchors and cadaveric fascia lata as sling material. A recurrence rate of 37.6% at a median of 10.6 months of follow up was attributed to fragmented or attenuated cadaveric sling material.

3. Efficacy of PVS

PVS remains one of the most popular techniques. It is easily harvested, even in patients with multiple abdominal operations. In some cases anterior rectus fascia is scarred and thickened owing to prior operations and it could be difficult to obtain a good length of the rectus sheath. It is durable and native and rarely causes urethral erosion[31]. The autologous pubovaginal fascial sling remains the gold standard for treating sphincter incontinence with minimal morbidity[32].

Using rectus abdominis muscle flap is useful in the repair of complex and refractory urethrovaginal fistulas. It can provide support to the bladder neck and proximal urethra after failed prior repair with the Martius flap procedure. The continence rate was 83% and patients were able to void to completion at a mean follow-up of 23 months[33]. Another advantage of PVS is that it is a durable option for women with reproductive potential. Both vaginal delivery and cesarean section are acceptable modes of delivery following this procedure[34].

PVS has potential for a repeat procedure. PVS can be easily performed after an initial failed operation with low morbidity and acceptable continence rates. It is considered a reasonable treatment option in select women with recurrent SUI[35]. The autologous facial pubovaginal sling can be used to salvage difficult SUI cases[36] with reasonable success in about two thirds of patients.

For the rectus fascia PVS, one study reports a postoperative continence rate of 81%-95% after 4 years[6]. Another study documented 70%-95% overall long-term cure rate[37]. Over 4 years, it showed 78%-92% continence rate, with patients with type 2 stress incontinence, having a higher success rate (91%) than patients with type 3 SUI (84%)[38]. After a mean follow-up of 25 months, 93.3% of patients reported being stress continent and 73.3% were satisfied with the result of the surgery, but with longer follow-up patients had a significantly lower satisfaction score[39].

PVS is rarely associated with urethral erosion or vaginal extrusion. The mechanism of erosion is thought to be secondary to infection of a synthetic material; excessive tension applied to the sling or unrecognized urethral injury at the time of the operation will result in urethral erosion[40].

A comparison of preoperative and postoperative urodynamic parameters indicates that PVS is followed by an increase in urethral resistance. PVR >100 mL and Qmax $\leqslant$20 Ml/S before surgery are risk factors for postoperative voiding dysfunction[41]. New-onset detrusor instability and voiding dysfunction are commonplace. Voiding dysfunction results from too much tension on the sling[39]. Preoperative urodynamics can only poorly predict the occurrence of voiding dysfunction and the necessity of long-term catheterization after surgery[42]. However, some studies reported the rate of new-onset detrusor instability to be in

the range of 3% to 24%[39].

Osteomyelitis is another potential complication, although it is very rare[43-46]. A case report on pubic osteomyelitis and granuloma formation was retrieved from the literature[47].

4. Comparative studies of PVS and other techniques

Synthetic slings are numerous with significant disadvantages including erosion, extrusion, bowel injury, bleeding, fistulas and infection[48].

Autologous and synthetic slings presented comparable success rates in treating SUI. Both fascial and vaginal wall slings are effective in treating women with ISD. However, the use of synthetic slings resulted in significantly shorter hospital stay, decreased catheterization time, decreased use of analgesics, and decreased loss of days of work compared with fascial slings[49].

When compared to Burch colposuspension, 1 year success rate and morbidity were comparable in patients with type I/II genuine stress incontinence[50]. Long term 5-year study revealed that continence rates were lower in the Burch colposuspension than in the fascial sling; continence rate decreased during 5 years, yet most women reported satisfaction with their continence status. Satisfaction was higher in continent women and in those who underwent fascial sling surgery, despite the voiding dysfunction associated with fascial sling[51].

Harvesting fascia lata with fascial stripper is minimally invasive, and it is easy to learn and provides an excellent fascial strip with minimal morbidity[52]. The histologic changes after fascia lata sling placement involve extensive remodeling with increased fibroblasts and connective tissue on biopsy specimens[53]. Autologous fascia lata sling is associated with high patient satisfaction and treatment efficacy is comparable to that of other sling materials, as determined by questionnaire. Harvest site morbidity is low[54]. Cadaveric fascia lata allografts are associated with reasonable efficacy and safety but longer follow-up is unavailable. After 15 months of follow-up, a 92% success rate was reported, with no evidence of rapid degradation of solvent-dehydrated cadaveric tissue[55].

The incision-less sling was sought in order to improve *de novo* urge incontinence. The incision-less sling includes the use of transvaginal bone anchors to create a solid and stable point of fixation for the suspension sutures. The avoidance of the vaginal and suprapubic incisions has not compromised efficacy and appears to reduce the incidence of urge incontinence. This versatile technique may be used in all patients with urethral hypermobility and/or ISD with SUI. No long-term follow up is available for this approach yet[56].

PVS and TVT seem to be equally effective regarding primary outcome of cure of stress incontinence. Symptom scores related to incontinence surgery as well as simultaneous correction of cystocele are comparable. PVS rectus fascia sling takes more time yet it is more economic[57]. Intermediate term success rate after 3 years for TVT and PVS were 86%[58] and 92% respectively[25,59]. But the long-term cure rates of 7-year is 59% for the autologous rectus fascia sling and 55% for the TVT[60].

The porcine dermis pubovaginal slings had poorer improvement rates (73%) than TVT (92%) and rectus sheath PVS (95%) at 6 months follow up. At 1 year follow up, improvement rates were 61%, 93% and 90% for porcine dermis slings, TVT and rectus sheath PVS respectively[61]. At long-term follow-up, porcine dermis PVS is not a durable material in sling surgery. Although QOL generally improves after surgery, most SUI recurrences occurred soon after surgery[62].

Autologous and cadaveric fascia had the most demonstrable graft degradation. No encapsulation was encountered with autologous fascia or polypropylene mesh while porcine dermis was the most encapsulated. No host infiltration had occurred with the encapsulated porcine grafts and only peripheral infiltration of fibroblasts had occurred in the cadaveric grafts. The polypropylene mesh grafts had the greatest number of fibroblasts throughout the entire graft. Neovascularity was the most prevalent in mesh and was also present in the autologous fascia. Giant cells were seen in two mesh and two porcine grafts[63].

Bone-anchored slings may be a reasonable option for treatment of patients with moderate to severe and/or recurrent SUI. The transvaginal placement of bone-anchored sling is thought to be safe and effective in treating patients with SUI. The use of bone drill is for fixation of the sling to the inferior aspect of the pubic bone, which is a potential cumbersome point in the technique[63].

Using allograft fascia lata could be a reasonable alternative to PVS with comparable efficacy at two years[64].

There is no difference in the overall success, satisfaction and complication rates of cadaveric fascia lata versus intravaginal sling plasty for the pubovaginal sling. Both procedures were found to be effective, durable and significantly improved quality of life in patients with SUI but long-term results are essential[65].

Small intestinal submucosa as a natural cellular biomaterial is composed of a matrix of collagen harvested from pigs and can be used as a suprapubic sling material. The initial studies reported excellent tolerance, with prompt postoperative voiding. This new biomaterial showed no encapsulation, and progressive transformation by host cell incorporation with no rupture. Other materials such as a

cellular collagen matrix or a cellular dermis are currently being developed commercially[66,67].

Data from the US national hospital discharge survey from 1979 to 2004 demonstrated an increase in the use of the MUS and a decrease in PVS due to the simplicity and reduced morbidity of the MUS compared to previous incontinence treatment modalities, such as the PVS[68].

5. The future of PVS, autologous slings

Non autologous grafts exhibit different elasticity and tensile strength provides more decrease in operative time and avoid the morbidity of autologous fascial harvest[69].

Results of non autologous grafts for sling surgery have been comparable to autologous slings with short- to intermediate-term follow up. Brown and Govier found cure rate of 74% and cure/improvement rate of 93% at a mean follow-up of 12 months after freeze-dried cadaveric fascia lata sling. Noteworthy, this was not significantly different from the 73% cure and 100% cure/improvement after autologous slings at the same institution at a mean follow-up of 44 months[70].

Durability was an issue raised regarding cadaveric grafts. Freeze-dried, gamma-irradiated cadaveric fascia lata had a tensile strength twice more than that of freeze-dried porcine small intestine submucosa. Solvent-dehydrated fascia is found to be significantly stronger on tensiometry testing. Although it is apparent that these grafts have different properties, it remains unclear which provides the best long-term results[71].

Although most allograft sling series report success rates comparable to autologous slings, follow-up period in the allograft series has been comparably shorter. Carbone *et al* reported disappointing results in 154 patients treated with freeze-dried cadaveric fascia lata and transvaginal bone anchor fixation. A high recurrence rate (38%) within 1 year was attributed to cadaveric allograft degeneration based on findings at reoperation[30]. Upon re-operating on freeze-dried cadaveric slings, they showed a form of degeneration or autolysis, and in some cases the sling could not be identified.

Human cadaveric fascia and porcine xenografts showed a marked decrease in tensile strength and stiffness up to 60%-89%, whereas polypropylene mesh and autologous fascia did not differ in tensile strength from baseline[72].

Another concern with the use of allografts has been the risk of disease transmission. Measures used to prevent disease transmission in tissue allografts include donor screening and a multistep tissue sterilization process. Despite these measures, the presence of intact DNA material has been reported. Another potential concern is for the transmission of prion disease, such as creutzfeldt-jakob disease. Prions are protein molecules that can resist conventional means of sterilization. Although there is a theoretical risk, to date there have been no reported cases of disease transmission with the use of cadaveric allografts in continence surgery[73].

Conflict of interest statement

The authors report no conflict of interest.

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