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Incidence of Urethrocutaneous Fistula Formation in Patients Undergoing Urethroplasty with and without Stent for Hypospadias

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ABSTRACT

Hypospadias is a common congenital anomaly in boys, and urethrocutaneous fistula (UCF) remains a frequent complication after urethroplasty. The routine use of urethral stents is still debated, especially in low-resource settings such as Pakistan. **Objectives:** To compare UCF incidence between stented and stentless urethroplasty and to identify factors associated with fistula formation. **Methods:** A randomized controlled trial was carried out in the Department of Pediatric Surgery, Children's Hospital Multan, from 10 May to 10 November 2025. A total of 110 boys aged 1–12 years with distal or mid-penile hypospadias were randomized to stent urethroplasty (Group A, n=55) or stentless urethroplasty (Group B, n=55). Data were analyzed using t-test, Mann–Whitney U test, chi-square test, and binary logistic regression with $p<0.05$ as significant. **Results:** Mean age was 6.1±2.6 years in Group A and 5.7 ± 2.9 years in Group B. Overall UCF incidence was 10% (11/110), higher in Group A than Group B (14.5% vs 5.5%; p=0.046). At 12 weeks, UCF occurred in 14.5% of stented repairs and 5.5% of stentless repairs (p=0.046). Postoperative infection and longer operative duration were independently associated with UCF. Hospital stays, a secondary outcome, were longer in the stented group. **Conclusions:** In this cohort, stentless urethroplasty demonstrated a lower 12-week UCF incidence compared with stented repair.

INTRODUCTION

Hypospadias is a severe malformation in boys that still leaves a huge surgical and psychosocial burden in places like Pakistan. Incidence of hypospadias is reported worldwide as 1 in 200-1 in 300 live male births, and it may be increasing [1]. There are scant strong population-based data in Pakistan, but single-center series suggest that hypospadias repair is one of the most popular pediatric urology procedures, and complications like urethrocutaneous fistula (UCF) are common [2, 3]. Hypospadias refers to the abnormal location of the urethral meatus on the ventral surface of a penis that is usually accompanied by ventral curvature (chordee) and underdevelopment of the corpus spongiosum and ventral prepuce. Recently, in Asia, an Indian study reported a mean UCF incidence of approximately 4% in children undergoing distal hypospadias surgery using tabularized incised plate (TIP) urethroplasty [4]. A different prospective cohort of children receiving TIP repair is also found to have a UCF rate of approximately 9.6 per cent in total, with a higher rate aged above three years old (25.9 %)[5]. Several systematic

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reviews and meta-analyses in the world literature have demonstrated that UCF rates following hypospadias repair range (less than 5 percent to over 30 percent) with severity of the hypospadias, surgical style, use of protective flaps, stent control, and other factors [6, 7]. To illustrate, a recent meta-analysis of double versus single dartos flap coverage in TIP urethroplasty discovered a considerably lower fistula rate when compared to the double dartos flap (odds ratio approximately 9.6) [8]. Nevertheless, such studies are frequently based on rich countries with well-equipped units and repairs at a young age; it is unclear whether they can be applied in resource-constrained environments [9]. In spite of these data, there are some important gaps in knowledge. To begin with, Pakistan (or other low-resource) based high-quality randomized information on a stented vs. stentless urethroplasty in hypospadias repair and its associated influence on UCF formation are rare. Second, numerous local series fail to stratify by stent use, length of stent, or end-follow-up at a standard point in time (e.g., 12 weeks) to be able to make meaningful comparisons. Third, the results of these studies conducted internationally using adequately resourced centers might not apply to the Pakistani setting, where patients are more likely to be older at the time they have surgery, the resources used in operating theatres are more limited, and the post-surgery follow-up is weaker [10]. The clinical burden is very high in the Pakistani setting. Repeat surgery may frequently be required, recovery time may be extensive, use of hospital resources and psychological impact on the child and family may be more significant in low-resource areas.

There is a lack of high-quality randomized controlled trial data that has compared stented versus stentless urethroplasty to hypospadias, and most of the local evidence is found in small observational studies or series with unequal follow-up times. Children's Hospital Multan's single-center design limits the generalizability to other regions in Pakistan with varying surgical facilities and patient populations. There is the possibility of detection bias, with the stented group being revealed in follow-up, because of the inability to blind outcome assessment at 12 weeks at UCF. This study aimed to compare UCF incidence between stented and stentless urethroplasty and to identify factors associated with fistula formation.

METHODS

All the eligible patients were enrolled after the approval of the synopsis by the College of Physicians and Surgeons, Pakistan, and ethical clearance by the Institutional Review Board of Children's Hospital and Institute of Child Health (approval number 898/IRB/CHICH). The research was carried out at the Department of Pediatric Surgery, Children's Hospital, Multan, from 10th May 2025 to 10th November 2025. This was a randomized controlled trial registered at ClinicalTrials.gov. The trial was registered at ClinicalTrials.gov (ID: NCT07243457) after recruitment had begun. Therefore, the registration was retrospective. It was a single-centered, hospital-based study. Urethrocutaneous fistula (UCF) was the primary outcome. All repairs were performed using a tubularized incised plate (TIP) technique. Children who met the inclusion criteria were enrolled consecutively. After enrolment, they were randomly allocated to the stent or stentless group using sealed, opaque envelopes. The purpose of the study and the possible risks were explained in simple language. Participation was voluntary, and families were free to withdraw at any time without affecting the child's care. All patient information was kept confidential, and the study was carried out in accordance with the Declaration of Helsinki (2013 revision). Randomization was done in a 1:1 ratio. A computer-generated random sequence was prepared by a statistician who was not involved in recruitment or surgery. The group assignments (stent or stentless) were printed on cards and placed in thick, opaque envelopes. Each envelope was sealed and numbered in sequence from 1 to 110. The envelopes were stored in a locked drawer. After a child met the inclusion criteria and written consent was obtained, the ward nurse took the next envelope in numerical order and opened it. The surgeon only learned the group assignment after the envelope was opened. This method kept allocation concealed until the moment of assignment. The sample size has been computed through the WHO sample size calculator according to the formula for comparing two independent proportions. The sample size was calculated using the WHO sample size calculator for two independent proportions. A two-sided alpha of 0.05 and a power of 80% were applied. The expected fistula rates (13.3% with stent and 33.3% without stent) were derived from a South Asian comparative study, as this study was considered the closest match to our population. Based on these parameters, a required sample of 55 patients per group (110 in total) was produced by the calculator. No adjustment for loss to follow-up was made, as the follow-up period was short (12 weeks) and early postoperative visits in our setting are usually completed. These were dependent on already published comparative studies on the hypospadias repair in South Asia [11]. All boys (children aged 1 to 12 years old) who had been planned to undergo urethroplasty to correct isolated cases of distal or mid-penile hypospadias and whose parents had provided informed written consent were included. The patients who had a history of failed urethroplasty, proximal hypospadias that needed a staged repair, or related disorders of sexual differentiation were excluded. This was randomly done through a lottery approach of assigning participants to two equal groups (A and B) using sealed opaque envelopes. Group A had

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urethroplasty and a stent, and Group B had no stent urethroplasty. The whole process of deciding who to categorize the patient under was influenced by blind selection and not by preference of the operator to eliminate selection bias. The data collector and the statistician were blinded to group allocation. Outcome assessment for UCF at 12 weeks could not be blinded, because the stent group could be identified during follow-up examinations, and the saline test required direct inspection of the repair site. For this reason, blinding of the outcome assessor was not feasible. All the procedures were done under general anesthesia by a consultant pediatric surgeon who had a history of over 5 years in hypospadias repair. The clinical confirmation of the diagnosis of hypospadias was through the position of the urethral meatus on the surface of the ventrally located penis and the presence of ventral curvature. It was a nasogastric tube of 6-8 Fr (B. Braun, Germany) used as a stent based on the age of the patient. This is a common and low-cost stent option in many South Asian pediatric surgery units when standard pediatric silicone stents are not available, and its use has been described in earlier regional studies. In calculating hemostasis, lignocaine 0.5 percent with 1:200,000 adrenaline (Medicaine, Pakistan) was infiltrated. All procedures were performed under general anesthesia by the same pediatric surgeon. After marking and degloving, the urethral plate was tabularized in two layers. Both layers were closed with 6/0 polydioxanone using interrupted sutures in the first layer and a continuous suture in the second layer. A vascularized dartos flap was then placed over the neourethra for additional protection. Finally, the skin was closed with 5/0 polyglactin sutures. The steps and suture materials were the same in both groups. All patients received the same postoperative antibiotic regimen. Intravenous ceftriaxone was given once daily for 24 hours, followed by oral cefixime for five days. This protocol is the standard postoperative practice in our hospital. The patients undergoing stentless urethroplasty underwent discharge to allow them to go home on the second day after the operation. Patients who underwent a stent-assisted urethroplasty were discharged seven days after the removal of the stents. After surgery, follow-up visits were set at 2, 6, and 12 weeks. Formation of urethrocutaneous fistulas was measured at the 12-week follow-up with sterile normal saline injected into the neourethra and later clamped at the base of the penis. The escaping of saline between two points in the ventral surface of the penis was defined as a positive aspect [12]. Clinical information was all entered into a structured proforma that was designed for this study. The continuous and categorical variables were recorded. Age and duration of surgery were taken as continuous variables, and location of hypospadias, type of procedure, presence of chordee, presence of infection, postoperative complications, and urethrocutaneous fistula were items under the categorical variables. Postoperative infection was assessed during the first 12 postoperative days. It was diagnosed when the wound showed redness, warmth, discharge, or when a fever above 38°C or a rise in CRP was present, leading to the start or change of antibiotics. All infections observed were wound infections; no urinary or catheter-associated infections occurred. Laboratory parameters were hemoglobin, serum creatinine, and C-reactive protein, as seen using a fully computerized analyzer (Roche Cobas C311, Switzerland). The cut-off was based on WHO pediatric values at less than 11 g/dL (anemia), greater than 1.0 mg/dL (elevated serum creatinine), and greater than 10 mg/L (elevated C-reactive protein). To reduce bias, all cases were standardized with respect to confounding variables, including surgeon experience, type of suture material, and infection control. Every operation was done by the same surgical doctor, with the same instruments, suture type, and postoperative care. Randomization served to adjust the bias of selection. Objective outcome evaluation, the data collector and the statistician were not informed of the group in which the study was conducted. Data collection began only with the approval of the ethics committee of the hospital. The patient information used in the study was confidential, and participation was voluntary. It was all done in accordance with the Declaration of Helsinki (2013 revision)(Figure 1).

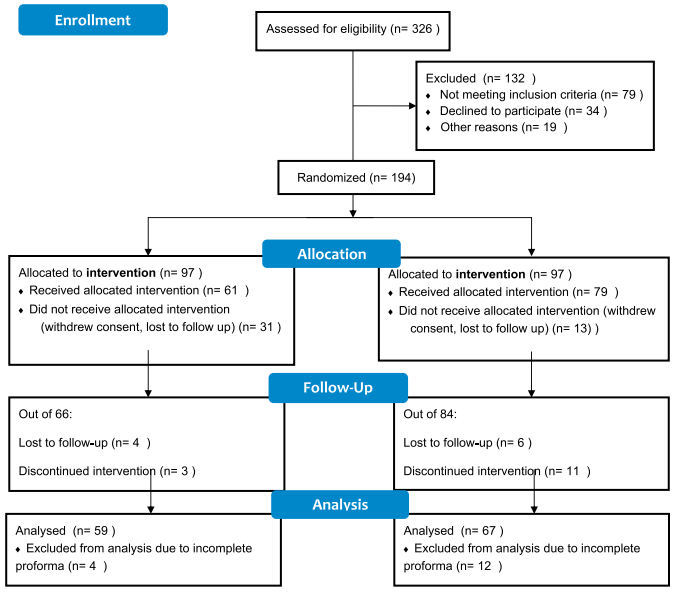

Figure 1: CONSORT Diagram of the Included Participants in the Study

The age and duration of surgery were normally distributed continuous variables, which were researched by Shapiro-Wilk tests and further visual analysis of the histograms and Q-Q graphs. It was found that age and duration of surgery were normally distributed, whereas hemoglobin and serum

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creatinine exhibited non-normal distributions. The normally distributed data were presented in terms of mean and standard deviation, and the non-normal data in terms of median and interquartile range.

Statistical analyses were done in Statistical Package of the Social Sciences (SPSS) version 26.0 (IBM Corp., Armonk, NY, USA). Demographic and clinical characteristics were summarized by descriptive statistics. Continuous variables such as age and duration of surgery were measured in terms of standard deviation and mean. Non-normally distributed laboratory values were quantified with median and inter-quantile range. Categorical variables like the location of hypospadias, the presence of infection, and the presence of urethrocutaneous fistula formation were checked as frequencies and percentages. The independent t-test was employed to provide the means of normally distributed variables between the two groups, e.g., age and length of surgery. The non-normally distributed continuous variables were tested by the Mann-Whitney U test. Categorical variables, such as type of hypospadias, infection status, and incidences of urethrocutaneous fistula, were compared through the chi-square test among the groups. The premise was to perform a logistic regression analysis to investigate the relationship that exists between the alleged risk variables (age, infection, duration of surgery) and the occurrence of fistula. The p-value of less than 0.050 was regarded as statistically significant. Age and type of hypospadias stratified confounders, and randomization, assessment blinding, and homogeneity of surgical and postoperative treatment minimized bias. Data were evaluated based on preset aims in order to understand whether the incidence of urethrocutaneous fistula varied significantly in the stented and the stentless urethroplasty groups.

RESULTS

A total of 110 boys were enrolled and randomized, with 55 in each group. The mean age of the whole sample was 5.9 ± 2.8 years. The mean age in the stent group was 6.1 ± 2.6 years, and in the stentless group it was 5.7 ± 2.9 years. The difference was not significant. All children received the assigned procedure. Follow-up at 12 weeks was completed by most participants. A small number had partial or no follow-up, and these cases were not included in the primary outcome analysis. Most continuous variables were normally distributed except for hemoglobin, serum creatinine, and CRP. The duration of surgery was similar in both groups (78.2 ± 11.6 minutes in the stent group vs 76.4 ± 12.3 minutes in the stentless group; p=0.438). Hospital stay was longer in the stent group (6.8 ± 2.1 days) compared with the stentless group (4.4 ± 1.8 days), and this difference was significant (p<0.001). Postoperative infection occurred in 9 children (16.4%) in the stent group and in 4 children (7.3%) in the stentless group. This difference was not statistically significant (p=0.158). At 12 weeks, urethrocutaneous fistula (UCF) occurred in 8 children (14.5%) in the stent group and 3 children (5.5%) in the stentless group. This difference was significant (p=0.046). No significant group differences were found for wound edema, hematoma, meatal stenosis, or laboratory values. In terms of postoperative outcomes, a significant difference was observed in hospital stay between the two groups. Children who underwent stentless urethroplasty had a shorter mean hospital stay (4.4 ± 1.8 days) compared to those who received stented repair (6.8 ± 2.1 days; p<0.001), indicating earlier recovery and discharge in the stentless group. The use of a stent was also associated with a higher incidence of urethrocutaneous fistula (14.5 % vs 5.5 %; p=0.046), suggesting that stent placement may increase the risk of fistula formation. Logistic regression analysis identified postoperative infection (OR 4.28; 95 % CI 1.22–14.99; p=0.023) and prolonged operative duration greater than 90 minutes (OR 3.61; 95 % CI 1.03–12.61; p=0.044) as independent predictors of fistula development. A moderate positive correlation was found between CRP levels and postoperative infection (ρ=0.46; p<0.001), confirming that higher inflammatory markers were associated with wound infection. Duration of surgery was also positively correlated with both patient age (r=0.29; p=0.004) and UCF occurrence (ρ=0.33; p=0.006), indicating that longer procedures in older children were more likely to result in fistula formation. Correlation analysis showed a weak positive relationship between age and duration of surgery (r=0.29, p=0.004). Infection was moderately correlated with higher CRP levels (ρ=0.46, p<0.001). Longer surgery time showed a moderate correlation with UCF (ρ=0.33, p=0.006). In the logistic regression analysis, postoperative infection (OR 4.28; 95% CI 1.22–14.99; p=0.023) and surgery lasting more than 90 minutes (OR 3.61; 95% CI 1.03–12.61; p=0.044) were the only independent predictors of UCF. Hospital stay and CRP level were not significant predictors. The overall UCF rate (10%) in this study is similar to reported South Asian rates. Most other variables showed no significant differences between groups. The study represents a report on the descriptive statistics of continuous variables: age, duration of surgery, hospital stay, hemoglobin, serum creatinine, and C-reactive protein (CRP) (Table 1).

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Table 1: Comparison of Continuous Variables between Stent (n=55) and Stentless (n=55) Urethroplasty Groups

Variables	Shapiro–Wilk W (p)	Group A (Stent) Mean ± SD / Median (IQR)	Group B (Stentless) Mean ± SD / Median (IQR)	Test Statistic	p-value
Age (Years)*	0.983 (0.21)	6.1 ± 2.6	5.7 ± 2.9	5.7 ±at = 0.78	0.438
Duration of Surgery (min)*	0.978 (0.33)	78.2 ± 11.6	76.4 ± 12.3	t = 0.78	0.438
Hospital Stay (Days)*	0.981 (0.26)	6.8 ± 2.1	4.4 ± 1.8	t = 5.78	<0.001
Hemoglobin (g/dL)†	0.903 (0.012)	11.6 (11.0–12.1)	11.7 (11.2–12.3)	U = 1410.0	0.720
Serum Creatinine (mg/dL)†	0.912 (0.018)	0.62 (0.55–0.69)	0.61 (0.56–0.67)	U = 1432.5	0.810
CRP (mg/L)†	0.894 (0.009)	9.8 (6.3–12.6)	8.9 (5.9–11.7)	U = 1398.5 2.9	0.680

*Data presented as Mean ± SD for normally distributed variables (independent t-test). †Data presented as Median (IQR) for non-normal variables (Mann–Whitney U test). Significance level p<0.050

Results present the categorical variables and frequencies of both study groups (Table 2).

Table 2: Frequency Distribution of Categorical Variables between Stent (n=55) and Stentless (n=55) Urethroplasty Groups

Variables	Group A (Stent), n (%)	Group B (Stentless), n (%)	χ^2 (df)	p-value
Hypospadias Location				
Coronal	22 (40.0%)	20 (36.4%)	1.12 (2)	0.570
Subcoronal	19 (34.5%)	20 (36.4%)		
Mid-Penile	14 (25.5%)	15 (27.2%)		
Chordee Severity				
Mild	32 (58.2%)	30 (54.5%)	0.98 (2)	0.610
Moderate	18 (32.7%)	20 (36.4%)		
Severe	5 (9.1%)	5 (9.1%)		
Other Factors				
Post-Operative Infection	9 (16.4%)	4 (7.3%)	1.99 (1)	0.158
Wound Edema	15 (27.3%)	12 (21.8%)	0.45 (1)	0.500
Hematoma	3 (5.5%)	2 (3.6%)	Fisher	0.650
Urethrocutaneous Fistula (UCF)	8 (14.5%)	3 (5.5%)	3.97 (1)	0.046*
Meatal Stenosis	4 (7.3%)	3 (5.5%)	0.16 (1)	0.680

The chi-square test is applied unless Fisher's exact test is stated. *p<0.050 is considered significant

The study shows a multivariate binary logistic regression analysis identifying independent predictors of urethrocutaneous fistula formation (Table 3).

Table 3: Logistic Regression Model Predicting Urethrocutaneous Fistula Formation (n=110)

Predictor Variables	Adjusted OR (95 % CI)	Wald χ^2	p-value
Post-Operative Infection	4.28 (1.22 – 14.99)	5.13	0.023*
Duration of Surgery > 90 min	3.61 (1.03 – 12.61)	4.08	0.044*
Hospital Stay > 5 Days	1.89 (0.61 – 5.84)	1.11	0.291
CRP > 10 mg/L	1.56 (0.43 – 5.66)	0.59	0.440

#Binary logistic regression analysis performed; reference category = no UCF. *Significant at p<0.050.

The analysis shows correlation and subgroup analyses between continuous variables (age, duration of surgery, hemoglobin, and CRP) and categorical variables such as infection and fistula presence. Pearson correlation was used for normally distributed data, and Spearman correlation for non-normal data (Table 4).

Table 4: Correlation and Subgroup Analysis of Continuous and Categorical Variables (n=110)

Variable Pair	Test Used	Correlation Coefficient (r/ρ)	95 % CI	Test statistic	p-value
Age vs Duration of Surgery*	Pearson	r = 0.29	0.10 – 0.46	t = 2.93	0.004*
CRP vs Infection Status†	Spearman	ρ = 0.46	0.29 – 0.61	Z = 4.22	<0.001*
Duration of Surgery vs UCF Occurrence†	Spearman	ρ = 0.33	0.11 – 0.52	Z = 2.81	0.006*
Hemoglobin vs Infection Status†	Spearman	ρ = –0.09	–0.28 – 0.11	Z = 0.92	0.360

*Pearson correlation used for normally distributed variables. †Spearman correlation used for non-normal variables. p<0.050 is considered significant

DISCUSSION

The most important results of this study revealed that the incidence of urethrocutaneous fistula (UCF) was 10 percent in the cohort and that it was higher in the stent-assisted group (14.5 percent) than the stentless group (5.5 percent). There were no significant differences in age, type of hypospadias, chordee severity, hemoglobin, creatinine, and CRP levels by groups. In this trial, stentless urethroplasty was associated with a significantly shorter hospital stay, indicating faster recovery and reduced inpatient burden. The stented group had a higher fistula rate, suggesting that stent use may contribute to local irritation or impaired healing. Postoperative infection and prolonged operative time were independent predictors of fistula formation, emphasizing the need for strict infection control and minimizing surgical duration. CRP showed a meaningful correlation with postoperative infection, supporting its role as a useful inflammatory marker. Longer operative times were also associated with increasing age and the occurrence of UCF, implying that more complex repairs in older children may carry a higher risk of complications. Comparison of these results with national studies in Pakistan showed that in one randomized controlled trial involving 260 patients, the total incidence of UCF was 8%, though 13% in the stented and 2% in the stentless group (p=0.001). The overall rate of the current study (10%) could be due to the use of a slightly older age

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group or possibly due to the limitation of resources in the hospital setting. An Indian single-centre cohort in the South Asian region did not find any significant difference in complication rates between distal hypospadias stented and unstented repairs (fistula rate of about 7%), and a study in Bangladesh observed similar results with shorter follow-up [12]. Studies in Europe and North America have reported that in unstented urethroplasty, there is no statistically significant risk increase in fistulas [13, 14]. Another recent North American study also indicated that the stent omission could reduce the hospital stay with no significant complication rate escalation ($p=0.310$) [15]. Mechanistically, the higher UCF in the stented group may be due to the longer duration of catheterization, which leads to local irritation, bacterial colonization, and impaired neourethral healing [16]. The fact that it was largely related to operative time implies that more advanced anatomy or a more comprehensive dissection can lead to longer surgery time, which may compromise tissue integrity [17]. The intermediate association between infection and high CRP, the stands-alone consideration of inflammatory burden, could explain why urethral repair integrity is compromised [18, 19]. In this study, age was not a predictor of fistula development, possibly implying that there are greater influences of surgical factors than age of the patients when repair is performed [20].

Such a major methodological constraint is the inability to blind outcome assessors to detect UCF because of visible evidence of previous stent use. The issue with retrospective trial registration could be selective outcome reporting. Resource limitations (the use of nasogastric tubes as urethral stents) instead of conventional silicone pediatric stents can limit comparability with studies that used specialized urethral stents. The follow-up (12 weeks) is too short to evaluate such late complications as the meatal stenosis recurrence and long-term cosmetic results. Single-surgeon design is less variable, but less generalizable to other surgical teams having varied experience levels. Future studies should seek to compare long-term (24 to 36 months) results of stent and no-stent repairs in Pakistan or other low- and middle-income nations, and consider the cost-effectiveness and patient/parent-reported outcomes.

CONCLUSIONS

In conclusion, the 12-week incidence of urethrocutaneous fistula was lower in the stentless group than in the stented group. Postoperative infection and longer operative time were the only factors linked with fistula formation. These findings suggest that stentless urethroplasty may be a safe option for selected distal and mid-penile cases. Larger studies with longer follow-up are needed to confirm these results.

Authors' Contribution

Conceptualization: MZK
Methodology: MKC, AS, MAH
Formal analysis: MNK
Writing and Drafting: SS, SUR
Review and Editing: SS, MKC, AS, MAH, MZK, SUR, MNK

All authors approved the final manuscript and take responsibility for the integrity of the work.

Conflicts of Interest

All the authors declare no conflict of interest.

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