



Original Article



Efficacy of Topical Testosterone in Hypospadias Patients Presenting with Microphallus

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ARTICLE INFO

Keywords:

Hypospadias, Microphallus, Topical Testosterone, Preoperative Androgen Stimulation, Pediatric Urology

How to Cite:

Khan, S., Azam, A., Jelani, U., Zara, Z., Qureshi, W. A., & Khan, M. A. (2025). Efficacy of Topical Testosterone in Hypospadias Patients Presenting with Microphallus: Efficacy of Topical Testosterone in Hypospadias Patients. *Pakistan Journal of Health Sciences*, 6(10), 42-47. <https://doi.org/10.54393/pjhs.v6i10.3465>

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Received Date: 15th July, 2025

Revised Date: 8th October, 2025

Acceptance Date: 22nd October, 2025

Published Date: 31st October, 2025

ABSTRACT

Hypospadias, a common congenital anomaly in males, is often linked with microphallus, complicating surgery. Preoperative androgen therapy may enhance penile size and outcomes, though most studies focus on intramuscular routes. Limited data exist on topical testosterone, especially locally. **Objectives:** To assess the effectiveness of topical testosterone in increasing penile length in children with hypospadias and microphallus. **Methods:** This quasi-experimental study was conducted at the Department of Plastic Surgery, Northwest General Hospital, spanned six months from November 2024 till May 2025. A total of 195 boys aged 1–10 years with hypospadias and microphallus received 5% topical testosterone cream, applied four times daily for 45 days. Stretched penile length was measured before and after treatment. A $\geq 50\%$ increase defined treatment success. Data were analyzed using SPSS version 25.0; significance was set at $p \leq 0.050$. **Results:** Median penile length increased from 42 mm (IQR: 8 mm) to 60 mm (IQR: 21 mm). Mean length rose from 41.32 mm to 59.18 mm ($p < 0.001$). A $\geq 50\%$ increase was seen in 52.3% of patients. No significant link was found between efficacy and age ($p = 0.316$) or hypospadias type ($p = 0.118$). **Conclusions:** Topical testosterone effectively increases penile length in children with hypospadias and microphallus, regardless of age or subtype.

INTRODUCTION

Hypospadias is defined as an abnormal opening of the urethra along the ventral aspect of the penis, starting from the glans up to the perineum. Its incidence is 1 in every 250 newborn males. Usually, there are three anatomic abnormalities present, hooded skin with deficient ventral foreskin, abnormal curvature of the skin toward the ventral area called Chordee and ventrally opened urethral orifice below the normal position [1, 2]. Hypospadias one of the most common male congenital anomalies often coexists with a small penile size (microphallus or “hypospadias with small penis”), which can complicate tissue handling, glans approximation, and flap perfusion during repair. Pre-

operative androgen stimulation (PAS), most commonly with topical or systemic testosterone or dihydrotestosterone (DHT), has been proposed to enlarge penile length and glans width, improve vascularity, and potentially reduce complications. Contemporary hypospadias reviews highlight a resurgence of interest in PAS as part of peri-operative optimization, particularly for distal repairs with small glans and for selected proximal cases [3, 4]. Quantitative syntheses now provide stronger estimates of PAS effects. A 2023 systematic review and meta-analysis reported that pre-operative testosterone increased stretched penile length by ~ 9.3 mm and glans



width by ~3.3 mm, with a possible reduction in urethrocutaneous fistula risk and no signal for higher overall complications [5]. Prospective and dose-response work shows that testosterone-associated glans growth is measurable, dose dependent, and persists beyond the peri-operative window—supporting a biologically meaningful effect on surgical anatomy [6]. More recently, a multicenter study of pre-operative topical DHT for hypospadias reported favorable increases in penile dimensions without excess early complications, further expanding the topical options under evaluation [7]. The most appropriate time for hypospadias repair has been controversial; however, the majority of surgeons prefer to do hypospadias repair between 6 months and 5 years of age. It is because it is believed that in the future the boy will not remember the surgery and will not have any effect on his psychological health. Operating on a small hypospadias phallus can be technically challenging [7, 8]. Achieving normal function and a natural appearance are the main objectives of surgical correction. Although hypospadias repair is widely and frequently performed, there is no consensus on the best practice guidelines to improve the clinical outcomes. One of the controversial topics involving hypospadias surgery is the use of preoperative testosterone. Typically, testosterone is offered to patients who require a technically challenging repair, such as those with proximal hypospadias and/or with small phallus [9]. The young age of the patient combined with a very small area of surgery make the repair challenging as the complications are related to the size and length of the penis. As a result, many surgeons focus on the role of testosterone either intramuscular or topical on the circumference and length of the penis and its relation with the overall outcome [2]. Various researchers presented contradictory results regarding the use of testosterone to increase the length of microphallus preoperatively. Most of the researchers have used intramuscular testosterone for this purpose. Only in a few studies, we have found the use of topical testosterone for the enlargement of penile length. Chalapathi used topical testosterone cream in 13 patients with hypospadias and microphallus and found that 7 (53.84%) of them improved in length by 50% or more [10]. Beyond high-income settings, regional series echo these benefits while underscoring heterogeneity in protocols. In a 2024 African cohort of proximal hypospadias, intramuscular testosterone given pre-operatively was associated with improved penile dimensions and acceptable complication rates [11]. Egyptian single-center experience in 2024 also found that pre-operative topical testosterone enlarged penile/glans size and aided technical ease, though the authors emphasized the need for standardized dosing and timing [12]. From South Asia,

an Indian prospective study (2019–2021) using parenteral testosterone documented significant pre-operative gains in penile length and glans diameter that translated into technically easier repairs [13]. Collectively, these regional data support feasibility of PAS across resource settings while highlighting protocol variability (drug, route, dose, and treatment interval). For this study, microphallus was defined as hypospadias associated with a stretched penile length below the normal mean for age, as per standard reference values. Hypospadias itself refers to a congenital anomaly in boys in which the urethral opening is ectopically located anywhere from just below the glans to the scrotum. The efficacy of topical testosterone was operationalized as a $\geq 50\%$ increase in penile length following therapy, measured in the stretched condition using a standard measuring tape. The working hypothesis was that topical testosterone would be effective in increasing penile length in this group of patients.

Despite widespread use of preoperative androgen stimulation in hypospadias management, most evidence originates from high-income countries with intramuscular testosterone administration. There is limited local data evaluating the efficacy of topical testosterone in Pakistani children, and existing studies often report small sample sizes or heterogeneous protocols. This paucity of region-specific evidence highlights the need to assess topical testosterone's effectiveness in improving penile length in children with hypospadias and microphallus. This study was aimed to determine the efficacy of topical testosterone in hypospadias patients presenting with microphallus.

METHODS

This quasi-experimental study was conducted in the Department of Plastic Surgery at Northwest General Hospital and Research Center. The study duration was a minimum of six months, starting from November 2024 to May 2025. Ethical Approval was obtained from the hospital's ethical review committee (Ref. No. IRB & EC/2024-GH/0137). A total of 195 patients were enrolled, calculated using the Raosoft online sample size calculator by taking the expected efficacy of topical testosterone in penile length enlargement as 53.84%, at 95% confidence interval, and a margin of error of 7% [10]. Consecutive non-probability sampling was employed for patient recruitment. Male children aged 1–10 years with hypospadias associated with microphallus (penile length less than normal for age, measured in stretched condition as per standard reference values). Patients with severe proximal or penoscrotal hypospadias, previously circumcised patients, those with chordee requiring interruption of the urethral plate, and those undergoing redo hypospadias repair were excluded. After obtaining

written informed consent from parents or guardians, all eligible patients underwent detailed history such as age, residence, socioeconomic status, family history, clinical examination e.g. (stretched penile length) and type of hypospadias were recorded (based on the anatomical location of the external urethral meatus observed during examination). Penile length was measured in stretched condition from the base to the tip of the glans using a measuring tape. Glans width was not included in the present study, as the primary objective was to evaluate the efficacy of topical testosterone in increasing penile length. Accurate and reproducible measurement of glans width requires specialized calipers and observer calibration, which were not feasible within the scope of this project. Moreover, stretched penile length is a validated and widely used parameter for assessing androgen response, and limiting the outcome assessment to penile length reduced variability and improved methodological consistency. All patients received 5% topical testosterone cream, initially applied under supervision during the first visit. Parents were instructed to continue applying the cream four times daily for 45 consecutive days. On the 46th day, penile length was measured again in the same standardized manner. Efficacy was defined as a $\geq 50\%$ increase in penile length compared to baseline. Data were analyzed using SPSS version 25.0. Continuous variables such as age and penile length were expressed as median with Interquartile Range (IQR), after checking for normality of distribution assessed by the Shapiro-Wilk test. Categorical variables such as hypospadias type and treatment efficacy were summarized as frequencies and percentages. Efficacy was stratified by age and hypospadias type. Post-stratification comparisons were performed using the chi-square test or Fisher's exact test, as appropriate. A p-value ≤ 0.050 was considered statistically significant. Results were presented in tables and figures.

RESULTS

A total of 195 patients with hypospadias and microphallus were included in the study. The median age of participants was 6 years (interquartile range (IQR)=5 years). At baseline, the median penile length was 42 mm (IQR = 8 mm), which increased to 60 mm (IQR=21 mm) following topical testosterone therapy. A median Increase in penile length by 20mm (IQR=20) was observed in the participants. Furthermore, the median percent increase as compared to penile length before Testosterone intervention was recorded as 51.08(IQR=48.23). The Shapiro-Wilk test indicated that the data were not normally distributed ($p < 0.050$)(Table 1).

Table 1: Age, Penile Length of the Participants

Characteristics	Median (IQR)	p-Value (Shapiro wilk)
Age of the participant (in years)	6 (5.00)	<0.001
Penile length before Testosterone (mm)	42 (8.00)	0.003
Penile length After Testosterone (mm)	60 (21.00)	0.033
Increase in Penile Length after Testosterone (mm)	20 (22)	<0.001
Percent Increase in Penile Length	51.08 (48.23)	<0.001

Regarding demographic distribution, more than half of the children (54.4%) resided in rural areas, while 45.6% were from urban areas. The majority (75.4%) had a monthly household income $\leq 100,000$ PKR, and most belonged to the middle socioeconomic class (57.9%), followed by the lower class (36.9%) and the upper class (5.1%). A family history of hypospadias was reported in 17.4% of cases. In terms of hypospadias subtypes, glandular hypospadias was the most common (28.7%), followed by coronal (25.6%), distal penile (21.5%), mid penile (13.8%), and proximal penile (10.3%). Over 52.3% (102) patients reported an increase in penile length by more than 50% while 47.7% (93) were recorded as increase in penile length less than 50% of the baseline. Overall, the efficacy of topical testosterone, (defined as a $\geq 50\%$ increase in penile length as compared to Baseline) was achieved in 52.3% (102 out of 195) patients, whereas in 47.7% (93 out of 195) of the participants, the increase in penile length was less than 50% of the baseline. The age distribution was nearly balanced, with 48.2% of children aged ≤ 5 years and 51.8% aged > 5 years (Table 2).

Table 2: Demographics, Hypospadias Types and Efficacy

Demographics, Hypospadias types and efficacy (N=195)	Frequency N (%)	
Residence	Rural	106 (54.4%)
	Urban	89 (45.6%)
Monthly income	≤ 100000	147 (75.4%)
	> 100000	48 (24.6%)
Socioeconomic status	Lower class	72 (36.9%)
	Middle class	113 (57.9%)
	Upper class	10 (5.1%)
Family history	Yes	34 (17.4%)
	No	161 (82.6%)
Type of Hypospadias	Coronal	50 (25.6%)
	Distal penile	42 (21.5%)
	Glandular	56 (28.7%)
	Mid penile	27 (13.8%)
	Proximal penile	20 (10.3%)
Percent Increase in Penile Length after Testosterone Therapy as compared to baseline	< 50% increase	93 (47.7%)
	>50% Increase	102 (52.3%)
Efficacy of topical testosterone ($\geq 50\%$ increase in penile length)	Yes	102 (52.3%)
	No	93 (47.7%)
Age Categories	≤ 5 years	94 (48.2%)
	> 5 years	101 (51.8%)

Analysis of efficacy in relation to hypospadias type revealed no statistically significant association ($p=0.118$). Although children with glandular and distal penile hypospadias showed relatively higher response rates, the difference did not reach statistical significance. Similarly, the efficacy of testosterone therapy did not differ significantly between age groups (≤ 5 years vs. > 5 years; $p=0.316$), indicating that response to treatment was independent of both hypospadias type and age (Table 3).

Table 3: Association Between Hypospadias Types, Age and Efficacy

Variables	Category	Efficacy of topical testosterone ($\geq 50\%$ increase)		Total	Chi-Square/ p-Value (<0.05)
		Yes	No		
Type of Hypospadias	Coronal	22	28	50	0.118
	Distal penile	27	15	42	
	Glandular	33	23	56	
	Mid penile	13	14	27	
	Proximal penile	07	13	20	
	Total	102	93	195	
Age	≤ 5 years	53	41	94	0.316
	> 5 years	49	52	101	
	Total	102	93	195	

When comparing penile length before and after treatment, the mean increased from 41.32 mm to 59.18 mm. A paired t-test demonstrated that this difference was highly significant ($p < 0.001$). This finding confirms that topical testosterone significantly enhances penile growth in children with hypospadias and microphallus, supporting its use as an effective preoperative intervention (Table 4).

Table 4: Mean Comparison Before and After Testosterone

Parameter	Mean Before Topical Testosterone	Mean After Topical Testosterone	Paired t-Test / p-Value
Penile Length (in mm)	41.32	59.18	<0.001

DISCUSSION

In the present study, topical testosterone therapy produced a significant increase in penile length among children with hypospadias and microphallus. The mean penile length improved from 41.32 mm before treatment to 59.18 mm after treatment, with the difference being highly significant ($p < 0.001$). More than half of the participants (52.3%) demonstrated an effective response, defined as a $\geq 50\%$ increase in penile size. Importantly, no statistically significant association was observed between treatment efficacy and either the type of hypospadias ($p=0.118$) or the age category of patients ($p=0.316$), suggesting that the benefits of testosterone were consistent across different subgroups no adverse effects were reported. In comparison to our study, Preoperative androgen stimulation (PAS) has emerged as a valuable adjunct in the

management of hypospadias, particularly in children with microphallus. Evidence from systematic reviews suggests that both topical and intramuscular testosterone reliably increase stretched penile length and glans width, providing a more favorable surgical field. A 2023 meta-analysis demonstrated significant penile growth with PAS and suggested a potential reduction in urethrocutaneous fistula formation, though long-term outcomes remain under study [5]. Lucaccioni *et al.* reported one of the more recent experiences with transdermal testosterone gel as a preoperative intervention in boys with severe hypospadias. Their small series of 10 patients showed an average increase of 0.76 cm in penile length and 0.42 cm in glans width following about six weeks of daily application. This represented nearly a 40% increase from baseline. Although no adverse effects were observed, surgical complications still occurred in 30% of cases, indicating that the effect in preventing surgical complications is still not clear [14]. Jackson *et al.* investigated the long-term effects of topical testosterone versus topical dihydrotestosterone (DHT) in boys with proximal hypospadias. They found that DHT was particularly effective, with glans width nearly doubling from 6.1 mm to 14.9 mm, while testosterone also produced significant increases from 10.5 mm to 14.6 mm [15]. Prospective clinical data further support these findings. Mittal *et al.* quantified a dose-dependent rise in glans width following testosterone therapy, highlighting its biological efficacy and potential to reduce technical challenges during repair [4]. Regional experience from Egypt also confirmed that topical testosterone enhanced penile and glans size, which surgeons perceived as beneficial for operative handling, though the authors emphasized the need for standardized dosing protocols [12]. Another meta-analysis by Do *et al.* found that testosterone therapy demonstrated a mean increase in stretched penile length of 9.3 mm (95% CI: 6.7–12.0 mm) and a glans width gain of 3.3 mm (95% CI: 2.5–4.0 mm) [5]. In a cohort of 368 patients undergoing distal hypospadias repair where two groups (testosterone vs controls) were compared, results showed that testosterone patients demonstrated significantly larger glans width (17.1 mm vs 14.6 mm, $p=0.001$). After adjusting for age, baseline glans width, testosterone exposure, and urethroplasty length, testosterone therapy was shown to be significantly associated with a reduced risk of postoperative complications (OR 0.4, $p=0.039$) [16]. Sembiring *et al.* compared post hypospadias repair complication rates between children who received testosterone therapy and controls. The study found that the testosterone group had a significantly lower rate of glans dehiscence (OR 0.40, 95% CI 0.17–0.97) compared to controls [17]. Another meta-analysis by Munawwir *et al.* found that PAS not only has an effect on the penile length

but also as significant effect on the overall complication rate (OR=0.68, 95% CI: 0.48–0.96; $p=0.03$) compared to controls. Analysis showed protective effects against several specific complications e.g. meatal stenosis (OR=0.66, 95% CI: 0.44–0.98), glans dehiscence (OR=0.46, 95% CI: 0.30–0.71; $p<0.001$), and urethrocutaneous fistula (OR=0.58, 95% CI: 0.36–0.94; $p=0.030$) [18]. Despite the growing international evidence base, national studies from Pakistan continue to focus predominantly on surgical outcomes of urethroplasty, with limited evaluation of preoperative hormonal strategies [19, 20]. This evidentiary gap underscores the importance of local data to assess efficacy, safety, and applicability of topical testosterone in Pakistani children presenting with hypospadias and microphallus.

The present study was limited by its quasi-experimental design, single-center setting, and lack of long-term follow-up to assess surgical outcomes and complications. Future studies with randomized controlled designs, larger sample sizes, and standardized dosing protocols are needed to confirm these findings and explore the impact of topical testosterone on post-surgical complications and functional outcomes.

CONCLUSIONS

In conclusion, topical testosterone had a significant effect in increasing penile length in children with hypospadias and microphallus. Around half of the children achieved a $\geq 50\%$ gain in penile length as compared to base line.

Authors' Contribution

Conceptualization: SK, UJ

Methodology: SK, AA, MAK

Formal analysis: UJ

Writing and Drafting: SK, AA, ZZ, WA, MAK

Review and Editing: SK, AA, ZZ, WA, MAK, UJ

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.

Source of Funding

The author received no financial support for the research, authorship and/or publication of this article.

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