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A prospective multicentric international study on the surgical outcomes and patients' satisfaction rates of the 'sliding' technique for end-stage Peyronie's disease with severe shortening of the penis and erectile dysfunction

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ABSTRACT

Objectives

To report the results from a prospective multicentric study of patients with Peyronie's disease (PD) treated with the 'sliding' technique (ST).

Patients and Methods

From June 2010 to January 2014, 28 consecutive patients affected by stable PD with severe penile shortening and endstage erectile dysfunction (ED) were enrolled in three European PD tertiary referral centres. The validated International Index of Erectile Function (IIEF) questionnaire, the Sexual Encounter Profile (SEP) Questions 2 and 3, and the Peyronie's disease questionnaire (PDQ) were completed preoperatively by all patients. At the follow-up visits (at 3, 6 and 12 months), the IIEF, the SEP Questions 2 and 3, the PDQ, and the Erectile Dysfunction Inventory of Treatment Satisfaction (EDITS) were completed. The outcome analysis was focused on penile length restoration, and intra- and postoperative complications classified according the Clavien– Dindo Classification.

Results

The mean (range) follow-up was 37 (9–60) months. A malleable penile prosthesis (PP) was implanted in seven patients, while an inflatable three-pieces PP was placed in the remainder. In the case of inflatable PP implantation, porcine small intestinal submucosa and acellular porcine dermal matrix were used to cover the tunical defects. While in patients undergoing malleable PP implantation, collagenfibrin sponge was used. The mean operative time was 145 min in the inflatable PP group and 115 min in the malleable PP group. There were no intraoperative complications. Postoperative complications included profuse

bleeding requiring a blood transfusion in one patient (3.5%) on anticoagulation therapy for a mechanical heart valve (Grade II) and PP infection requiring the removal of the device (7%) (Grade III). There were no late recurrences of the shaft deformation. The postoperative functional data showed a progressive improvement in the score of all questionnaires, peaking at 12 months postoperatively. The mean (range) penile lengthening was 3.2 (2.5–4) cm and no patient reported recurrence of the curvature.

Conclusions

The present series suggests that, in the hands of experienced high-volume surgeons, penile length restoration with the use of the ST represents an effective option for end-stage PD associated with ED and severe shortening of the shaft. Larger series and longer follow-up will be required to fully establish the efficacy of this procedure.

Introduction

Peyronie's disease (PD) is an acquired wound-healing disorder leading to an irregular collage deposition with the formation of fibrous inelastic scars in the tinica albuginea of the penis. It occurs in genetically susceptible patients after trauma to the penis. As the scar does not stretch with the surrounding tunica albuginea it may produce a variety of penile deformities, including shortening, narrowing and 'hinge' effect, which can significantly compromise penetrative sexual intercourse. PD is strongly linked to cardiovascular disease, with around two-thirds of patients presenting at least one of the recognised cardiovascular risk factors such as diabetes mellitus, hypertension, and dyslipidaemia [1–3]. Diffuse cardiovascular disease, as well as the change in interface between the corpus cavernosum and the tunica albuginea caused by the formation of the plaque, may explain the progressive worsening of the quality of the erection, which is a common finding in this group of patients [1–4]. Therefore, the quality of life of sexually active patients with PD and their partners is often severely affected, and this may cause depression, low self-esteem, and difficulty in the relationship with the partner [5].

Surgical correction represents a valuable option for patients with stable disease, severe and disabling penile deformity or severe erectile dysfunction (ED) impairing coital activity. The aim of surgery is to guarantee a penis straight and hard enough to allow the patient to engage in penetrative sexual intercourse [2–6]. In the presence of normal erectile function, two different approaches can be considered: plication procedures or plaque incision and grafting. Penile prosthesis (PP) implantation is instead indicated in patients with refractory ED or with a degree of ED and a complex deformity and/or short penis who otherwise would require plaque incision and grafting [2,3,5]. Although PP implantation with or without additional straightening manoeuvres guarantees a penis rigid and straight enough in almost all patients, the satisfaction rates of patients with PD tend to be the lowest among the PP implant population [5,6]. This is mainly because PP implantation allows the correction of the deformity and guarantees adequate rigidity, but does not restore the loss of length, which is reported subjectively by 80% of patients [4]. In

selected cases of end-stage PD with ED and significant penile shortening, a lengthening procedure, which involves simultaneous PP implantation and penile length restoration, such as the 'sliding' technique (ST), can be therefore considered [7–11].

Although the ST has widely adopted in recent years, only a few prospective studies focused on this peculiar approach have been published to date. The present study is a prospective multicentric study of patients treated with ST, focusing on surgical outcomes and patients' satisfaction.

Patients and Methods

From June 2010 to January 2014, 28 consecutive patients affected by stable PD with severe penile shortening and endstage ED where enrolled in three European PD tertiary referral centres. All patients had stable disease and were unable to engage in penetrative sexual intercourse due to the combination of penile curvature, severe shortening, and ED.

All patients underwent a thorough physical examination and the presence of palpable fibrotic plaques was assessed in all cases. The stretched penile length (from the pubic bone to the tip) was recorded. Echo-colour-Doppler ultrasonography after intracavernosal administration of prostaglandin E1 was performed to quantify the deformity and to assess penile vascular parameters. A severe arterial inflow deficiency was confirmed in all cases. All patients were adequately counselled about all the surgical options available to correct the penile curvature and guarantee the rigidity necessary to engage in penetrative sexual intercourse. Patients were also offered the choice to undergo the ST with the aim to restore the length lost due to PD. Patients who opted to undergo the ST were fully aware of the complexity of the procedure and of the potential increased risks associated with the procedure, when compared with PP implantation alone. As following the partial disassembly of the penis necessary to perform the ST the vascularisation of the glans relies on the two dorsal arteries of the penis and on the arterial flow of the spongiosum, patients with known spongiofibrosis secondary to previous urethral surgery were not considered suitable for the ST, to reduce the chance of developing ischaemia of the glans.

Main Outcome Measures

The validated International Index of Erectile Function (IIEF) questionnaire, the Sexual Encounter Profile (SEP) Questions 2 and 3, and the Peyronie's disease questionnaire (PDQ) were completed preoperatively by all patients [11,12]. The outcome analysis was focused on penile length restoration, intra- and postoperative complications, classified according to the Clavien–Dindo classification [13]. Postoperatively, patients were reassessed at 3, 6 and 12 months. At the follow-up visits, the IIEF, the SEP Questions 2 and 3, the PDQ and the Erectile Dysfunction Inventory of Treatment Satisfaction

(EDITS) were completed. Data analysis was performed using

IBM SPSS Statistics Software version 20 (SPSS - IBM, New York, NY, USA).

Surgical Technique

The penile shaft was adequately exposed though a combined penoscrotal and subcoronal incision with complete degloving of the shaft in all cases (Fig. 1). The dissection of Buck's fascia was initiated from two longitudinal paraurethral incisions and the neurovascular bundle (NVB) was then completely mobilised from the underlying tunica albuginea down to the insertion of the suspensory ligament, in order to guarantee maximum lengthening, as the length of the NVB represents the limiting factor in penile size restoration, as it does not stretch. The urethra was then dissected off of the corpora cavernosa and the penis partially disassembled [14]. Two longitudinal incisions of the tunica albuginea of at least 4 cm in length were then made. The edges of these two incisions were then joined by two hemi-circumferential transverse incisions. Contrarily to the initial report, the proximal transverse hemi-circumferential incision was made on the ventral side of the penis at the level of the penoscrotal junction, to allow for the insertion of the cylinders and connecting tubing of the inflatable PP, thus obviating the need to make a second proximal ventral corporotomy, while the distal incision was carried out on the dorsal side of the shaft [11]. The combination of these two incisions functionally transected the corpora completely, allowing the surgeon to gently elongate the shaft by pulling the glans penis away from the patient. This manoeuvre literally led to the sliding of the distal part of the corpora away from the proximal aspect of the shaft along the two previously performed longitudinal incisions (Fig. 2). At this stage, the maximum elongation of the NVB dictated how much the two sections of the shaft could be slid apart, as the spongiosum of the urethra could elongate significantly more than the NVB. When the maximum tension on the NVB and the urethra was obtained, the two segments of the shaft were fixed laterally along the two longitudinal tunical incisions with resorbable sutures. The sliding of the two segments of the shaft led to the formation of two rectangular tunical defects on opposite sides of the shaft penis, which were covered with a graft. In case of an inflatable PP implantation, porcine small intestinal submucosa (SIS, Surgisis, Cook medical, West Lafayette, IN, USA) and acellular porcine dermal matrix (Pelvicol; Bard Urological, Covington, GA, USA) were used to cover the tunical defects to prevent aneurysmal dilatation of the cylinder and reduce the risk of haematoma formation. While in patients undergoing malleable PP implantation collagen-fibrin sponge (TachoSil; Nycomed, Linz, Austria) was instead used to reduce the risk of haematoma formation. The cylinders of a PP were then implanted through the ventral albugineal defect; in the case of an inflatable PP, the cylinders were left semi-inflated to reduce the risk of haematoma formation and to allow the formation of a capsule around the cylinders. An adequate straightening of the shaft was documented intraoperatively in all patients (Fig. 3). In the case of an inflatable PP, the curvature was assessed with the cylinder inflated at 80% of maximum capacity, as initially suggested by Wilson et al. [15–17]. A compressive dressing was then applied to the scrotum and shaft and left in situ for 2–3 days.

Results

Baseline patient characteristics and surgical outcomes are summarised in Tables 1 and 2, respectively. The mean (range) follow-up was 37 (9–60) months. Malleable PP implantation was performed in seven

patients, while an inflatable three-pieces PP was placed in the remainder. The mean operative time was 145 min in the inflatable PP group and 115 min in the malleable PP group. An effective lengthening of the shaft was achieved in all patients. No intraoperative complications were detected. Postoperative complications included profuse bleeding requiring a blood transfusion in one patient (3.5%) on anticoagulation therapy for a mechanical heart valve (Grade II) and PP infections requiring the removal of the device in two diabetic patients (7%) (Grade III). After an initial, unsuccessful, conservative attempt with the administration of i.v. broad-spectrum antibiotics, both infected PP implants were removed at 32 and 74 days after surgery, respectively. Haematoma formation postoperatively was common, but was managed conservatively with elevation and compression in all cases. There were no late recurrences of the shaft deformation.

Functional outcomes are reported in Table 3; the two patients who needed PP removal for infection are not included. Postoperative functional data showed a progressive improvement in the score of all questionnaires, peaking at 12 months postoperatively. One patient reported permanent loss of glans sensation. The mean (range) penile lengthening was 3.2 (2.5–4) cm and no patient reported recurrence of the curvature.

Discussion

When the deformity is mild and the patient is still able to have comfortable penetrative sexual intercourse, with or without the use erectogenic drugs, a conservative approach is suggested [2,3,18,19]. While surgical treatment represents the standard of care for patients with stable disease, severe and disabling penile deformity or severe ED that compromise coital activity. Traditionally, the management of patients with PD and refractory ED consisted of the placement of a PP, with additional straightening manoeuvers to guarantee adequate rigidity and curvature correction [15–17,20–23]. Although the current guidelines suggest that the aim of surgery is to guarantee a penis straight and hard enough for penetrative sexual intercourse, the recent evidence suggests that most patients with PD are bothered by the loss of length associated with the disease and that further loss in length due to the surgical correction leads to additional bother, irrespective of the magnitude of the loss [4–6]. Furthermore, patients with PD undergoing PP implantation report the lowest satisfaction scores among the PP implant population, mainly because of the shortening and the change of shape of their penis [6]. Although adequate preoperative counselling and correct management of unrealistic patient expectations from surgery may play a role in improving postoperative satisfaction rates, from the above evidence it becomes obvious that, in order to achieve adequate patients' satisfaction rates, the aim of surgery should be not only guaranteeing adequate rigidity and straightening, but also trying to restore part of the length lost due to the tunical scarring [23].

Therefore, in selected cases of PD with ED and a significant penile loss of length, which would compromise successful penetrative intercourse, the option of undergoing a form of penile length restoration combined with PP implantation should be discussed in depth with the patient. Rigaud and Beger [24] described the first series of penile length restoration in conjunction with PP implantation in 13

patients. This technique consisted of a partial penile disassembly with complete mobilisation of the NVB and urethra from the underlying corpora cavernosa, followed by a circumferential incision of the tunica albuginea, which allowed the elongation of the corpora cavernosa. After the implantation of the cylinders of the PP, the circumferential defect of the tunica albuginea was repaired with a graft in only five patients and left open in the remainder. This procedure was associated with increased complication rates, with 15% of the patients ultimately requiring removal of the PP for infection [24]. More recent series have shown more encouraging results, in terms of complications and long-term outcome [10,25–27]. Initially described by Rolle et al. [11] in 2012, the ST represents a modification of the original penile restoration technique described by Rigaud and Beger [24]. This technique replaces a single circumferential incision with two hemi-circumferential incisions, thus allowing the sliding of the distal segment of the corpora away from the proximal aspect of the penis without producing a complete interruption of the tunica albuginea, which is re-sutured together along the two initial longitudinal incisions. This incomplete interruption of the tunica albuginea is expected to confer further stability to the implant and to reduce the risk of excessively stretching the NVB after the implantation of the PP [11]. After this initial description, other authors have implemented modifications to the ST, in order to reduce the operative times, such as not repairing the tunical defects with a graft [9]. Although reducing operating times should translate into lower chance of PP infection, grafting creates a protective barrier around the implant and reduces the risk of aneurysmal dilatation, haematoma formation, and ultimately of infection. The graft also leads to a better cosmetic result as it bridges the gaps produced by the incisions in the tunica albuginea. We do therefore strongly recommend grafting the albugineal defects rather than cutting steps of the procedure just to reduce operative times. We suggest the use of a xenograft with adequate tensile strength, such as SIS and Pelvicol, in patients undergoing inflatable PP implantation. This is because these grafts guarantee adequate support to the cylinders and reduce the risk of aneurysmal dilatation, which can occur for tunical defects of >1 cm [1,3,15–17]. In the case of implantation of a malleable PP, a graft of good tensile strength is not necessary, as the rods cannot develop aneurysmal dilatation; therefore we advise the use of TachoSil rather than a xenograft to bridge the tunical defects and minimise the risk of haematoma formation. This is because TachoSil does not require suturing to the edges of the tunica albuginea, thus significantly reducing the operative time.

The present study reports the outcome of the first multicentric prospective series of patients with PD who have undergone penile length restoration with the use of the ST in combination with PP implantation. The present series suggests that the ST is a useful tool in the management of the patient with PD, ED and severe penile shortening as it guarantees a mean increase in penile length of 3.2 cm at the cost of only a slight increase in complications. This procedure is quite complex but seems to yield satisfactory results in the hands of experienced, large-volume surgeons. Certainly patients need to be highly motivated, have realistic expectations, and be fully counselled of the potential risks and benefits of surgery. In particular, they need to be aware that, due to the extensive disassembly of the penis and the overall complexity of

the procedure, the risk of PP infection is 7%, more than seven times higher than in virgin implants, and loss of glans sensation may occur.

One of the main strengths of the present series is that patients' satisfaction rates are not assessed subjectively by the surgeon, but with the use of validated questionnaires for PD and PP, guaranteeing a more objective evaluation.

The main limitations of the present series are the relatively few patients enrolled and a median follow-up of only 37 months. Certainly larger series will be required to establish more realistically the rate of complications. Also patients will need to be followed up for longer periods to establish whether the ST is associated with a statistically significant increase in long-term mechanical failure, as the graft does not guarantee the same kind of support to the PP that the normal tunica albuginea does.

In conclusion, the present series suggests that, in the hands of experienced high-volume surgeons, penile length restoration with the use of the ST represents an effective option for endstage PD associated with ED and severe shortening of the shaft. However, larger series and longer follow-up will be required to fully establish the efficacy of this procedure.

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