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ARTICLE

Extended TIP vs. Standard TIP for primary distal hypospadias repair: randomized study for comparing functional and cosmetic outcomes

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ABSTRACT

Objectives: The aim of this study was to critically evaluate distal extension of the midline urethral plate incision, extended tubularized incised plate (e-TIP) technique, with the standard TIP and investigating predictors of functional and cosmetic success.

Methods: In a prospective study, consecutive patients with primary distal hypospadias presented for repair were randomized to undergo either extended TIP (e-TIP) or standard TIP (s-TIP) technique. Cosmetic outcome was evaluated postoperatively using Hypospadias-Objective-Penile-Evaluation (HOPE) score and measurement of ventral-glans-closure-length (VGCL) and meatal length (ML). Functional outcome was evaluated by maximal flow rate (Qmax), average flow rate (Qave), and postvoid residual urine (PVR). The effect of preoperative parameters on the outcome was assessed with regression analysis.

Results: In all 94 cases, out of 110 randomized, were available for analysis. Forty-six in e-TIP group and 48 cases in s-TIP group with comparable preoperative demographics. Median (inter-quartile range) of postoperative total HOPE-score was 57(45–60) vs. 55(44–60) for e-TIP and s-TIP ($p < 0.001$), respectively. The mean (SD) ratio of VGCL/ML was 87% (26) versus 46% (12) for e-TIP vs. s-TIP, respectively ($p < 0.001$). Both complications and functional outcomes were comparable. Urethral plate (UP) width and the use of e-TIP technique were significant predictors of successful cosmetic outcome in regression analysis ($p = 0.019$ and $p = 0.001$), respectively.

Conclusion: Extension of midline urethral plate can potentially create a vertical slit-like meatus located at the glans tip without compromising the functional outcome, thus providing better cosmetic outcome compared with the standard technique. The UP width was a significant predictor of superior cosmetic outcome.

Abbreviations: e-TIP: Extended tubularized incised plate; HOPE: Hypospadias objective penile evaluation; UCF: Urethro-cutaneous fistula; ML: Meatal length; PVR: Post void residual urine; Qave: Average flow rate (ml/s); Qmax: Maximum flow rate (ml/s); s-TIP: Standard tubularized incised plate; TGD: Transverse glans diameter; UP: Urethral plate; VGCL: Ventral glans closure length

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KEYWORDS
Hypospadias; tubularized incised plate; technique; evaluation

Introduction

Hypospadias is the second most common anomaly in boys after undescended testes [1]. Despite the description of >300 surgical techniques for repairing hypospadias, there is no consensus on an optimal technique [2]. In early nineties, Snodgrass introduced the tubularized incised plate (TIP) and since that time it became the preferred choice by most surgeons. In the standard TIP (s-TIP), by Snodgrass, the urethral plate (UP) incision should not extend to the apical part of the glans for fear of meatal stenosis. Therefore, the meatus would not reach the glans tip [3,4]. To improve the cosmetic outcome and bring the meatus at the tip of the penis emulating the normal position, a distal extension of the urethral plate midline incision was described with promising early results regarding the cosmetic and functional outcomes [5]. In 2013, van der Toorn and co-workers from the Netherlands, Belgium and the United states introduced and validated The HOPE Score (Hypospadias Objective Penile Evaluation) by an article published in the Journal of Pediatric Urology. This score is used for objective assessment of the cosmetic outcome after hypospadias surgery based on reference pictures for six correctable items [6]. The aim of the present study was to objectively compare cosmetic and functional outcomes between the extended tubularized incised plate (e-TIP) and standard TIP (s-TIP) techniques and assess the impact of preoperative penile biometrics on these outcomes.

Patients and methods

Study design and patients population

Patients with primary distal hypospadias presented at our tertiary care hospital between June 2015 and January 2019 were included in this prospective study after obtaining appropriate informed parental consents to participate and

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according to Benha Faculty of Medicine, Research Ethics Committee (REC: IDIRB2017122601). Patients with mega meatus intact prepuce, circumcised, proximal hypospadias, narrow fibrotic plate, patients previously exposed to hormonal stimulation, cases with micropenis, and those who had previous urethral operations were excluded. Using simple computer-generated randomization scheme at the website (http://www.randomization.com/), patients were allocated into two groups either e-TIP or s-TIP.

Description of surgical technique

In brief, first measurements of the UP width and length, and maximal transverse glans diameter (TGD_{max}) were taken (Figure 1(a,b)). Adopting the previously described e-TIP technique [4,5], starting from within the hypospadiac meatus and extended up to the apical part of the glans tip, the UP vertical midline incision was made and tubularization initiated from the distal end ensuring adequate diameter of the future neomeatus using a 7/0 polyglactin suture (Figure 1(c–e)). The neourethra was then covered with a second layer of dartos flap. A 6 F or 8 F urethral stent was left for 5–7 days, with a non-compressive dressing for 48 h. Unless necessary, all patients were discharged the next morning of surgery. A third-generation cephalosporin was given to all patients until the urethral stent was removed. After this, patients were examined at 1 month, 3 months and six months. All cases were performed by four consultants 'Y.N, T.Gh, T.E, A.A' with experience in hypospadias repair.

Outcome evaluation

The primary endpoint was technical success, including a straight penis without residual chordae, with cosmetically accepted slit-like meatus and single urinary stream of adequate force and calibre with no fistula or complications or need for redo surgery.

Cosmetic evaluation: done by an independent urological surgeon (KE) using HOPE Score at the six-month visit after surgery [6]. Basically, it is a picture-based scoring system assesses six surgically correctable items during hypospadias surgery which should reflect on the cosmetic appearance of the penis following hypospadias repair (position of meatus, shape of meatus, shape of glans, shape of penile skin, penile axis including penile torsion and penile curvature) [6]. Scoring ranges from scale of 1 (minimum) to 10 (maximum) for each parameter using standardized reference pictures for each of the six items [6]. This should give a minimum total score of 6, up to a maximum total score of 60. The HOPE score was validated for children and adolescents as the authors provided the validity and the

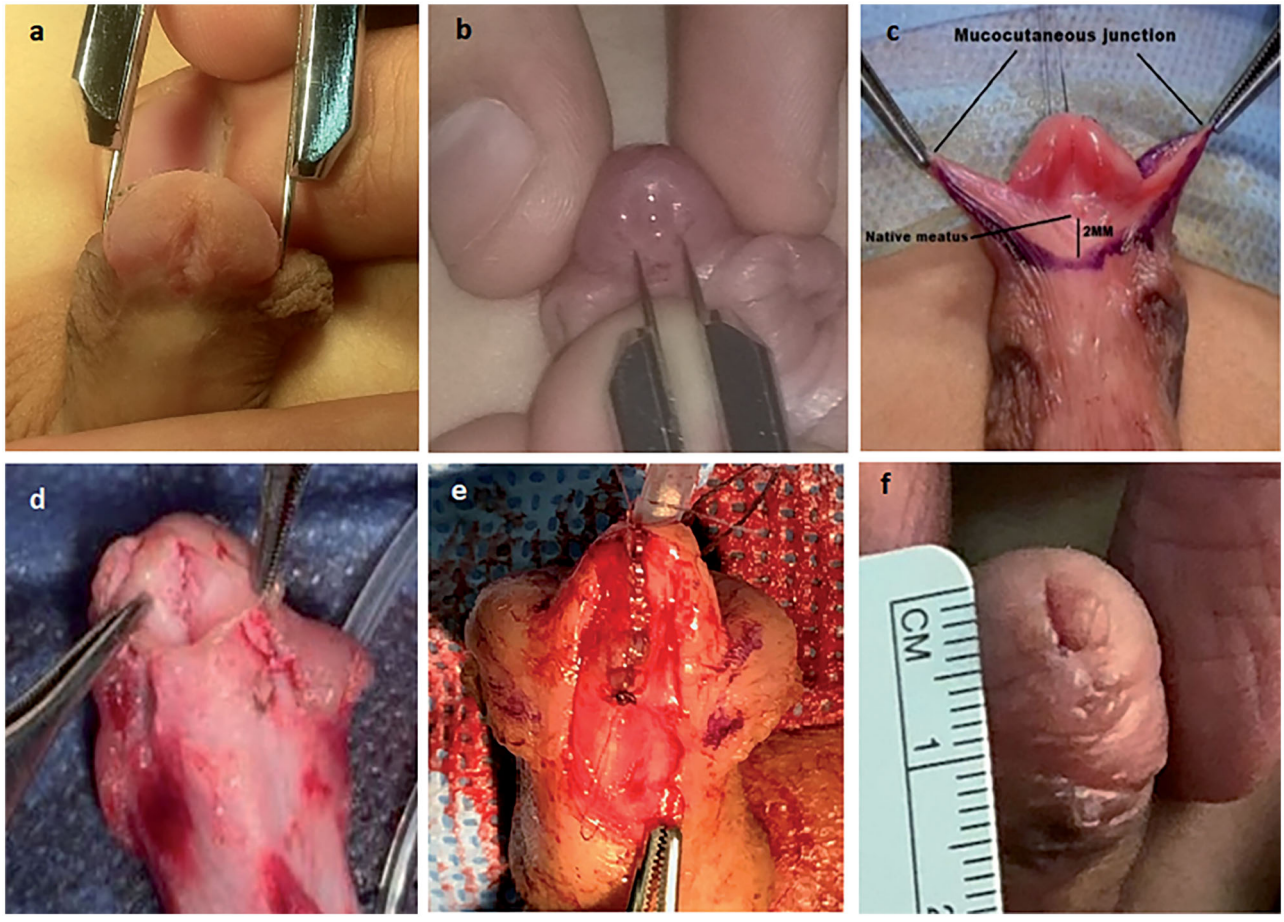


Figure 1. (a) Measuring TGD. (b) Measuring width of UP. (c) Marking of ventral incision. (d) Deep extended midline incision. (e) Tubularization of the neourethra with7/0 polygalactin suture. (f) Measuring ventral glans closure and meatal length.

Table 1. Preoperative patients' characteristics stratified by groups, data presented as median and inter-quartile range (IQR).

Variable	e-TIP (46)	s-TIP (48)	*P* value
Age at operation (months)	11 (7–32)	13 (6–32)	0.924*
Follow-up (months)	11 (6–27)	12 (6–48)	0.233*
TGD (mm)	14 (11–15)	14 (11–15)	0.652*
UP width (mm)	7 (4–9)	7 (4–9)	0.169*
Meatus Location, *n* (%)			
Coronal	13 (28.3)	13 (27.1)	0.992**
Sub-coronal	16 (34.8)	17 (35.4)	
Distal penile	17 (37)	18 (37.5)	

*Mann-Whitney U. ** Chi square test.
TGD: transverse glanular diameter; UP: urethral plate.

reliability based on 70 high-quality reference pictures taken from 352 patients preoperatively and at 6 months, 5 years, 10 years and 15 years postoperatively [6]. HOPE score reporting was given according to Table 1 and Figure 2 in the original article by van der Toorn and colleagues. However, the authors mentioned that HOPE-score = mean number of points question 1-5. In the current study, we found it easier to report the total score out of (6–60). Additionally, the proportional relationship between meatal length (ML) and ventral glans closure length (VGCL) was assessed (Figure 1(f)), where normally VGCL and ML are equal or the VGCL is slightly less than meatal length [7].

Functional evaluation

Secondary endpoints were uroflow (using Laborie Dorado™ KT urodynamic device) and ultrasound measured residual urine (PVR), at last clinic visit at the 6-month visit in uncomplicated toilet-trained boys. Shape of voiding curve, the maximum (Qmax) and average flow rate (Qave) at a voided volume of >50 mL, and voiding time were assessed. Qmax and Qave was then plotted against voided volume on age matched nomogram [8]. Complications were categorized according to modified Clavien classification [9].

Statistical analysis

The required sample size was computed by G*Power program version 3.1 using a priori analysis with medium effect size convention of 0.3 for t-test. A total sample size of 82 cases was estimated for 80% power, α error probability of 0.05, and 20% dropout rate. To perform the study, 110 patients were statistically adequate. Statistical analysis was performed with SPSS, Version 22.0. (Released 2013, IBM, Armonk, NY: IBM Corp, USA). Normality of data were tested using Kolmogorov-Smirnov and Shapiro-Wilk test. Categorical data were summarized as numbers and percentages. Comparisons between the e-TIP and s-TIP were done using independent *t*-test or Mann–Whitney U-test, whenever appropriate. Categorical data were compared using Chi-square test or Fisher's exact test, as appropriate. Multivariate linear regression analysis was done for the prediction of total HOPE score at 6 months. Regression coefficient with 95% CI was calculated for predictors. All *p*-values were two sided and were considered significant if less than 0.05.

Results

From a total of 110 randomized patients, 16 patients (14.5%) dropped out from the study, seven of 55 (12.7%) from e-TIP group and six of 55 (11%) from s-TIP group and were lost to follow-up. Participants flow diagram is shown in Figure 2. In all, 94 patients were available for analysis: 46 in group 1 (e-TIP) and 48 patients in group 2 (s-TIP) with a median (IQR) age at operation of 11 (7–32) and 13 (6–32) months for both groups, respectively. The median (IQR) follow-up was 11 (6–27) months for the e-TIP group and 12 (6-48) months for the s-TIP cases. Other demographic and baseline criteria are presented in Table 1.

Cosmetic outcome

Acceptable cosmetic outcome was obtained in both groups. Details of HOPE score are depicted in Table 2, where there was significant difference in the total HOPE score in favour of e-TIP, mainly in the items of meatal position and shape. Regarding the postoperative outcome (Table 3), The VGCL to ML ratio was significantly larger in e-TIP group, mean (SD) was 87% (26) in e-TIP group versus 46% (12) in s-TIP group. Accordingly, the HOPE score regarding meatal position and shape were significantly higher in e-TIP group.

Prevalence of complications following both techniques was statistically insignificant, yet, after e-TIP, there were 3 cases of meatal stenosis (MS). There were seven complications in five cases in the e-TIP (Table 3). Second surgical intervention was needed in four cases that were managed after 6 months postoperatively, while one case of MS (Clavien grade 3a) was treated with dilatation under local anaesthesia (Table 3). Complicated cases had significantly smaller TGD, mean ± SE (range) of 12.6 ± 0.4 (11–14) mm vs. 14 ± 0.1 (11–15) for uncomplicated cases (*p*-value <0.001). Similarly, width of urethral plate was 5.4 ± 0.5(4–8) mm versus 7.1 ± 0.1 (5–9) mm, respectively ($p < 0.001$). Age at operation was insignificant factor in occurrence of complications.

Functional outcome using uroflow study was available for 28 uncomplicated toilet-trained boys (29.8%), mean (SE) of age was 43.1 (1.5) months and range from 30 to 60 months at a follow-up period of 23.4 (1.4) months and range from 11 to 48 months. Twelve cases (26%) in e-TIP group and 16 cases (33.3%) in s-TIP group. Functional outcomes were comparable between the two groups, detailed data regarding Qmax, Qave, flow time, voided volume, and PVR are depicted in Table 3 and (Figure 3(a,b)). Preoperative parameters that thought to impact the total HOPE score (TGD, width of UP, and employment of the e-TIP technique) were entered in linear regression analysis for prediction of total HOPE score. The e-TIP was a significant predictor for higher HOPE score ($p = 0.001$) (Table 4). Additionally, the preoperative width of UP was another significant predictor of high score ($p = 0.019$) (Table 4).

Discussion

Hypospadias repair is a challenging reconstructive procedure with different techniques being currently employed aiming

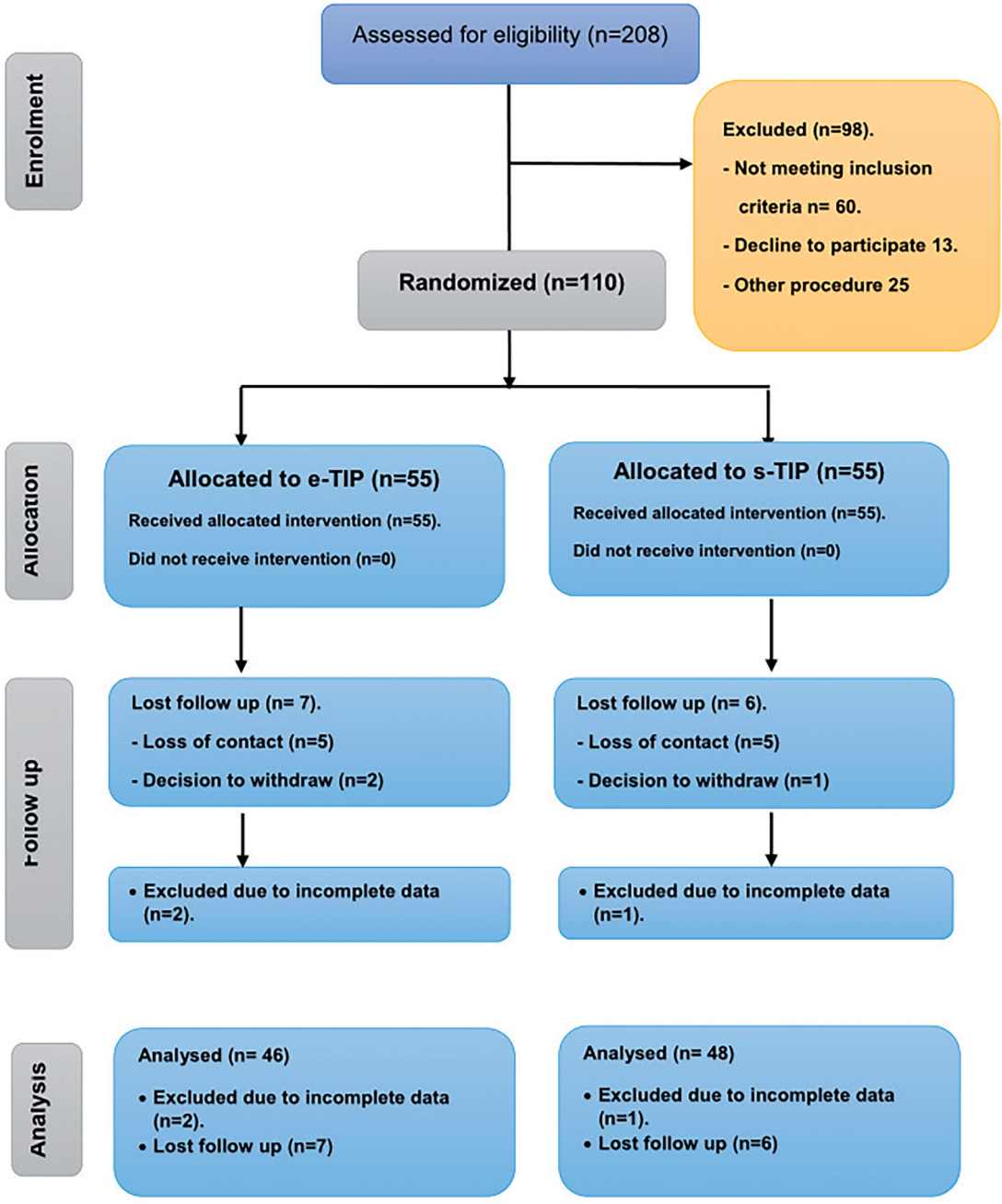
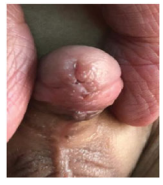
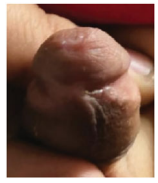
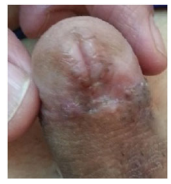


Figure 2. Participants flow diagram.

to create a functionally and cosmetically looking normal penis. Re-evaluation of the already settled techniques with objective assessment of outcomes have a major impact on the evolution of new strategies for creation of a penis that looks normal. The present study showed that extension of midline urethral plate can potentially create cosmetically better vertical slit-like meatus located at the glans tip without compromising the functional outcome.

The e-TIP was first described by Jayanthi [4] in 2003 and applied for 110 boys (5–60 months) with primary hypospadias and a follow-up reached 3.5 years with no complications except a fistula in one patient. Ten years later, other authors adopted the concept of extending the UP-midline incision to the very tip of the glans and incorporate the glans cushions in urethroplasty that were deeply dissected from glans wings with deep midline incision [5]. In that study, the technique was performed on 43 patients with primary distal hypospadias cases and the cosmetic outcome was assessed by the hypospadias objective scoring evaluation (HOSE) and the functional outcome by assessment of Q-max and PVR. The study found that the new modification ensured the fashioning of a vertical slit-like neomeatus located at the tip of the glans, competing with the normal anatomy [5]. In contrast, Snodgrass and colleagues emphasized that the relaxing should be limited to the UP as it may create a 'shelf' [10]. In another study by Snodgrass team, they proposed that suturing the plate too far distally may induce meatal stenosis, while the neomeatus should have a wide oval

Table 2. Hypospadias Objective Penile Evaluation (HOPE Score) in studied groups.

	e-TIP group $n = 46$	s-TIP group ($n = 48$)	p Value
Meatus			
Meatus			
Position of meatus			
Position 1, *n* (%)	38 (82.6)	11 (22.9)	<0.001*
Position 2, *n* (%)	8 (17.4)	37 (77.1)	
Position of meatus Score			
Mean (SD)	9.4 (1.3)	8.3 (1.1)	<0.001**
Shape of Meatus			
Normal, *n* (%)	38 (82.6)	25 (52.1)	0.002*
Slightly abnormal, *n* (%)	8 (17.4)	23 (47.9)	
Shape of Meatus Score			
Mean (SD)	9.5 (1.2)	8.5 (1.6)	0.001**
Glans penis			
Glans penis			
Shape of Glans			
Normal, *n* (%)	33 (71.7)	31 (64.6)	0.511*
Slightly abnormal, *n* (%)	13 (28.3)	17 (35.4)	
Shape of Glans Score			
Mean (SD)	9.2 (1.3)	8.9 (1.4)	0.287**
Shape of Skin			
Shape of Skin			
Shape of Skin			
Normal, *n* (%)	26 (56.5)	23 (47.9)	0.418*
Slightly abnormal, *n* (%)	20 (43.5)	25 (52.1)	
Shape of Skin Score			
Mean (SD)	8.7 (1.5)	8.4 (1.5)	0.368**
Torsion			
Torsion			
Mild torsion, *n* (%)	0 (0.0)	0 (0)	–
No, *n* (%)	46 (100)	48 (100)	
Torsion Score			
Mean (SD)	10 (0)	10 (0)	–
Curvature			
Curvature			
No, *n* (%)	46 (100.0)	48 (100.0)	
Curvature Score			
Mean (SD)	10 (0)	10 (0)	–
Total score			
Mean (SD)	56.9 (3.6)	54.2 (3.4)	
Median (IQR)	57 (45–60)	55 (44–60)	<0.001**

*Fisher's exact test. **Mann–Whitney U-test.

Table 3. Postoperative cosmetic and functional outcomes in both studied groups.

Variable	e-TIP $N = 46$	s-TIP $N = 48$	p Value
Cosmetic outcome			
Vertical meatal length (mm)	5 (3–6)	6 (4–6)	<0.001*
Ventral glans closure (mm)	4 (3–6)	3 (1–4)	<0.001*
VGC/ML%, median (IQR)	80% (50-150)	50% (20–80)	<0.001*
HOPE total score (out of 6-60)	57 (45–60)	55 (44–60)	<0.001*
Functional outcome			
Uroflow n (%)	12 (26)	16 (33.3)	
Qmax (mL/s)	14.1 ± 3.7	13.9±3.2	0.780*
Qave (mL/s)	8±2.1	8.1±2	0.908*
Flow time (s)	22.4±7.7	17.6±7.7	0.05*
Voided volume	159.3±47.5	132.5±50.3	0.104*
PVR	9.0±9.6	5.9±7.7	0396*
Qmax nomogram			
Normal (>25th percentile)	7 (58.3)	8 (50)	
Equivocal flow (25th–50th)	3 (25)	6 (37.5)	0.777***
Obstructed (<5th percentile)	2 (16.7)	2 (12.5)	
Flow curve pattern			
Bell	7 (58.3)	9 (56.3)	
Intermittent	1 (8.3)	2 (12.5)	0.975***
Slightly flat	2 (16.7)	3 (18.8)	
Plateau	2 (16.7)	2 (12.5)	
Post-operative complications			
Complications, *n* (%)	5 (10.9)	4 (8.3)	0.737**
UCF, *n* (%)	4 (8.7)	3 (6.7)	0.711**
GD, *n* (%)	0	1 (2.1)	0.99**
MS, *n* (%)	3 (6.5)	0	0.113**
Clavien grade			
None	41 (89.1)	44 (91.7)	
Grade 3a	1 (2.2)	0	0.587***
Grade 3b	4 (8.7)	4 (8.3)	
Second intervention, n (%)	4 (8.7)	4 (8.3)	0.99**

*Mann–Whitney U-test. ** Fisher's exact test. ***Chi square test. Values are shown in median (IQR), Mean ± SD (range) or *n* (%).
VGC: Ventral glans closure. ML: Meatal length. UCF: Urethrocutaneous fistula. GD; Glans dehiscence; MS: Meatal stenosis; Qmax: Maximum flow rate; Qave: Average flow rate; PVR: Post void residual volume.

Table 4. Linear regression analysis for prediction of total HOPE score.

Variable	Unstandardized Coefficients B	95% Confidence Interval	p Value
TGD	0.62	–0.14–1.37	0.108
Width of UP	0.72	0.12–1.32	0.019
e-TIP technique	2.48	1.11–3.85	0.001

Dependent Variable: HOPE score.
TGD: transverse glans diameter; UP: urethral plate; TIP: tubularized incised plate.

configuration by allocating the most distal stitch at the mid-glans level to avoid meatal stenosis [11].

The width of UP is a paramount factor of TIP technique, Holland and Smith found that complications were more prevalent when UP width <8mm. The authors evaluated 48 patients who underwent distal repair, they found 13% stenosis and 55% fistulae when the UP was flat and narrow and that was not the situation when the plate was moderately or deeply grooved. The authors concluded that the midline relaxing incision enabled tubularization but did not lead to adequate neourethral calibre when the plate was narrow or flat in order to avoid fistulas or meatal stenosis [12]. Likewise, another study reported that UP characteristics were significant predictors of success [5]. In contrary, Nguyen and Snodgrass proclaimed that TIP urethroplasty was applicable regardless of initial UP configuration or width when paying attention to technical details leading to achievement of good cosmetic and functional outcomes with few complications [10].

In the present study, the validated and reliable photograph-based HOPE score [6] was significantly higher in e-TIP group compared to s-TIP group ($p < 0.001$). This significant difference was attributed to the shape and position of the neomeatus, which was the objective of the modified technique. In e-TIP, normal vertical slit-like meatus at position 1 (distal glans) was achieved in 38/46 (82.6%), while in eight patients the meatus was at position 2 (proximal glandular) due to the need to start tubularization slightly lower down in a conical glans. Regarding glans shape, slightly abnormal glans is suggested to be due to excessive glandular wing dissection which happened during glanuloplasty aiming to avoid postoperative glandular dehiscence. In s-TIP technique, normal-like meatus was achieved in 25/48 patients (52.1%); only 11 patients (22.9%) had meatus at position 1 while the rest of the patients had meatus at position 2.

In normal children, external urethral meatus anatomy was investigated by Hutton and Babu [7], they examined the proportional relationship between the VGCL and ML in normal

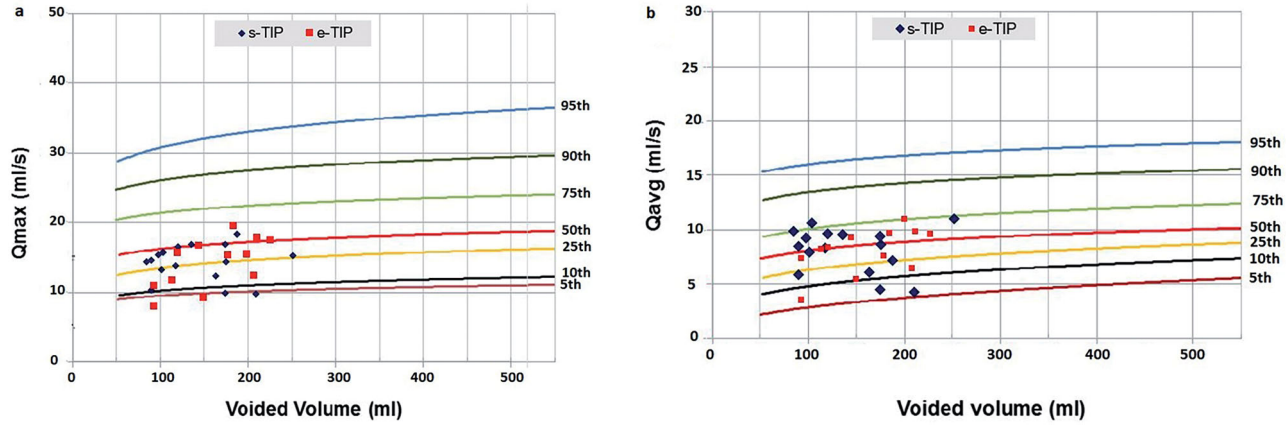


Figure 3. (a) Qmax values plotted against voided volume. (b) Qave values plotted against voided volume.

children. The authors found that vertical meatal length was 5.4 (1) mm, ventral glans closure was 4.7 (1.2) mm, and ventral glans closure was 88% of the vertical meatal length [7]. In the present study, the mean VGCL to ML was 87% for the e-TIP group while it was 46% for the s-TIP group with statistically significant difference ($p < 0.001$). This means that VGCL/ML in the e-TIP group was almost close to normal boys compared with the s-TIP.

Functional outcome following TIP repair using uroflowmetry had been investigated in many studies signifying the importance of long-term follow-up of those boys and the obtained results were quite controversial. While some studies claimed that majority of patients exhibited normal flow pattern [13–16], others reported an obstructed flow in a significant proportion of cases [17,18]. In a systematic review addressing the importance of uroflowmetry studies after TIP repair, 11 studies reported obstructive flow in 24.6% of patients (93/378) [19]. In the current study, 28 patients were eligible for uroflowmetry, 12 in e-TIP and 16 in s-TIP group. Using a nomogram for age-matched children [8], the Qmax was plotted against the voided volume and four out of 28 cases (14.3%) had obstructed flow with a Qmax $< 5^{th}$ percentile on the nomogram (two in each group), and this was below than previously reported in the literature [19]. Qmax values in most cases were between 25th and 50th percentile of the nomogram, while Qave values were above the 5th percentile (Figure 3(a,b)).

The obtained functional results in the current study are comparable with the findings of a previously mentioned study using the same technique where uroflow data were available for 26 asymptomatic toilet-trained boys. Qmax and Qave tended to cluster below the 50th percentile and 4/26 (15.3%) had a Qmax below the 5th percentile denoting obstructed flow, while their Qave was above the 5th percentile on the same nomogram [5]. Eassa *et al.* assessed the repair of 59 boys with distal hypospadias by s-TIP technique found that the uroflow curve pattern postoperatively was bell shaped in 16 patients, interrupted in eight, slightly flattened in 20 and a plateau in six [20]. The authors found that 36 patients were above the 20th percentile, nine were below 5th percentile and six were in-between, and there was a significant PVR in nine patients. Regarding postoperative complications, there was insignificant difference between both groups ($p = 0.737$).

Linear regression showed that e-TIP and UP width were significant predictors for higher HOPE score. The e-TIP led to increase in total HOPE score by about 2.5 points more than the s-TIP technique (Table 4) and the preoperative width of UP was another significant predictor of high score ($p = 0.019$).

There are some limitations to the present study such as the possibility of subjective misinterpretation of HOPE score by study participants, inter-individual variations that led to unintentional errors when measuring TGD and UP width and their impact on reliability of measures. Another limitation is the relatively small number of cases available for uroflow study, which could be due to the relatively young age at operation and short period of follow-up as most children were not old enough to perform uroflow, in addition to absent preoperative uroflow data. Finally, the authors do not know whether the randomization website is validated or not. Nevertheless, this study enjoys important advantages such as the randomized prospective nature and the use of three objective methods for cosmetic and functional assessment.

In conclusion, the eTIP ensures creation of a vertical slit-like meatus located at the glans tip comparable to normal anatomy without compromising the functional outcome, leading to better cosmetic outcome compared with the sTIP. The UP width was a significant predictor of superior cosmetic outcome. Future multi-center studies with longer duration of follow-up are recommended to expand on these results in terms of the cosmetic and functional outcomes, and the occurrence of UCF following e-TIP.

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Ethical statement, approval and consent to participate

Ethical approval was obtained from the institution Research Ethics Committee of Faculty of Medicine, Benha University (REC:

IDIRB2017122601). Clinical data were obtained with the written consent of patients' sponsors.

Consent for publication

Written informed consent for publication were obtained from parents.

Disclosure statement

The authors declare that they have no competing interests and no funding was obtained for this study.

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Data availability statement

The datasets generated and/or analysed during the current study are available from corresponding author upon reasonable request.

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