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Validation Article

Rate of Suture Material Absorption Does Not Impact Short Term Outcome of Tubularized Incised Plate Repair of Distal Penile Hypospadias in Children: A Randomized Controlled Study

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Abstract:
Background: There is an agreement on the use of absorbable sutures for urethroplasty of distal penile hypospadias (DPH) repair in children. Early absorbable sutures may cause less tissue reaction, less stricture formation but increase the risk of fistula formation, while delayed absorbable sutures may decrease the rate of fistula formation but can cause more tissue reaction and increase the stricture formation rate.
Aim of the work: To study the effect of tabularizing the urethral plate in DPH in children using 2 different absorbable suture materials, rapidly absorbable braided 6/0 glycolide (Vicryl) and slowly absorbable monofilament 6/0 polydioxanone (PDS), on outcome and complication rates.
Subjects and Methods: A prospective randomized controlled study included 78 boys with DPH. It was conducted at the Urology Department, Cairo University Specialized Pediatric Hospital, between September 2021 and September 2022. They were randomly divided into 2 groups: group (A): Vicryl and group (B): PDS. Each group included 39 children. Tubularized incised plate (TIP) was the surgical technique used by a single pediatric urologist. Follow up was performed in outpatient clinic at 7 days, 1, 3, 6 and 12 months postoperatively. The complications and reoperation rates for both groups were compared.
Results: The mean ± SD age at the time of surgery for groups (A) and (B) was 46.95 ± 28.07 and 39.33± 21.63 months respectively (p = 0.353). The number of children with complications was 8/39 (20.5%) in group (A) while it was 9/39 (23.1%) in group (B) (p = 0.784). The rates of urethro-cutaneous fistula, wound dehiscence and wound infection were 4/39 (10.3%), 2/39 (5.1%) and 4/39 (10.3%) in group A, while they were 4/39 (10.3%), 3/39 (7.7%) and 5/39 (12.8%) in group B respectively, (p = 1.000, 0.644 and 0.723 respectively). The reoperation rates were the same for both groups 6/39 (15.4%) (p= 1.000). There was no correlation between the suture material type used in urethroplasty and urethra-cutaneous fistula (UCF), or overall complication rate or reoperation rate.
Conclusion: The short-term outcome of TIP procedure was not different among the studied groups using either rapidly absorbable braided suture or slowly absorbable monofilament sutures. The rate of absorption and braiding did not influence the tubularization of the neourethra in children with DPH, rate of complications or re-operation rate.

Keywords: Hypospadias; polydioxanone; PDS; tubularized incised plate; TIP; Vicryl; children
Abbreviations: DPH: distal penile hypospadias; PDS: Polydioxanone suture; TIP: tubularized incised plate; UCF: Urethro-cutaneous fistula

Introduction

Hypospadias is the second most common genital anomaly after undescended testes among approximately 1 in 250 newborn males. Several techniques have been described to repair different forms of hypospadias (*1*). Since Snodgrass described the tubularized incised plate repair (TIP) in 1994, many studies reported different outcomes with urethra-cutaneous fistula (UCF) rates ranging from 0-28% (*2*, *3*). Efforts are ongoing to improve the results of hypospadias surgery and to achieve the best functional and cosmetic outcomes. Proper handling of tissues, meticulous dissection with preservation of vascularity, use of microsurgical instruments, proper magnification and surgical experience are all factors that significantly improve the outcome of surgery and reduce its morbidity. The proper choice of suturing material and needle size are also very important (*4*).

The use of absorbable sutures for urethroplasty during hypospadias repair. Skin is closed with absorbable sutures to avoid the need for stitch removal. Different absorbable sutures have different tensile strengths and absorption times. Vicryl, an absorbable multifilament, loses half its tensile strength after 3 weeks and is completely resorbed after 56-70 days. Being multifilament, it carries greater risk of wound infection. On the other hand, PDS is an absorbable monofilament that loses 31% of its tensile strength at 41 days and is completely absorbed after 180 days (*5*). The early absorbable sutures cause less tissue reaction and thus less stricture formation. However, these sutures carry the potential risk of breakdown of the neourethra and increased risk of fistula formation (*6*, *7*). The delayed absorbable sutures last for a long time that decreases the rate of fistula formation but can cause more reaction with the tissues and the possibility of stricture formation (*8*). The controversy about the effect of type of suture on outcome remains. Most of the studies that compared the effect of suture material on the outcome of hypospadias surgery were retrospective and included different types of hypospadias and different repair techniques (*5*). We tried to re-address the same issue prospectively and obviated any other variable that could affect the final outcome. We used Vicryl and PDS for urethroplasty. We standardized the type of hypospadias (DPH), the type of repair (TIP), the duration for catheter removal and wound exposure. All operations were performed by a single pediatric urologist. We aimed to study the effect of tubularizing the urethral plate in DPH in children using 2 different absorbable suture materials, rapidly absorbable braided 6/0 Vicryl and slowly absorbable monofilament 6/0 polydioxanone (PDS) on outcome, complication and reoperation rates.

Subjects and Methods

The current prospective case control study was conducted between September 2021 and September 2022 at the Cairo University Pediatric Hospitals. Informed written consent was obtained from the parents of all recruited patients. The study protocol submitted to ClinicalTrials.gov (ClinicalTrials.gov ID: NCT06413901). The Cairo University Research Ethics Committee reviewed and approved the study protocol (IRB code: N-421-2023).

Participants

This study included 78 uncircumcised boys with DPH, with no chordee or previous repairs. Children with recurrent or proximal hypospadias were excluded. All patients had favorable anatomy for TIP (the only type of repair used). All boys had glans width $\geq$14mm and urethral plate width $\geq$ 7mm. The stretched penile length was adequate for age for all patients. They were randomly divided into 2 groups. Each group included 39 patients. We used closed envelopes for randomization. In group (A) 6/0 Vicryl (polyglactin) was used for urethroplasty while in group (B), 6/0 PDS (polydioxanone) was used. All operations were performed by a single pediatric urologist.

Methods

The operation was performed under general anesthesia with a caudal block (0.25% bupivacaine at 1 ml/kg body weight) for postoperative pain and antibiotic (3rd generation cephalosporin) was administered at time of induction of anesthesia. Using magnifying loups, urethroplasty was performed in a running one-layer subcuticular fashion, using 6/0 Vicryl (13 mm ½ circle needle, Ethicon Inc, Somerville, New Jersey, USA) for group A and 6/0 PDS (13mm ½ circle needle, Ethicon Inc, Somerville, New Jersey, USA) for group B, strictly stopping at the mid glans. All cases had a dorsal dartos pedicled flap as a second covering layer. Glanuloplasty was performed in 2 layers using 6/0 Vicryl. The skin was always sutured in an interrupted fashion using 6/0 Vicryl.

All children were circumcised at the end of the operation. A 6 Fr urethral nelaton catheter was kept for an average of 7 days. A gauze dressing impregnated with the antibiotic framycetin was placed. Oral antibiotic (amoxicillin/clavulanic acid 50 mg/kg in 2 divided doses) and alpha amylase were prescribed for 5 days. All patients were discharged on the day of surgery and were asked to return after 5 days to remove the dressing. All patients were followed up after 1 week and at the end of first, third, sixth and twelfth months post-operatively. Care takers were asked to follow the urine stream and the number of openings getting urine. They were also asked to make videos during voiding for toilet trained children. The rates of urethra-cutaneous fistula, wound infection, wound dehiscence, overall complications, and reoperation rates for both groups were recorded and compared.

Statistical Analysis

The collected data were analyzed using the statistics software, SPSS version 26 (Statistical Package for the Social Science, IBM Corp, USA), Quantitative variables described as mean ± SD, while qualitative variables described as count and percentage. The distribution of the data was analyzed by the Kolmogorov–Smirnov test. To measure association between categorical variables: Fisher exact test or Chi-square test was done to compare between two independent percentages. T-test used for equality of means of two independent Quantitative normally distributed variables, while Mann-Whitney test was done for non-normally distributed variables. P-value < 0.05 considered statistically significant. The study included 78 patients (divided into 2 groups 39 in each group). The sample size calculated with G*Power 3.1.9.7 software (Franz Faul, Universitat Kiel, Germany) with input data odds ratio= 0.127, proportion P1=0.14, proportion 2=0.56, α= 0.05, power =0.95, and the chosen test for proportions differences between two independent proportions (fisher exact test) with calculated sample size= 70. Sample size was increased by 10% for possible dropouts. The parameter used was the total proportion of complications in the 2 groups, which was 7/50 (0.14) in group A and 28/50 (0.56) in group B. Reference of the parameter used: Guarino et al.,2009) (*9*).

Results

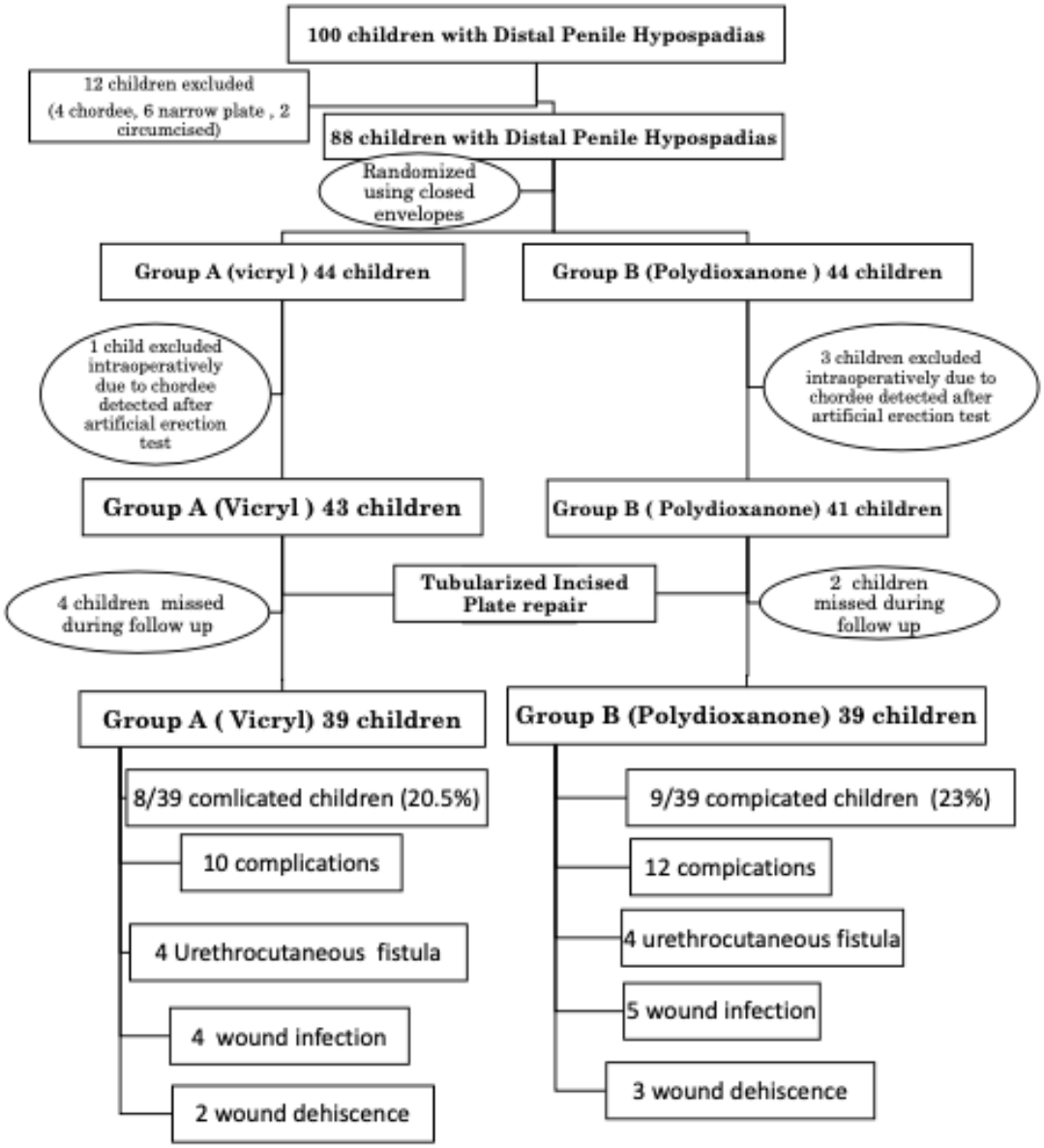

Figure 1. Flow Chart of Studied Groups (Vicryl braided and Polydioxanone single filament sutures)

The age range of the included 78 children was 8-120 months. The mean ± SD age at the time of surgery for groups A and B was 46.95 ± 28.07 and 39.33± 21.63 months respectively (p= 0.353). There was no statistically significant difference between both groups as regard penile length (p= 0.086). Mean operative time for group A and B was 119.5±7.7 minutes and 119.21±6.118 minutes respectively (p = 0.822). All patients were followed up postoperatively for 1 year.

Table 1. Complications and reoperation rates among studied groups

	Group A Vicryl Number=39		**Group B PDS Number=39**		**Total Number=78**		**P value**
	Mean age ± SD		Mean age ± SD		Mean age ± SD		
Mean age at surgery	46.95 ± 28.07		39.33± 21.63		43.14 ± 25.188		0.353
Age of Patients with complications	50.13± 32.682		49.67± 34.420		49.88± 32.6		0.784
Age of Patients without complications	46.13± 27.302		36.23± 15.595		41.26± 22.7		
	Number	%	Number	%	Number	%	
Number of patients with complications	8	20.5	9	23.1	17	21.8	0.784
Urethro-cutaneous fistula	4	10.3	4	10.3	8	10.3	1.000
Wound dehiscence	2	5.1	3	7.7	5	6.4	0.644
Wound infection	4	10.3	5	12.8	9	11.5	0.723
Total number of complications	10	25.6	12	30.8	22	28.2	0.784
Reoperation rates	6	15.4	6	15.4	12	15.4	1.000

PDS: Polydioxanone; SD: Standard deviation

The mean age of patients with and without post-operative complications was 49.88± 32.55 and 41.26±22.696 months respectively (p= 1.000). Only 17 (21.8%) patients had complications: 8 (20.5%) in group (A) and 9 (23.1%) in group (B). The total number of children who developed complications was 22; more than 1 complication occurred in the same patient. The complications encountered were urethro-cutaneous fistula in 8/78 patients (10.3%), 4 (10.3%) in group A and 4 (10.3%) in group B (p= 1.000), wound dehiscence in 5/78 patients (6.4%), 2 (5.1%) in group (A) and 3(7.7%) in group (B) (p= 0.644) and wound infection in 9/78 (11.5%) patients, 4 (10.3%) in group A and 5 (12.8%) in group B (p= 0.723). (Table 1).

Table 2. Details of the patients who developed complications

		Urethro-cutaneous fistula	Dehiscence	Wound infection
Group A	Patient 1			√
	Patient 2	√		
	Patient 3			√
	Patient 4		√	√
	Patient 5	√		
	Patient 6	√		
	Patient 7		√	√
	Patient 8	√		
	Total	**4**	**2**	**4**
Group B	Patient 1		√	√
	Patient 2	√		√
	Patient 3		√	√
	Patient 4	√		
	Patient 5	√		
	Patient 6			√
	Patient 7		√	
	Patient 8			√
	Patient 9	√		
	Total	**4**	**3**	**5**
Total		8	5	9

Wound infection occurred in 9 (11.5%) patients within the first 2 post-operative weeks. It represented 9/22 (40.9 %) of complications and contributed to dehiscence in 4/22 and UCF in (1/22) (22.7%) of complications. Four (5.1%) out of the 9 (11.5%) patients who experienced wound infection ended up with wound dehiscence, 1 (1.3%) patient with wound infection from group B was complicated by urethro-cutaneous fistula and the remaining 4 (5.1%) patients with wound infection improved without further complications. The total number of complications for groups

A and B were 10/39 (25.64%) and 12/39 (30.8%) respectively (p=0.784). The overall reoperation rate was the same in both groups (6 /39) (15.4%). None of the patients in either group developed urethral stricture or meatal stenosis requiring surgery in 1 year follow up. There was no statistically significant relationship between the type of suture material used in urethroplasty and the rates of urethro-cutaneous fistula, wound infection, wound dehiscence, overall complications or reoperation rates. Those who needed reoperations were scheduled for surgery 6 months after the date of the primary operation. Table 2 illustrates that some children developed more than a complication.

Discussion

The number of post-operative complications and reoperation rates were similar among children with DHR who underwent of TIP using Vicryl or PDS in our current study. Both sutures were absorbable and achieved good short-term outcome.

The outcome of hypospadias surgery depends on different factors, including patient factors regarding the site of the meatus, urethral plate width, glans width and presence of chordee in addition to surgical experience in hypospadias surgeries, the use of proper microsurgical instruments and magnification, the type of suturing material and the suturing technique used (*10*). Hypothetically, rapidly absorbable sutures can cause breakdown of the neourethra and wound dehiscence with less tissue reaction and stricture formation (*7*) while slowly absorbable sutures can cause tissue reaction and stricture formation with possibility of decreasing fistula rate (*5*). There evidence is conflicting on the type of absorbable sutures to be used (*11*). Hence, we recommend using whichever is available or more economic. This was a validation study as we routinely use 6/0 vicryl for TIP repair in our hospital.

The total number of our patients is relatively small when compared to other studies. Yet, our study was a prospective one designed to address a single variable which is the effect of suture material used for urethroplasty on outcome while other studies are mostly retrospective over a longer period of time with multiple variables that affect outcome other than the suture material used. They included different types of hypospadias (distal, mid and proximal) and different techniques of repair. We chose a 1 year follow up as we believe that UCF, wound infection and dehiscence, after TIP repair for DPH, occur in the early post-operative period and that any complications happening later after 1 year would not be related to suture material used as PDS is completely resorbed after 180 days. This was stated by Snodgrass that 64% of the complications of TIP repair occurred within the first postoperative visit and (81%) within the first year (*12*). The draw back of a one year follow up period is that it is not sufficient to know the exact percentage of post urethroplasty urethral strictures that could present later. We do believe that urethral strictures after TIP repair are caused by tubularization of a narrow urethral plate (< 7 mm urethral plate width) rather than reaction from the suture material used. It was reported that 74.6% of the patients who developed UCF occurred within 1 month after hypospadias repair and that the longest period from repair to having UCF was 15 months (*13*).

In the present study, the number of patients with complications was higher in the PDS group than in the Vicryl group (23.1 % vs 20.5%) but it was not statistically significant (p = 0.784). On the contrary, Shirazi reported that the number of complications in the Vicryl group was statistically higher than in the PDS group, 15.1% vs 5.3%, (p <0.001). He advised to use PDS for hypospadias repair especially for proximal hypospadias (*11*) which contradicts our findings. Our overall reoperation rates, complication rates and UCF rates were 15.4%, 28.2% and 10.3% respectively, with no statistically significant difference between the Vicryl and PDS groups. In a similar study, Guarino and coworkers used TIP repair for 100 boys with distal and coronal hypospadias, they divided them into 2 groups according to the suture material used for both urethroplasty and skin closure; a 6/0 polyglytone group and a 7/0 polydioxanone group. They reported a 10% fistula rate, as our fistula rate, with no statistically significant difference between the 2 groups and similar rates of wound dehiscence and infection for both suture materials (*9*). Cimador et al retrospectively compared 6/0 polyglactin to 7/0 polydioxanone in flap urethroplasties for different types of hypospadias. They reported a fistula rate of 3.8% and 6 % for the polyglactin and polydioxanone respectively which was not statistically significant different (*14*). In an older study, Ulman et al compared 6/0 polyglactin full thickness urethral reconstruction to 7/0 polydioxanone subcuticular urethroplasty in Mathieu repair. They found a significantly lower fistula rate and no difference in stricture rates using polydioxanone (16.6% and 4.9% respectively). This could be attributed to the difference in suturing technique used in the 2 groups and not to the suturing material itself (*8*).

Fistula rates are variable in the literature. Some studies have reported very low fistula rates. Oswald et al reported a 0% fistula rate for 30 patients with DPH repaired by TIP. They used 7/0

polyglactin for urethroplasty (*15*). Snodgrass reported a fistula rate of 2% in his study on 459 patients. He attributed his low fistula rates to proper surgical technique, short duration of catheterization, good postoperative care and careful wound handling (*16*). Our fistula rate is higher probably because of the higher rates of wound infection which is caused by either ischemic injury to tissues or postoperative wound infection related to patient hygiene but not related to the type of suturing material used.

Two studies from Mansoura reviewed the results of TIP repair. El-Sherbiny et al reported an overall complication rate of 15%, a UCF of 9%, a wound dehiscence rate of 3%, a meatal stenosis rate 5% and a urethral stricture rate of 0.8%. Seventy nine percent of their patients had distal hypospadias (*17*). However, Sarhan et al had 18.6% reoperation rate, UCF 9.4%, complete disruption 6.4% and meatal stenosis 2.8%. 74.2% of their patients had coronal and DPH (*10*). Both have results near to ours, probably because of sharing the same patients' culture and hygiene.

Our overall complication rate was high when compared to other studies mentioned because we added wound infection rates that were not added in other studies. It is important to mention wound infection rates when comparing braided to monofilament suture material.

One of the limitations of our study is that it did not assess the effect of weight or height percentiles on the results of either group. Most of the studies mentioned earlier are retrospective studies with different urethral meatus sites and different techniques of repair. Our study is a prospective, randomized controlled study performed for DPH using TIP repair only by a single surgeon with similarity of all other variables between the 2 groups, thus studying the effect of suturing material as a single variable. Hence, our results are reliable. The conflicting complication rates among studies may be related to other confounding factors, and not the suture material.

Conclusion

The short-term outcome of TIP procedure was not different among the studied groups using either rapidly absorbable braided suture or slowly absorbable monofilament sutures. The rate of absorption and braiding did not influence the tubularization of the neourethra in children with DPH, rate of complications or re-operation rate.

Author Contributions

Waseem Aboul Ela, Ahmed Salem contributed to the study of conception and design. Material preparation, project administration, data collection and analysis were performed by Mohamed Abdelghany, Mohamed Salah Amr Amin, Ahmed Shouman and Mohamed Abdelwahab. The first draft of the manuscript was written by Mohamed Abdelghany and Mohamed Abdelwahab. All authors read and approved the final manuscript.

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CONFLICT OF INTEREST

The authors declare no conflict of interest in connection with the reported study.

References

1. L. S. Baskin, M. B. Ebbers, Hypospadias: anatomy, etiology, and technique. *Journal of Pediatric Surgery* **41**, 463–472 (2006).
2. R. Hamid, A. A. Baba, A. Shera, S. Ahmad, Tunica vaginalis flap following 'Tubularised Incised Plate' urethroplasty to prevent urethrocutaneous fistulaa. *Indian J Plast Surg* **48**, 187–191 (2015).
3. L. H. Braga, A. Lorenzo, J. Pippi Salle, Tubularized incised plate urethroplasty for distal hypospadias: A literature review. *Indian J Urol* **24**, 219 (2008).
4. A. Bhat, General considerations in hypospadias surgery. *Indian J Urol* **24**, 188 (2008).
5. M. Shirazi, A. Haghpanah, A. Dehghani, S. Haghpanah, M. Ghahartars, M. Rahmanian, Comparison of post-urethroplasty complication rates in pediatric cases with hypospadias using Vicryl or polydioxanone sutures. *Asian Journal of Urology* **9**, 165–169 (2022).
6. A. F. Alkandari, D. M. Soliman, S. Madhyastha, A. A. Alawadhi, F. A. Alawadhi, N. M. Almotairi, O. Alozairi, Using Absorbable Sutures for Traumatic Wound Closure to

Avoid Additional Hospital Visits for Suture Removal During the COVID-19 Pandemic: A Randomized Controlled Trial. *Cureus*, doi: 10.7759/cureus.30012 (2022).
7. M. DiSandro, J. M. Palmer, Stricture incidence related to suture material in hypospadias surgery. *Journal of Pediatric Surgery* **31**, 881–884 (1996).
8. I. Ulman, V. Erikçi, A. Avanoğlu, A. Gökdemir, The Effect of Suturing Technique and Material on Complication Rate Following Hypospadias Repair. *Eur J Pediatr Surg* **7**, 156–157 (1997).
9. N. Guarino, S. A. Vallasciani, G. Marrocco, A New Suture Material for Hypospadias Surgery: A Comparative Study. *Journal of Urology* **181**, 1318–1323 (2009).
10. O. M. Sarhan, A. S. El-Hefnawy, A. T. Hafez, M. T. Elsherbiny, M. E. Dawaba, A. M. Ghali, Factors affecting outcome of tubularized incised plate (TIP) urethroplasty: Single-center experience with 500 cases. *Journal of Pediatric Urology* **5**, 378–382 (2009).
11. M. Shirazi, A. Haghpanah, A. Dehghani, S. Haghpanah, M. Ghahartars, M. Rahmanian, Comparison of post-urethroplasty complication rates in pediatric cases with hypospadias using Vicryl or polydioxanone sutures. *Asian J Urol* **9**, 165–169 (2022).
12. W. Snodgrass, C. Villanueva, N. C. Bush, Duration of follow-up to diagnose hypospadias urethroplasty complications. *Journal of Pediatric Urology* **10**, 208–211 (2014).
13. J.-W. Chung, S. H. Choi, B. S. Kim, S. K. Chung, Risk Factors for the Development of Urethrocutaneous Fistula after Hypospadias Repair: A Retrospective Study. *Korean J Urol* **53**, 711 (2012).
14. M. Cimador, M. Castagnetti, M. Milazzo, M. Sergio, E. De Grazia, Suture Materials: Do They Affect Fistula and Stricture Rates in Flap Urethroplasties? *Urol Int* **73**, 320–324 (2004).
15. J. Oswald, I. Körner, M. Riccabona, Comparison of the perimeatal-based flap (Mathieu) and the tubularized incised-plate urethroplasty (Snodgrass) in primary distal hypospadias. *BJU International* **85**, 725–727 (2000).
16. W. T. Snodgrass, N. Bush, N. Cost, Tubularized incised plate hypospadias repair for distal hypospadias. *Journal of Pediatric Urology* **6**, 408–413 (2010).
17. M. T. El-Sherbiny, A. T. Hafez, M. S. Dawaba, A. A. Shorrab, M. A. Bazeed, Comprehensive analysis of tubularized incised-plate urethroplasty in primary and re-operative hypospadias. *BJU International* **93**, 1057–1061 (2004).