

Prospective Randomized Comparison of Distal Extension of Midline Urethral plate Incision and Standard Tubularized Incised Plate Urethroplasty – Do Anatomical Penile Measurements Influence the Outcomes?

Ahmed Mahmoud Al Adl (✉ ahmed.aladl@fmed.bu.edu.eg)

Benha University Faculty of Medicine <https://orcid.org/0000-0001-7655-0437>

Yasser A Nouredin

Benha University Faculty of Medicine

Ashraf Mohamed Abdel Aal

Benha University Faculty of Medicine

Tarek Mohamed Gharib

Benha University Faculty of Medicine

Kareem Ali El Attar

Benha University Faculty of Medicine

Tarek Mohamed El Karamany

Benha University Faculty of Medicine

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Abstract

Background: Since invention of tubularized incised plate urethroplasty, many modifications have been proposed searching for excellence and perfection. Distal extension of the midline urethral plate incision beyond glanular demarcation as a modification of the standard technique was critically evaluated and compared with the original technique in a prospective study and investigating predictors of success.

Methods: In this prospective study, patients with primary distal hypospadias presented for repair between June 2015 and January 2019 were randomized to undergo either extended midline incision of the urethral plate (e-TIP) or standard technique (s-TIP). Cosmetic outcome was evaluated postoperatively using Hypospadias Objective Penile Evaluation (HOPE) score and measuring ventral glans closure length (VGCL) and meatal length (ML). The functional outcome was assessed by uroflowmetry and postvoid residual urine. Qmax and Qave values were plotted against voided volume on a nomogram of age matched children. The impact of preoperative parameters on the outcomes were assessed with linear regression analysis.

Results: Out of 110 randomized, 94 cases were available for analysis, 46 in e-TIP group and 48 cases in s-TIP group with comparable preoperative demographics. Postoperatively, higher median (range) of HOPE score in e-TIP was 57(45–60) versus 55(44–60) in s-TIP ($p < 0.001$). Mean (SD) ventral glans closure to meatal length ratio was 87% (26) versus 46% (12) in e-TIP vs. s-TIP, respectively ($p < 0.001$). Complications and functional results were insignificantly different between both groups. On linear regression analysis, the urethral plate (UP) width and the use of e-TIP technique were significant predictors of better cosmetic outcome ($p = 0.019$ and 0.001 , respectively).

Conclusion: The e-TIP ensures creation of a vertical slit-like meatus at the glans tip emulating the normal anatomy with satisfactory functional, and apparently better cosmetic outcomes compared with the s-TIP. Wide urethral plate and the use of e-TIP were significant predictors of higher HOPE score, implying better cosmetic outcome.

Background

Hypospadias is the second most common anomaly in boys after undescended testes [1]. Despite the description of more than 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 shouldn't extend to the apical part of the glans for fear of meatal stenosis. Therefore, the meatus won't reach the glans tip [3]. To improve the cosmetic outcome and bring the meatus at the tip of the penis mimicking the normal position, distal extension of the urethral plate midline incision was described with promising early results regarding the cosmetic and functional outcomes [4]. In the present study, we objectively compared functional and cosmetic outcomes between the extended tubularized incised plate (e-TIP) and standard TIP (s-TIP) techniques and assessed the impact of preoperative penile biometrics on these outcomes.

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 according to Benha Faculty of Medicine, Research Ethics Committee (REC: IDIRB2017122601). Patients with megameatus intact prepuce, circumcised, proximal hypospadias 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*). This technique enabled more distal sewing of the glans and more distal location of the neomeatus to the very tip of the glans. The neourethra was then covered with a second layer of dartos flap. A urethral stent was left for 5–7 days, with a non-compressive dressing for 48 hours. Unless necessary, all patients were discharged the next morning of surgery. IV third-generation cephalosporin was given to all patients until the urethral stent was removed. Patients were examined weekly for 1 month then every month for six months. Preoperative local or systemic androgen therapy was not used.

Outcome evaluation:

The primary outcome (technical success) included a straight penis, an acorn-shaped glans, slit-like meatus located at the tip of the penis and single urinary stream of adequate force and calibre with no complications or need for redo surgery. *Cosmetic evaluation* done by an independent urological surgeon (KE) using Hypospadias Objective Penile Evaluation (HOPE Score) at least 3 months after surgery [6]. HOPE Score assesses 6 parameters (position of meatus, shape of meatus, shape of glans, shape of penile skin, penile axis including penile torsion and penile curvature). Scoring ranges from scale of 1 (minimum) to 10 (maximum) for each parameter, giving a minimum total score of 6, up to a maximum total score of 60 when giving the highest score for each variable. 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 outcomes were uroflow (using Laborie Dorado™ KT urodynamic device) and ultrasound measured residual urine (PVR), at last clinic visit at least 6 months after repair in uncomplicated toilet-trained boys. Shape of voiding curve, the maximum (Q_{max}) 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 based on the procedure needed to correct the defect after with the primary surgery [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. Categorical data were compared using Chi-square test or Fisher's exact test, as appropriate. Multivariate linear regression analysis was done for 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, 7 of 55 (12.7%) from e-TIP group and 6 of 55 (11%) from s-TIP group 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. Sites of the native meatus were coronal in 26 cases (27.7%), subcoronal in 33 cases (35.1%), and distal penile in 35 cases (37.2%). The median (IQR) of transverse glanular diameter (TGD) 14 (11–15 mm), and UP width 7 (4–9 mm).

Cosmetic Outcome

Acceptable cosmetic outcome was obtained in both groups. Details of HOPE score are depicted in *table 1*, 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 2*), ML was significantly longer in the s-TIP group, while the VGCL was significantly larger in the e-TIP group. 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 7 complications in 5 cases in the e-TIP. Second surgical intervention was needed in 4 cases that were managed after 6 months postoperatively, while one case of MS (Clavien grade 3a) was treated with dilatation under local anaesthesia (*Table 2*). Complicated cases had significantly smaller TGD, mean \pm SE (range) of 12.6 \pm 0.4 (11–14) mm versus 14 \pm 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-value 0.003, Mann-Whitney U test). Age at operation is 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 outcome was comparable between the two groups, detailed data regarding Qmax, Qave, flow time, voided volume, and PVR are depicted in *table 2* and (*Figure 3 a, b* and *Figure 4 a, b*). Preoperative parameters that thought to impact the total HOPE score (namely TGD, width of UP, and employment of the e-TIP technique) were entered in linear regression analysis for prediction of total HOPE score. It was found that e-TIP is a significant predictor for HOPE score as it leads to increase in total HOPE score by about 2.5 points more than s-TIP, p = 0.001 (*Table 3*). Additionally, the preoperative width of UP is another significant predictor of high score (p-value 0.019).

Discussion

Hypospadias repair is a challenging reconstructive procedure with different techniques being currently employed aiming to create a functionally and cosmetically 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 objectively compared cosmetic and functional outcomes following a modification of the standard TIP technique (s-TIP) that entails extension of midline incision beyond glanular demarcation (e-TIP) and assessed impact of penile biometrics on the outcomes after both techniques.

In this modification (e-TIP), deep UP midline relaxing incision was done started from within the hypospadiac meatus and to be extended distally to the very tip of the glans then the neourethral tabularization was started from distal to proximal in a way allowing fashioning neomeatus of a suitable calibre located at glans tip. This idea was first described by Jayanthi [5] 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 fistula in one patient. The authors incorporated glans cushions (glanular tissue adjacent to urethral plate) during urethroplasty which naturally created a wider urethra and no need for performing deep incision of plate in all cases [5]. 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 [4]. 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 [4]. In contrast, Snodgrass and colleagues emphasized that the relaxing should be limited to the UP as it may create a “shelf” [10]. The same authors in another study proposed that suturing the plate too far distally

may induce meatal stenosis while the neomeatus should have a wide oval 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 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, in a previously mentioned study, the authors found that UP characteristics were significant predictors of success [4]. 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 HOPE score, a photograph-based instrument [6], was applied for cosmetic evaluation, the score has good reliability when experienced by 13 paediatric urologists [13]. Cosmetic outcome as presented by mean (SD) total HOPE score was significantly higher in e-TIP group compared to s-TIP group (56.9 (3.6) versus 54.2 (3.4); $p < 0.001$). This significant difference was attributed to the shape and position of the neomeatus, which was the objective of the modified technique. Details of HOPE score evaluation are depicted in table 1. In e-TIP, normal vertical slit-like meatus at position 1 (distal glans) was achieved in 38/46 (82.6%), while in 8 patients the meatus was at position 2 (proximal glanular) due to the need to start tabularization slightly lower down in a conical glans. Regarding glans shape, slightly abnormal glans is suggested to be due to excessive glanular wing dissection which happened during glanuloplasty aiming to avoid postoperative glanular 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 ventral glans closure length and meatal length in normal children. The authors found that mean (SD) vertical meatal length was 5.4 (1) mm, ventral glans closure was 4.7 (1.2) mm, and mean (SD) ventral glans closure was 88% (22%) of the vertical meatal length. They concluded that position and size of the external meatus are constant in normal boys and VGC is equal to or slightly less than ML [7]. In the present study, mean (SD) VGC to ML was 87%(26) for the e-TIP group while it was 46%(12) for the s-TIP group with statistically significant difference (p value < 0.001) that was comparable to normality in the e-TIP group.

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 [14–16], 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. Uroflow data are depicted in table 2. Using a nomogram for age matched children [8], the Qmax was plotted against the voided volume where 4 out of 28 cases (14.3%) had obstructed flow with a Q-max values below the 5th percentile on the nomogram, two in each group, that is 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 [4]. In a study performed by Snodgrass, the flow rate was low in only one patient out of 17 patients underwent TIP repair and followed up for 45 months [20]. 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 [21]. The authors used Gaum Nomogram [22] and found that 36 patients were above the 20th percentile, 9 were below 5th percentile and 6 were in-between, and there was a significant PVR in 9 patients. Regarding postoperative complications, there was insignificant difference between both groups ($p = 0.737$).

Linear regression analysis was run to investigate preoperative parameters that thought to impact the total HOPE score. It was found that e-TIP and width of UP were significant predictors for total HOPE score. The e-TIP led to increase in total HOPE score by about 2.5 points more than the s-TIP technique, $P = 0.001$ (Table 3) and the preoperative width of UP was another significant predictor of high score (p -value 0.019).

There are some limitations to the present study, the possibility of subjective misinterpretation of HOPE score by study participants, interindividual variations that led to unintentional errors when measuring TGD and UP width and their impact on reliability of measure. 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. Nevertheless, this study enjoys important advantages as it is a randomized prospective study used three objective methods for cosmetic and functional assessment of our results.

Conclusion

Extension of midline urethral plate incision ensures creation of a vertical slit-like meatus located at the glans tip comparable to normal anatomy without compromising the functional outcome, but even better cosmetic outcome compared with the standard tubularized incised plate technique. The UP width was a

significant predictor of better cosmetic outcome. Future studies with longer duration of follow-up are recommended to expand on these results.

Abbreviations

e-TIP: Extended midline tubularized incised plate. HOPE: Hypospadias Objective Penile Evaluation. HOSE: Hypospadias objective scoring evaluation. ML: Meatal length. PVR: Post void residual urine volume. Qmax: Maximum flow rate (ml/s). Qave: Average flow rate (ml/s). s-TIP: Standard tubularized incised plate. TGD: Transverse glans diameter. UP: Urethral plate. VGC: Ventral glans closure.

Declarations

Ethics 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 obtained from parents regarding table 1 and figure 1.

Availability of data and materials

The datasets generated and/or analysed during the current study are available in the eTIP.sav [DataSet1] repository file.

Competing interests

The authors declare that they have no competing interests.

Funding

No funding was obtained for this study.

Authors' contributions

AMA made conception and design of the study, participated in acquisition, analysis and interpretation of data, and substantively revised the paper. YAN made participated in the acquisition, analysis, and interpretation of data, and substantively revised the paper. AMAA participated in the acquisition and interpretation of data and substantively revised the paper. TMG participated in acquisition of data, and substantively revised the paper. KAE participated in the acquisition, analysis, and interpretation of data, and drafting the paper. TME made substantial contributions to the conception and design of the study, participated in the acquisition, and interpretation of data, and substantively revised the paper.

All authors read and approved the final manuscript.

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Not Applicable.

Author details

¹Urology Department, Faculty of Medicine, Benha University, Benha, Egypt.

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Tables

[Due to technical limitations, Table 1 could not be displayed here. Please see the supplemental files section to access the table.]

Table 2: Postoperative cosmetic and functional outcomes in both studied groups.

	e-TIP N = 46	s-TIP N= 48	P value
Postoperative 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 score	57 (45-60)	55 (44-60)	<0.001*
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)	1**
MS, n (%)	3 (6.5)	0	0.113**
Clavien grade			
None	41 (89.1)	44 (91.7)	0.587***
Grade 3a	1 (2.2)	0	
Grade 3b	4 (8.7)	4 (8.3)	
Second intervention, n (%)	4 (8.7)	4 (8.3)	1**
Functional outcome Mean \pm SD (range)			
Uroflow n (%)	12 (26)	16 (33.3)	
Qmax (mL/s)	14.1 \pm 3.7 (7.9-19.5)	13.9 \pm 3.2 (5.8-18.3)	0.967 ^{\$}
Qave (mL/s)	8 \pm 2.1 (3.5-10.9)	8.1 \pm 2 (4.4-10.9)	0.734 ^{\$}
Flow time (s)	22.4 \pm 7.7 (13.4-38.9)	17.6 \pm 7.7 (8.7-37.2)	0.616 ^{\$}
Voided volume	159.3 \pm 47.5 (92-226)	132.5 \pm 50.3 (61.2-251)	0.385 ^{\$}
PVR	9.8 \pm 9.7 (0-30)	5.9 \pm 7.7 (0-25)	0.258 ^{\$}
Qmax nomogram			
Normal (>25 th percentile)	7 (58.3)	8 (50)	0.777***
Equivocal flow (25 th -50 th)	3 (25)	6 (37.5)	
Obstructed (<5 th percentile)	2 (16.7)	2 (12.5)	
Flow curve pattern			
Bell	7 (58.3)	9 (56.3)	0.975***
Intermittent	1 (8.3)	2 (12.5)	
Slightly flat	2 (16.7)	3 (18.8)	
Plateau	2 (16.7)	2 (12.5)	

*Mann-Whitney U. ** Fisher's Exact test. ***Chi square test. ^{\$}Student's t-test. Values are shown in median (IQR), Mean \pm 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 3: Linear regression analysis coefficients for prediction of total HOPE score.

Model	Unstandardized Coefficients B	Standardized Coefficients Beta	P value	95% Confidence Interval for B
TGD	0.616	0.162	0.108	-0.138-1.37
Width of UP	0.723	0.241	0.019	0.124-1.322
Technique= e-TIP	2.477	0.335	0.001	1.109-3.846

Dependent Variable: HOPE score.

TGD, Transverse glans diameter. UP, urethral plate. TIP, Tubularized incised plate.

Figures

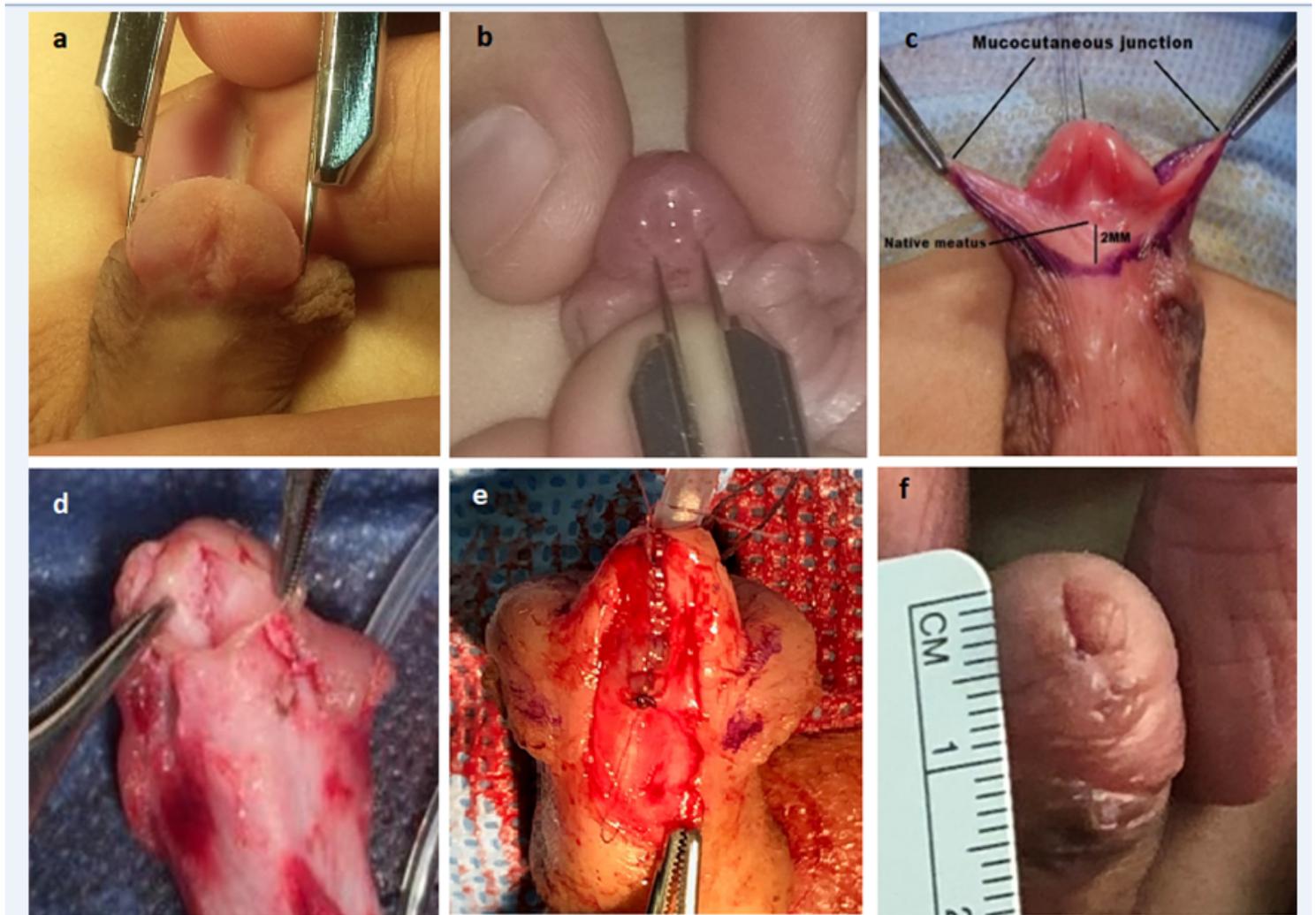


Figure 1

a) Measuring TGD. b) Measuring width of UP. c) Marking of ventral incision. d) Deep extended midline incision. e) Tubularization of the neourethra with 7/0 polygalactin suture. f) Measuring ventral glans closure and meatal length.

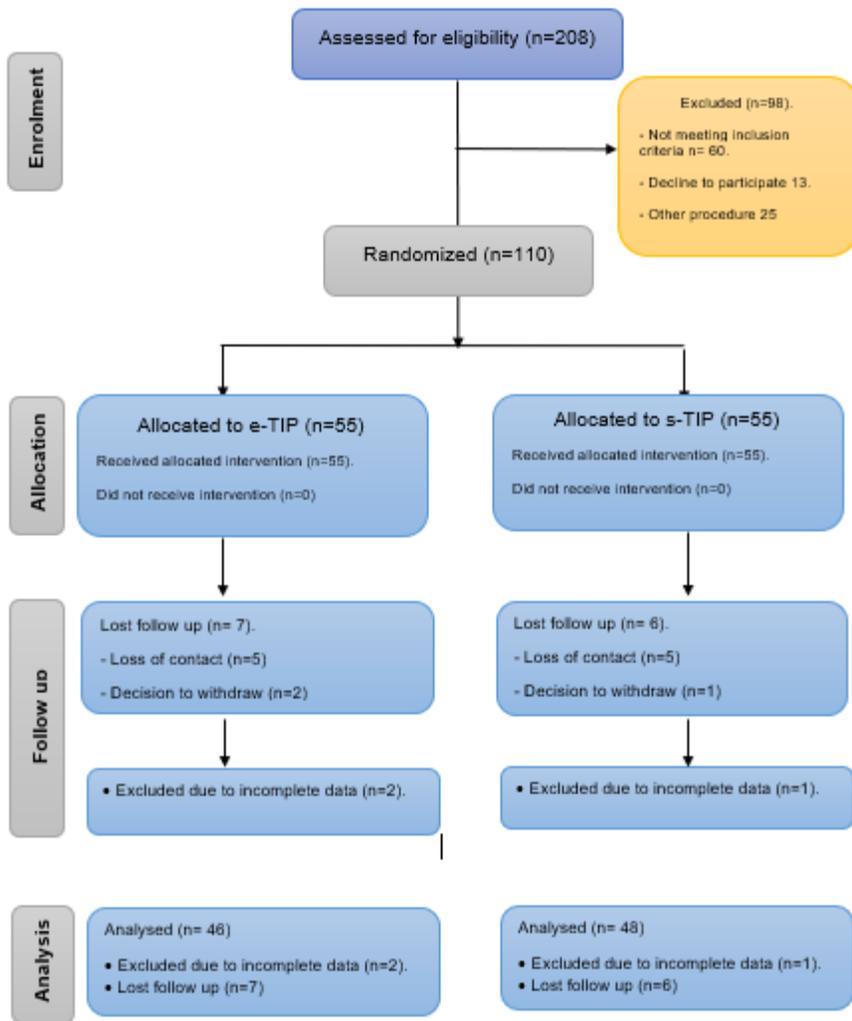


Figure 2

Participants flow diagram.

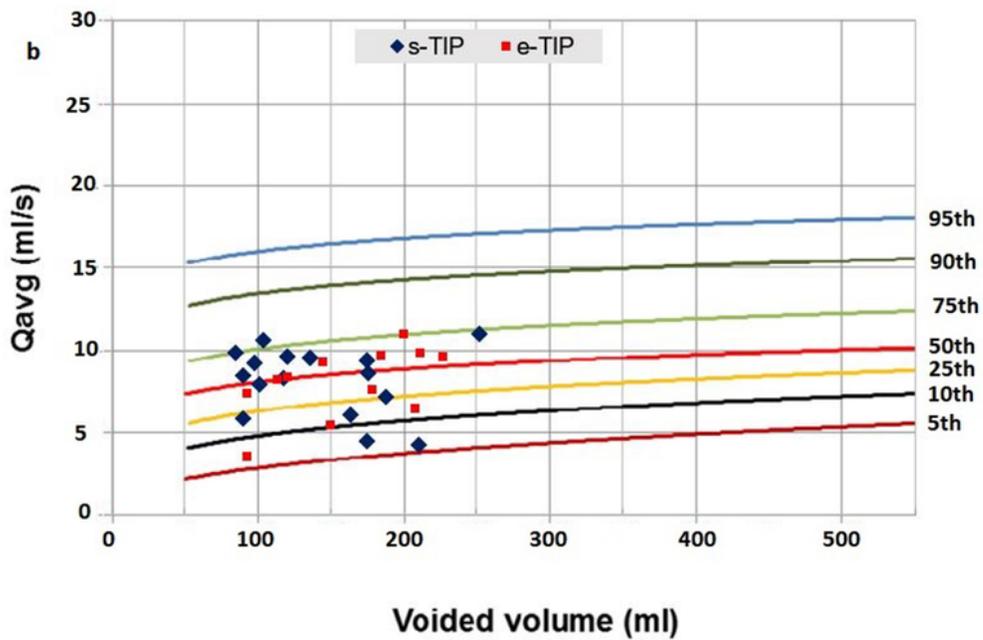
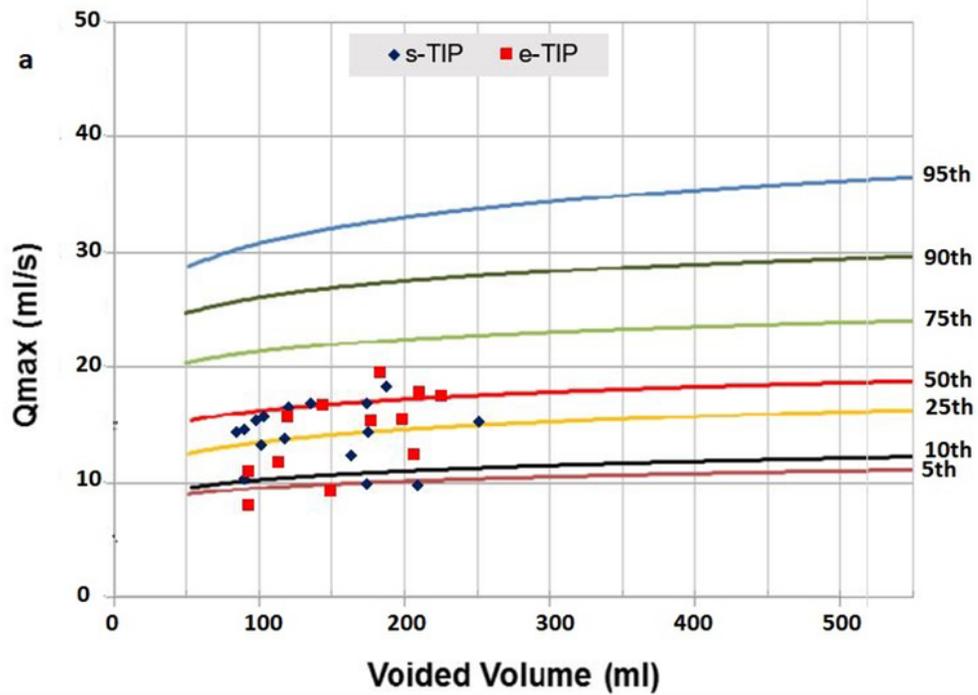


Figure 3

a: Q_{max} values plotted against voided volume. b: Q_{ave} values plotted against voided volume

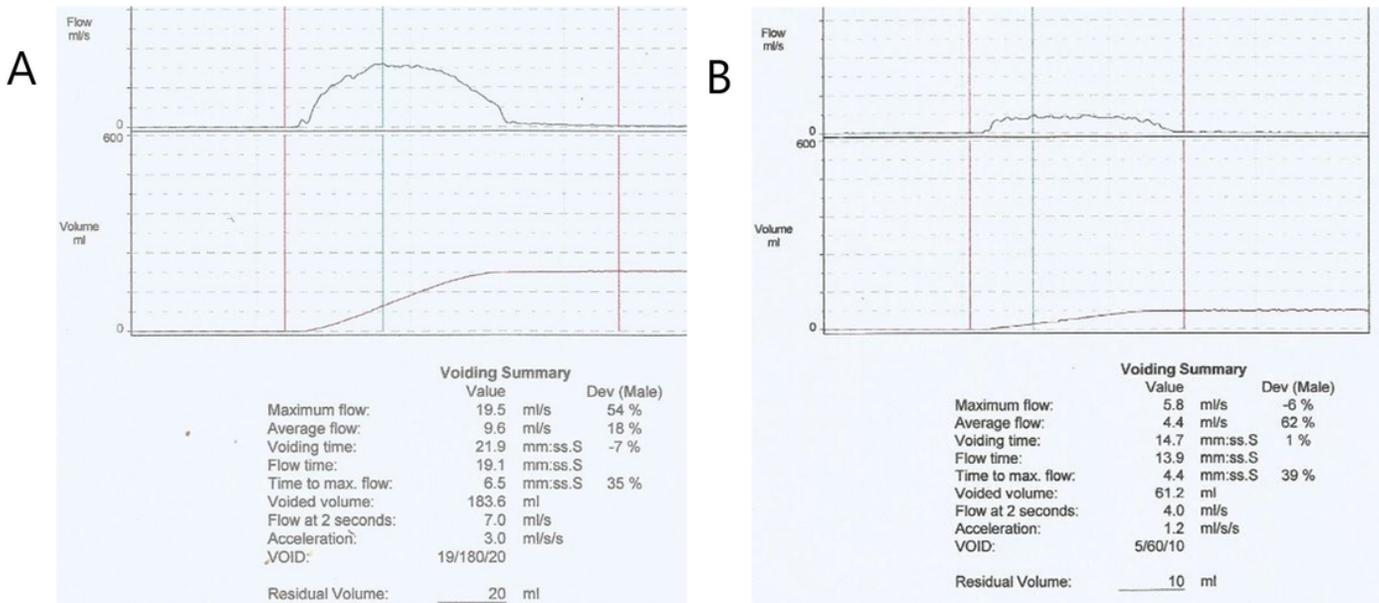


Figure 4

a: Bell-shaped voiding curve of normal values. b: Plateau voiding curve of an obstructed case.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- [eTIP.sav](#)
- [Table1.docx](#)