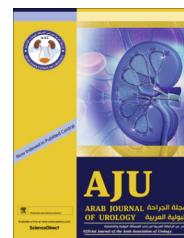




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PEDIATRIC UROLOGY
ORIGINAL ARTICLE

Tubularised incised-plate versus tubularisation of an intact and laterally augmented plate for hypospadias repair: A prospective randomised study



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ABBREVIATION

TIP, tubularised
incised-plate

Abstract Objectives: To compare the outcome of hypospadias repair using tubularised incised-plate (TIP) urethroplasty and tubularisation of an intact and laterally augmented urethral plate.

Patients and methods: This prospective randomised study included 370 patients with primary distal hypospadias. All had urethral plate widths of 8–10 mm and a glans of ≥ 15 mm. Exclusion criteria were previous repair, circumcision, a wide urethral plate of > 10 mm or a narrow plate of < 8 mm in diameter, a small glans of < 15 mm in diameter, chordee of $> 30^\circ$, and hormonal stimulation. Patients were randomised into two groups: Group 1 (185 patients) underwent TIP urethroplasty and Group 2 (185 patients) underwent tubularisation of the intact plate with lateral augmentation of the urethral plate using penile skin. The follow-up period was 12–28 months.

Results: There were 172 evaluable patients in Group 1 and 177 in Group 2. The urethroplasty was successful in 83.2% and 94.4% in Groups 1 and 2, respectively. Complications occurred in 16.8% in Group 1 and 5.6% in Group 2 ($P = 0.001$). Meatal stenosis occurred in 7% and 3.4% in Groups 1 and 2, respectively ($P = 0.130$). There were statistically significant differences in the wound dehiscence, fistula, and re-operation rates of Group 1 versus Group 2, at 6% versus 0%, 9.8%

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versus 2.8%, and 13.4% versus 5.6%, respectively. The presence of mild chordee did not affect the complication rate ($P = 0.242$). The mean (SD) operative time was 56.7 (8.9) min in Group 1 and 93.7 (8.3) min in Group 2 ($P < 0.001$).

Conclusion: The outcome of tubularised intact and laterally augmented plate is better than classical TIP urethroplasty of hypospadias. Further trials are mandatory to extend the indications of the technique.

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Introduction

Hypospadias is a common congenital anomaly of the male urethra, with a reported incidence ranging between two and three per 1000 live births [1]. Embryological defects causing hypospadias are failure of tubularisation of urethral folds and a defective epithelial–mesenchymal interaction leading to failure of the formation of the glanular urethra [1,2]. An obvious approach to repairing hypospadias is essentially directed towards tubularisation of the urethral plate. Tubularisation of an intact urethral plate was first described by Thiersch [3] and Duplay [4] in the 19th century. Since then, tubularisation of the intact urethral plate has been used for urethroplasty of primary hypospadias; King [5] used tubularisation of the intact urethral plate for hypospadias urethroplasty up to the coronal sulcus but did not reach the tip of the glans; Sadlowski et al. [6] extended tubularisation of the intact plate to the proximal part of the glans; whilst Firlit [7] described tubularisation of the intact urethral plate up to the tip of the glans. The same procedure of tubularised intact urethral plate up to the glans tip was reported by Zaontz [8] and Montfort et al. [9]. These authors reported excellent functional and cosmetic results. Kass and Chung [10] used the same technique for repair of hypospadias and reported complication rates of 1.7% for distal and 7.7% for mid-shaft hypospadias repair. However, the tubularisation of the intact plate has not been widely disseminated because it is optimally indicated when the urethral plate is deep and wide.

Tubularised incised-plate (TIP) urethroplasty is an easy and popular technique. It makes tubularisation of shallow and narrow plates feasible. However, it has considerable complication rates of 11.1–33.3%, with a mean complication rate of 21.8% [11]. Basically, the deeply grooved plate can be easily tubularised without the need for a midline incision, while narrow, shallow and/or deficient plates need augmentation by meatal-based or onlay flaps [12–15]. In 2000, Holland and Smith [13] classified urethral plates into: (1) narrow and shallow plate; (2) moderately grooved plate; and (3) deeply grooved plate; in which the urethral plate width is < 8 mm, 8–10 mm, and > 10 mm, respectively. This classification seems fairly reasonable and corresponds

with the objective anatomical features of the urethral plate. The moderately grooved plate (8–10 mm width) is an optimal indication for classical TIP urethroplasty. However, the dorsal plate incision creates a raw area and gaping wound that requires healing by secondary intension and epithelial creeping to cover it after TIP urethroplasty [12,13].

In the present study, we compared the outcome of TIP urethroplasty for moderately grooved plates in distal hypospadias with the outcome of tubularisation of the intact plate in such cases without a midline incision but with the width of the plate increased by taking 2–2.5 mm of penile skin on both sides of the borders of the plate when performing the U-shaped incision.

Patients and methods

From February 2008 to January 2014, 693 patients eligible for hypospadias repair were received. Inclusion criteria were valid for 370 children with distal hypospadias and they were included in this prospective randomised study (Fig. 1). All the included patients had distal penile, coronal or glanular hypospadias and a moderately grooved urethral plate of 8–10 mm width, according to the Holland and Smith classification [13]. None of the patients were circumcised and had had no previous hypospadias repair or any other penile surgery. Circumcised patients and those with previous trials of hypospadias repair were excluded. Patients with a urethral plate width of > 10 mm are amenable to the Duplay technique without the need for a midline incision [5–10] and thus they were not included in the study. Those with a shallow urethral plate width of < 8 mm, usually require too deep an incision, which results in higher complication rates [12,13] and thus were excluded. Patients with small glans (transverse diameter of < 15 mm) or those who received preoperative hormonal treatment were also excluded. Patients were randomised into two groups using a computer-generated system. Patients in Group 1 (185 patients) underwent TIP urethroplasty of hypospadias and those in Group 2 (185 patients) underwent tubularisation of the intact and laterally augmented plate without a midline incision. All the authors are experienced in hypospadias

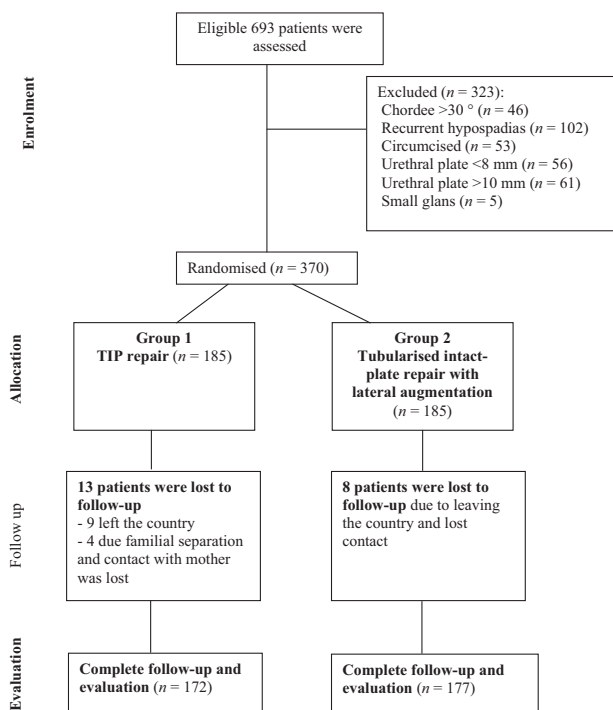


Figure 1 Consolidated Standards of Reporting Trials (CONSORT) flow diagram showing the flow of patients with anterior hypospadias through each stage of the randomised trial.

surgery and have adequate experience to complete the technical demands of the surgeries.

Operative techniques

In Group 1, a TIP urethroplasty was carried out. Two parallel vertical incisions are made at the borders of the urethral plate, and then a circumferential incision is made proximal to the hypospadiac meatus. The penile skin is degloved to the base of the penis. Intermittent tourniquet is applied at the penile base. Triangular glans wings are dissected and pulled laterally using traction sutures. Any fibrous bands around the plate are excised to correct chordee. If chordee persists after degloving and removal of ventral fibrous bands; a dorsal midline single tunical suture is made achieving full orthoplasty. The urethral plate is incised along the midline; the incision is extended distally to the glans tip (modification of Jayanthi [16]). A suitably sized silicone urethral catheter (6–8 F) is inserted. The urethral plate is closed, from proximal to distal, using subcuticular 6/0 polyglactin interrupted tensionless sutures leaving a neomeatus of adequate diameter. A well-vascularised dartos flap, derived from the prepuce, is dissected and used to cover the neourethra. The glans flaps are approximated and closed using 6/0 polyglactin transverse mattress sutures.

In Group 2, the vertical parallel incisions are made 2–2.5 mm lateral to the border of the urethral plate (Fig 2a, b). This manoeuvre adds 4–5 mm to the width

of the urethral plate, i.e. lateral augmentation of the plate. The lateral edges of the augmented plate are dissected and undermined. The whole thickness of underlying fascia including fibrovascular spongiosal bands are meticulously dissected off of the corpora cavernosa, keeping a generous fascial backing as much as possible. The wider and intact plate is tubularised without tension around a suitably sized silicone urethral catheter (6–8 F) using interrupted subcuticular 6/0 polyglactin sutures. A vascularised preputial dartos flap is dissected to cover the repair and to cover distal few millimetres of native urethra, particularly if the spongiosal tissue is deficient distally. The glans flaps are remodelled by excision of a piece of glanular tissue at the inner aspect of the glans wings to facilitate glans closure without tension using 6/0 polyglactin transverse mattress suturing (Fig. 2c, d). The patient is circumcised and the penile skin is closed using 5/0 rapidly absorbable polyglactin sutures (Fig. 2e, f).

The urethral catheters were removed after 7 days. Patients were followed-up every 2 weeks for 3 months; then every 3 months for at least 12 months. At all follow-up visits, the neourethra was calibrated and the repair inspected for the development of complications.

Statistical analysis

We hypothesised that a neourethra with an intact epithelial lining would have a better outcome and fewer complications than a neourethra with a dorsal incision and wide gap with a raw surface requiring healing by secondary intention. We assumed a type I error of 5% and type II error of 20% to achieve a study power of 80%. According to Grosos et al. [17] the fistula rate in Duplay urethroplasty of distal hypospadias was 9.1%, whilst the fistula rate in a TIP urethroplasty was 20% according to Sharma [18]. Thus the calculated sample size was 161 patients in each group. The sample size was increased by 15% to compensate for the suspected attrition rate of patients during follow-up. Consequently the sample size was estimated to be 185 patients in each group.

The outcome data of the repair were tabulated in a Microsoft Excel spreadsheet. Fisher's exact test and the chi-square test were used for analysis of categorical variables. The *t*-test was used to compare the mean of patient's age and the Mann–Whitney test was used to compare the operative time in the two studied groups.

Ethical considerations

An informed consent was obtained from the parents of children on admission and the importance of follow-up explained to them. The study was approved by the local scientific board and the ethics committee of scientific research and publication.

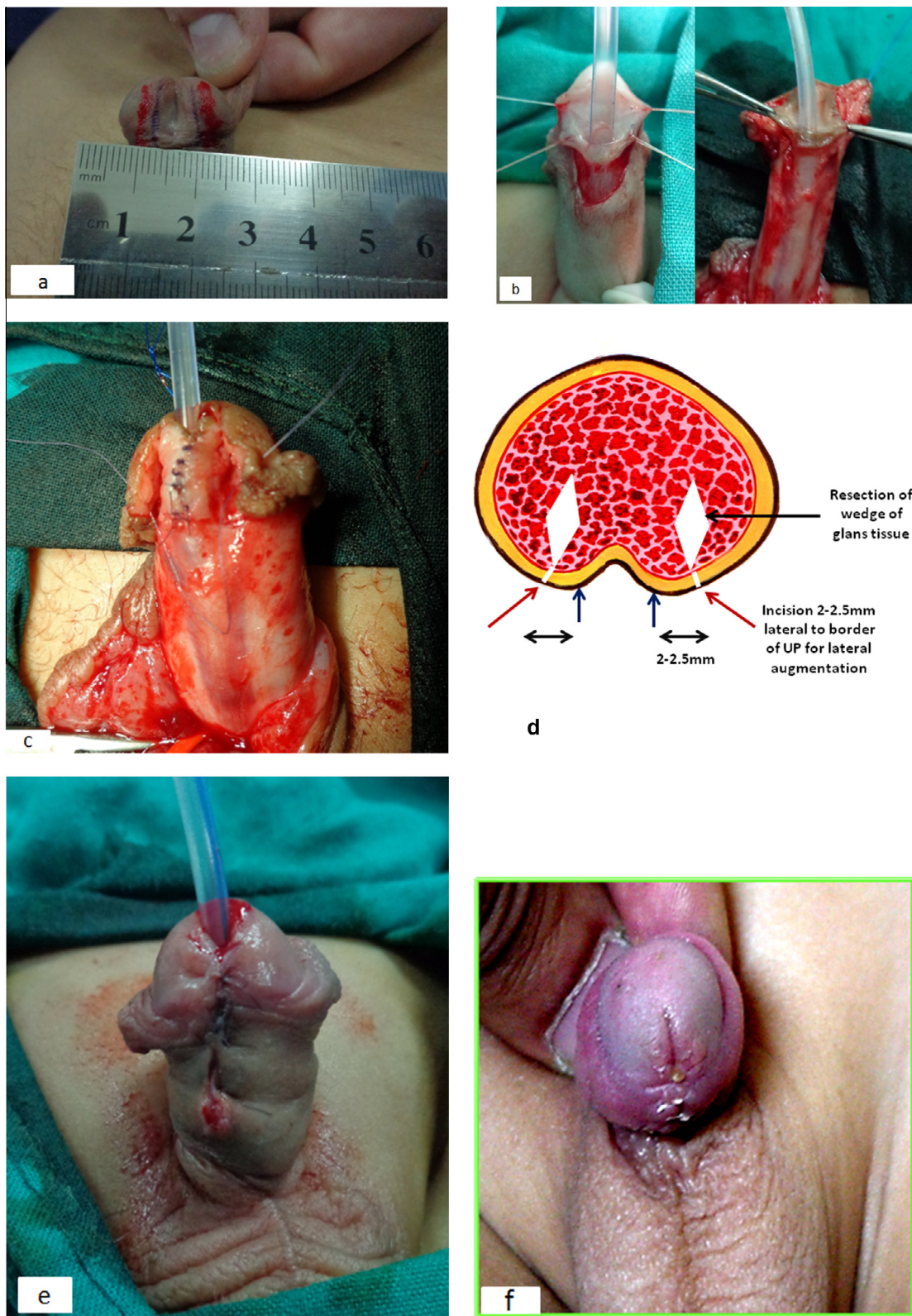


Figure 2 (a) Urethral plate 8-mm width, blue lines determine the lateral borders of the plate, red lines indicate incisions 2.5 mm lateral to the borders of the plate. (b) The augmented intact plate with an adequate width for tubularisation without a midline incision. (c) Closure of the neourethra using subcuticular interrupted sutures. (d) Diagram showing the technique and resection of glans tissue for remodelling to facilitate tensionless glans closure. (e) Circumcision is done and the penile skin is closed using 5/0 rapidly absorbable polyglactin sutures. (f) Neomeatus and normal glans shape after removal of catheter.

Results

Of the 370 patients, 21 patients (13 in Group 1 and eight in Group 2) were lost to follow-up due to various social causes. Thus, there were 172 evaluable patients in Group 1 and 177 in Group 2. The mean (SD, range) age of patients was 2.8 (1.09, 1–5) years in Group 1 and 2.5 (1.07, 1–5) years in Group 2. There was no significant difference between the groups for the location of the hypospadias orifice. The operative time was longer in Group 2 than in Group 1, at a mean (SD, range) of 93.7 (8.3, 80–120) versus 56.7 (8.9, 45–75) min ($P < 0.001$; Table 1). The overall cosmetic and functional success rate in Groups 1 and 2 was significantly different, at 83.2% and 94.4%, respectively ($P = 0.001$; Table 2). Also, the postoperative complication rate was significantly different, at 16.8% and 5.6% of patients in Groups 1 and 2, respectively ($P = 0.001$). There was no difference in meatal stenosis rates between Groups 1 and 2, at 7% and 3.4%, respectively ($P = 0.130$). There were statistically significant differences in the rates of dehiscence of the repair, urethrocutaneous fistula, and re-operation in Groups 1 and 2, at 6% versus 0%; 9.8% versus 2.8%, and 13.4% versus 5.6%, respectively, (Table 2). Six patients in Group 1 had fistula associated with meatal stenosis and were re-operated upon; another six cases of meatal stenosis responded to regular dilatation. There was no significant difference in chordee, which was detected in 21 (12.2%) patients in Group 1 and 31 (17.5%) in Group 2 ($P < 0.164$). The presence of chordee had no significant effect on the complication rate ($P = 0.242$; Table 2).

Discussion

The present study provides evidence of the superiority of construction of a neourethra that is entirely lined with an intact epithelium [3–10]. Although, the Snodgrass TIP urethroplasty has gained wide popularity, being easy to perform and not time consuming; this technique has significant complication rates. In a meta-analysis, complications have been reported in up to 33.3% of cases [11]. The pathological background to complications of TIP urethroplasty includes creation of a raw area at the dorsal aspect of the neourethra. It heals by secondary intension, necessitating deposition of a thin layer of granulation tissue and creeping of epithelium to cover it with a susceptibility to a degree of fibrosis and stiffness of the neourethra [11–16,19–22]. Moreover, the two raw surfaces of the dorsal midline incision of the urethral plate usually have a natural tendency to contract and shrink – not scar contracture – to re-approximate to each other minimising the raw area needs epithelial creeping and covering [19–22]. Thus, the width of the dorsal incision of the urethral plate decreases after complete healing, which can result in neourethral and/or meatal stenosis [20,23,24]. Thus, the healing of the TIP neourethra is unpredictable; it seems that this process may exert tension on the ventral suture line affecting its primary healing (Fig. 3) [20–25].

In the present study, although there was no statistically significant difference in the rate of meatal stenosis, it was twofold higher in Group 1 than in Group 2 (7% versus 3.4%). Wang and Zhong [24] have published a systematic review and meta-analysis comparing TIP

Table 1 Characteristics of patients in studied groups.

Characteristic	Group 1 (172 patients)	Group 2 (177 patients)	Test	<i>P</i>
Mean age (SD, range), years	2.8 (1.09, 1–5)	2.5 (1.07, 1–5)	<i>t</i> -test	0.886
Mean operative time (SD, range), min	56.7 (8.9, 45–75)	93.7 (8.3, 80–120)	Mann–Whitney	<0.001*
Glanular hypospadias, <i>n</i> (%)	27 (15.7)	21 (11.9)	Chi-square	0.377
Coronal hypospadias, <i>n</i> (%)	85 (49.4)	76 (42.9)	Chi-square	0.268
Subcoronal hypospadias, <i>n</i> (%)	60 (34.9)	80 (45.2)	Chi-square	0.063
Chordee, <i>n</i> (%)	21 (12.2)	31 (17.5)	Chi-square	0.063

* $P < 0.05$ is statistically significant.

Table 2 Comparison of complications in Group 1 and Group 2.

Complications	Group 1 (172patients) <i>N</i> (%)	Group 2 (177patients) <i>N</i> (%)	Test	<i>P</i>
Fistula	17 (9.8)	5 (2.8%)	Chi-square	0.013*
Dehiscence	6 (3.4)	0	Fisher's exact	0.012*
Meatal stenosis	12 (7.0)***	6 (3.4)**	Chi-square	0.130
Overall complications	29 (16.8)	10 (5.6)	Fisher's exact	0.001*
Re-operation rate	23 (13.4)	10 (5.6)	Fisher's exact	0.017*
Correlation of chordee to complication rate			Fisher's exact	0.242

* $P < 0.05$.

** One patient had a fistula associated with meatal stenosis.

*** Six patients had a fistula associated with meatal stenosis.



Figure 3 Diagram showing natural tissue contraction of dorsal raw area of TIP technique minimising the gap (black arrows), and direction of tension on the ventral suture line (blue arrows).

urethroplasty and a perimeatal-based flap technique in which the total lumen of the neourethra is lined with an intact epithelium similar to our present technique except for two lateral suture lines instead of a single midline suture line in the tubularised intact plate; they reported a meatal stenosis rate of 7.69% for TIP urethroplasty versus 2.88% for the perimeatal-based flap. Thus, regarding meatal stenosis the findings of our present study are consistent with the outcome of their meta-analysis [24].

In the present study, a fistula was found in 17 patients in Group 1 (9.8%), which is consistent with reported fistula rates after TIP urethroplasty with an overall average of 20% of patients [11–13,24]. A fistula was found in five patients in Group 2 (2.8%); the difference in the fistula rate in Group 1 and Group 2 was statistically significant, indicating better results using the tubularisation of laterally augmented plate ($P = 0.013$; Table 2). The reduced fistula rate in Group 2 may be explained by the meticulous dissection of an adequate width of the laterally augmented plate, preserving the underlying fascia, and the tensionless suturing of the neourethra, which is entirely lined with an intact epithelial layer. These surgical manoeuvres provide ideal conditions for optimal healing and minimal chance of fistula formation.

Wound dehiscence was detected in six (3.4%) patients in the TIP urethroplasty group. Wound breakdown has been reported in up to 8.6% after TIP urethroplasty [15]. The reported overall rate of wound dehiscence after TIP urethroplasty is 2.56% [11,28]. In the present study, there was no wound dehiscence in Group 2 ($P = 0.012$;

Table 2), probably due to the tensionless suturing of the neourethra and glans flaps, which were remodelled to be easily re-approximated in the midline.

Glans remodelling is not a new manoeuvre in hypospadias surgery; it decreases glans dehiscence and does not compromise the glans vasculature. It is carried out by resection of some of its tissue from the inner aspect of the glans flaps facilitating a tensionless closure. It should be made carefully to preserve the cosmesis of the glans [26].

The operative time was significantly longer in Group 2 than in Group 1, at a mean (SD) of 93.7 (8.3) versus 56.7 (8.9) min ($P = 0.001$). The technique using the intact and laterally augmented plate required more time due to the meticulous dissection and undermining of the lateral edges of the augmented urethral plate and preservation of a full thickness of underlying fascia and fibrovascular bands of spongiosal tissue. Fascial attachment to the plate provides an optimal blood supply to the neourethra promoting healing. These additional technical manoeuvres, including glans remodelling, probably explain the longer operative time in Group 2.

The overall complication rate was 16.8% (29/172) in Group 1 and 5.6% (10/177) in Group 2, revealing a better outcome of the tubularised intact and laterally augmented plate method ($P = 0.001$). Thus, the re-operation rate was significantly lower in Group 2 (5.6%) than in Group 1 (13.4%) ($P = 0.016$). These findings confirm the superiority of tubularisation of an intact and augmented plate for hypospadias repair.

In an attempt to modify healing of the neourethra in the TIP urethroplasty creating a neourethra entirely lined with epithelium; grafting of the dorsal incised area using the inner prepuce has been described by many authors to increase the surface area of healthy epithelium, increase the diameter of the epithelialized plate, and not to leave the neourethra with large raw area liable to scarring [27–29]. However, inlay free grafting of the incised plate requires a relatively prolonged healing process until imbibition, inosculation and revascularisation of the graft have been established and the neourethra has healed. This process is not only time consuming but also liable to healing problems, such as deposition of thick granulation tissue, graft detachment due to catheter friction, infection, and contracture. Loss of elasticity and compliance of the neourethra after TIP urethroplasty of primary hypospadias is unquestionable [21,22,30]. In a controlled experimental study, it has been shown that dorsal inlay grafting of the incised plate does not improve elasticity and compliance of the neourethra [30]. The tubularisation of an intact and laterally augmented plate technique avoids several healing problems of the dorsal midline incision and a wide raw area, provide a neourethra completely lined with healthy and innate epithelium with an optimal calibre, and a single suture line. Moreover, our present technique is not likely to induce granulation tis-

sue with subsequent fibrous, stiffness, and stenosis of the neomeatus and/or neourethra.

To our knowledge this is the first prospective randomised study comparing the outcome of TIP versus intact and laterally augmented plate in hypospadias repair in children with a moderately grooved plate (8–10 mm). There are few studies implementing the Duplay technique for hypospadias repair; however, these studies did not indicate the anatomical characteristics of urethral plate [17] or select a wide plate >10–12 mm in width for application of the Duplay technique [31].

There are limitations to the present study. The technique was used in highly selected patients with plate widths of 8–10 mm, thus excluding many. The technique may be demanding and require more experience to master it. It is more time consuming than classical TIP urethroplasty; however, we think that the improved outcome of the technique justifies this. The follow-up period is relatively short (12–28 months) and long-term follow-up for several years, until the patients become adolescents is essential for appropriate functional evaluation of the neourethra, which may have a reduced growth rate in relation to normal penile tissue. Late complications may not appear until after a year [32].

Thus, we recommend this technique for repair of hypospadias with a moderately grooved urethral plate. Further trials to extend indications of the technique minimising exclusion criteria such as circumcision, a plate width of <8 mm, and selected cases of re-do hypospadias repair should be addressed.

Conclusion

The outcome of our present technique is superior to the classical TIP urethroplasty. It respects the rules for optimal urethral reconstructive surgery, in that it minimises the length of suture lines providing rapid healing by primary intension and avoids creation of a raw area in the neourethra requiring healing by secondary intension, which may be problematic and unpredictable. Laterally augmented intact-plate tubularisation requires skill, meticulous dissection, and more operative time. However, its outcome is promising and should be applied whenever possible. More trials are required to expand its indications for repair of different varieties of hypospadias.

Source of funding

None.

Conflicts of interest

All authors disclose no financial and personal relationships with other people or organisations that could inappropriately influence this study.

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