

## The Efficacy of Active Fistulation in Duckett Procedure for Proximal Hypospadias in Children

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**Purpose:** To explore the efficacy of active fistulation in the treatment of proximal hypospadias in children by comparing one-stage and two-stage Duckett procedure.

**Materials and Methods:** A total of sixty-seven children who were diagnosed with proximal hypospadias and underwent Duckett operation at our hospital between January 2013 and January 2021 were selected for this study. These subjects were divided into two groups: the research group (n = 36), using two-stage Duckett procedure with active fistulation, and the control group (n = 31), using one-stage Duckett procedure. The incidence of postoperative complications and the score of pediatric penile perception Scale were compared between the two groups.

**Results:** The research group exhibits a significantly lower incidence rate of urethral fistula (8.3% Vs 16.1%) and urethral stricture (5.6% Vs 12.9%) in comparison to the control group ( $P < 0.01$ ). Furthermore, the analysis of Pediatric Penile Perception Scale scores indicates that the research group achieves significantly higher scores in terms of urethral shape, penile skin shape, and overall appearance than the control group ( $P < 0.05$ ).

**Conclusion:** In the treatment of proximal hypospadias in children, active fistulation within the two-stage Duckett procedure significantly reduces the rate of stage 1 postoperative complications and improves parental satisfaction. Active fistulation may offer a more promising option for the treatment of proximal hypospadias in children.

**Keywords:** hypospadias; urethroplasty; active fistulation; children; Duckett

### INTRODUCTION

Hypospadias is a congenital urinary disorder with an incidence of approximately 1/300. Its clinical features include ectopic urethral meatus, penile curvature, and abnormal preputial distribution.<sup>(1)</sup> Currently, surgery is generally recognized as the only effective treatment. However, there are still some challenges in the repair of proximal hypospadias,<sup>(2)</sup> such as severe penile curvature, extended urethral defects, and limited repair materials, which consequently results in a high incidence of postoperative complications. Despite the ongoing innovations and advancement in surgical techniques, there is still much controversy over the choice of various surgical procedures. This study seeks to validate the efficacy of the two-stage Duckett procedure with active fistulation for the treatment of proximal hypospadias and to compare its results with those of the conventional one-stage Duckett procedure, with the aim of providing a better option for proximal hypospadias management.

### PATIENTS AND METHODS

#### Study population

The study participants consist of children who underwent either one-stage or two-stage Duckett procedure for proximal hypospadias in the Department of Pediatric Surgery, Affiliated Hospital of Nantong University from January 2013 to January 2021 were selected as

the research subjects. The research group underwent the two-stage Duckett procedure with active fistulation, and the control group received the one-stage Duckett procedure. During the research period, we informed all patients and their family members about the research in detail and obtained their informed consent. And this study obtained approval from the hospital's Ethics Committee (approval number: 2024-K047).

The inclusion criteria for this study are as follows: (1) pediatric patients who underwent their first surgical intervention; (2) pediatric patients diagnosed with proximal hypospadias, which refers to the urethral meatus located in the proximal part of the penis, penile-scrotal junction, or the perineum after degloving of penis; (3) pediatric patients who underwent either a one-stage Duckett procedure or a two-stage Duckett procedure with active fistulation had a follow-up duration exceeding one year and complete medical records.

Conversely, the exclusion criteria involve: (1) patients with circumcision; (2) patients with a previous history of hypospadias surgery; (3) patients with hermaphroditism.

#### Surgical technique

The Research Group: The first surgical steps of two-stage Duckett procedure with active fistulation: We can see the appearance of severe hypospadias (**Figure 1**). The inner prepuce plate incision was made at a distance of 0.5cm-1cm from the coronal sulcus. Then, the incision was extended to the penile body and made around

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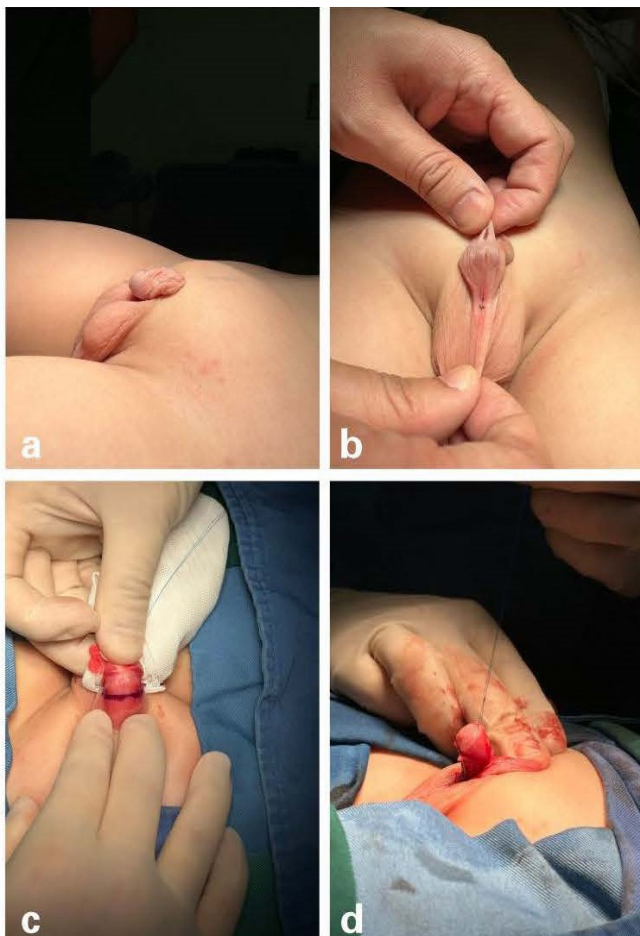
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**Table 1.** Comparison of complication rates between the two groups [n(%)].

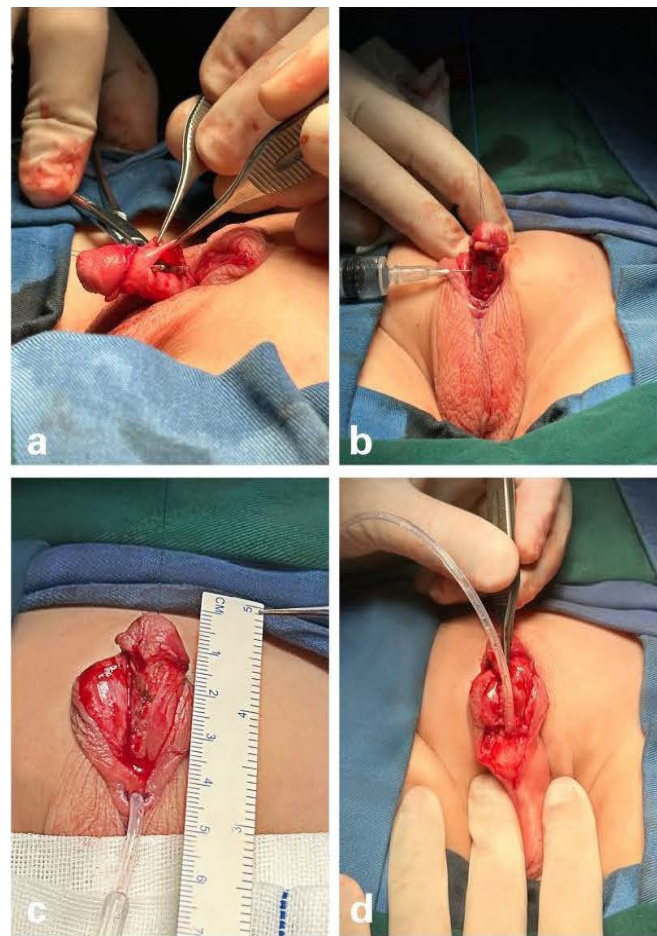
| Complications             | Research Group N(%) | Control Group N(%) | OR    | 95%CI       | p       |
|---------------------------|---------------------|--------------------|-------|-------------|---------|
| Total                     | 36                  | 31                 | /     | /           | /       |
| Urinary fistula           | 3 (8.3)             | 5 (16.1)           | 0.083 | 0.028–0.246 | < 0.001 |
| Ureterostenosis           | 2 (5.6)             | 4 (12.9)           | 0.056 | 0.014–0.214 | < 0.001 |
| Fissured Glans            | 0                   | 1 (3.2)            | /     | /           | 0.46    |
| Urethrocele               | 0                   | 1(3.2)             | /     | /           | 0.21    |
| Penile Recurvature        | 0                   | 0                  | /     | /           | /       |
| Overall complication rate | 13.9                | 38.7               | 0.139 | 0.062–0.313 | 0.003   |

the meatus. Subsequently, we degloved the penile skin to the root of penis along the Buck's fascia. The urethral plate was transected at the most obvious curvature of the penis. The fibrous cord on the ventral side of penis was loosened, and the external urethral orifices together with the urethral plate is free adequately. (Figure 1c,1d). The artificial erection test was performed to check whether the penis was fully straight. If the penis still had more than 15 degrees of curvature, the dorsal tunica albuginea was tightened after the dorsal neurovascular bundle of the penis was dissociated to completely correct the curvature of the penis. (Figure 2a,2b) Trimmed the urethral meatus so that the end was angled and fixed to the ventral tunica albuginea. (Figure 2c,2d) We

transversely cut the skin at the junction of the inner and outer prepuce plates on the dorsal side of the penis, and a rectangular flap with vascular pedicle was separated. The length was based on the length required for the new urethra, and the width was about 1.2cm. (Figure 3a,3b) The flap was then wrapped around a 6-8 Fr urinary catheter, which was continuously sutured to form a skin tube. We released both wings of the glans, then the tube was transferred to the ventral side of the penis. (Figure 3c,3d) The distal end of the tube was poked from the subcutaneous tunnel of the glans to the scaphoid fossa to form a new urethral meatus. The next step was to free both wings of the glans, which wrapped the new urethra without tension. The skin tube and the back wall of the



**Figure 1.** One-stage urethroplasty :a-b severe hypospadias appearance before surgery;c-d Male Circumcision, transect the urethral plate, traction glans, detach the penile skin along Buck's fascia to the base of the penis, loosen the fibrous scarring on the ventral side of the penis, but bad performance for strengthening the penis.



**Figure 2.** One-stage urethroplasty :a-b free the dorsal vascular-nerve bundle of the penis plus do a tightening of the dorsal tunica albuginea, completely correcting the penis curvature, and erection test the penis is straightened.; c-d free the urethral orifice and see the distance between the urethral orifice and the glans defect is approximately 4.0 cm.

**Table 2.** Comparison of PPPS scores of children's parents for penile appearance after hypospadias surgery in the two groups [M (P25, P75)]

| Groups            | Research Group (n=36) | Control Group(n=31) | Z      | P     |
|-------------------|-----------------------|---------------------|--------|-------|
| Urethra           | 2(2,2)                | 2(1,2)              | -2.116 | 0.034 |
| penis length      | 2(2,2)                | 2(2,2)              | -1.128 | 0.259 |
| Glans penis       | 2(2,2)                | 2(1,2)              | -1.710 | 0.087 |
| Penis skin        | 2(2,2)                | 2(1,2)              | -3.082 | 0.002 |
| Penile curvature  | 2(2,2)                | 2(2,2)              | -0.888 | 0.375 |
| Penile Appearance | 2(2,2)                | 2(1,2)              | -2.426 | 0.015 |
| Total Score       | 12(11,12)             | 10(9,12)            | -2.818 | 0.005 |

external urethral meatus were made of oblique anastomosis, and the anterior wall was preserved for the fistula. The foreskin was dorsally incised, and transferred to the ventral side. Subsequently, the skin of the ventral side of the penis was sutured to the urethra at the preserved fistula to form a fistula, about 3mm in size (Figure 4a,4b). The fistula was located at the root of the penis, and the remaining skin was sutured with absorbable thread. The postoperative catheter is retained in place for 2-4 weeks (Figure 4c,4d).

The children in the research group underwent a second operation 1 year after the first operation, and the specific surgical procedures were as follows: Initially, A 6 Fr drainage tube was inserted into the urethra tract through the urethral meatus. The flushing of the urinary tract was conducted with iodophor, and the presence of fistulas other than the active fistula was checked. A 6F balloon catheter was then inserted, and 4-0 proline sutures were employed to provide traction glans. A circular incision was made about 0.2cm from the urethral fistula, and the fistula was meticulously freed up to the urinary tract. The fistula was trimmed, followed by interrupted suture using 7-0 absorbable line. Subsequently, we freed the subcutaneous fascia around the fistula and used 7-0 absorbable line to suture subcutaneous fascia, effectively covering the fistula till satisfied. The skin was closed using 6-0 absorbable sutures. The penis was then dressed with particular attention to maintain blood supply to the glans. In addition, if the skin of the middle and distal penis was bloated, we would remove the excess foreskin. The 8F urethral catheter was indwelled and removed 2-3 weeks after surgery.

The Control Group: Most of the surgical procedures, including the selection of the incision at the inner prepuce plate, the method of correcting penile curvature, the separation of the pedicled rectangular flap, the suture of the skin tube and the management of glans, were the same as the first operation of the research group. The difference was that, the skin tube of the control group was transferred to the ventral side and the proximal end of the tube was anastomosed oblique to the original meatus. The postoperative catheter was also kept for 2-4 weeks.

All surgeries were performed by a senior doctor.

#### Observational indicators

(1) Two groups of patients' age at surgery, preoperative penile length, and regular follow-up for observing complications such as urethral fistula, urethral stricture, urethral diverticulum, recurrent penile curvature, and glans dehiscence.

#### (2) Pediatric Penile Perception Scale

To assess postoperative satisfaction regarding the appearance of children who have undergone hypospadias surgery, this study employs the Pediatric Penile Perception Scale (PPPS). The scale was developed by Weber et al and contains six scoring items: penile length, urethral meatus position and shape, glans penis shape,

penile skin shape, penile curvature, and overall penile appearance.<sup>(3)</sup> Each item is scored from 0 to 3, where 0 represents very dissatisfied and 3 represents very satisfied. In this research, all the assessments of children were conducted at the 3-month postoperative mark. Considering that all the patients were under 10 years old, the subjective evaluation of the parents was considered a more accurate reflection of the children's postoperative penile morphology satisfaction. Therefore, the scales were completed by the parents of the patients.

#### Statistical methods

We used SPSS 21.0 software for statistical analysis. For normal distributions' data, they were presented as means ( $\pm$  standard deviation) and the independent samples t-tests were applied to compare the differences between the two groups; Data that do not conform to normal distributions were expressed as medians and interquartile range M(P25, P75) and analyzed using the Mann-Whitney U test for comparison between groups; Unordered categorical variables were expressed as case numbers and percentages, and comparisons across the two groups were carried out using chi-square test or Fisher's exact test to evaluate inter-group disparities. All statistical analyses were performed using two-sided tests, and differences were considered statistically significant at  $P < 0.05$ .

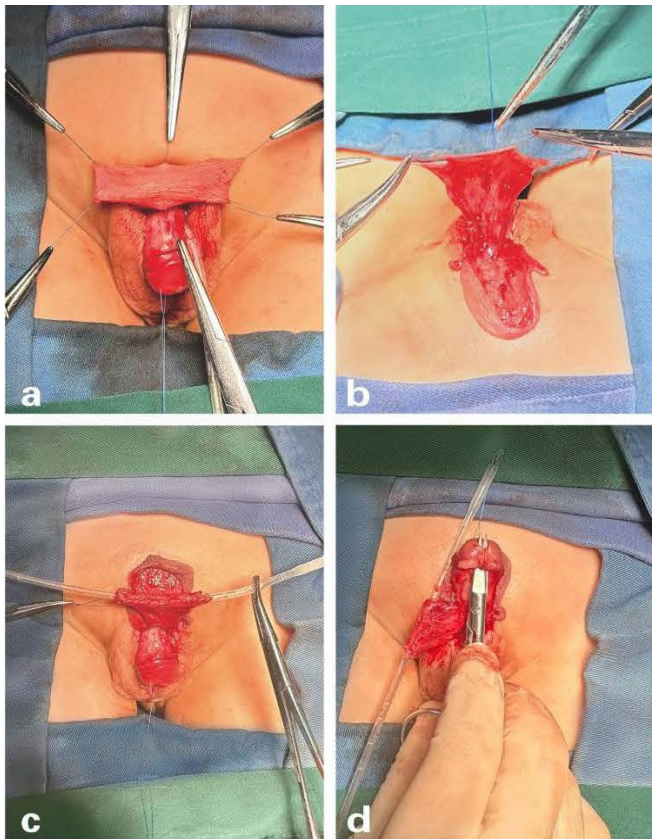
## RESULTS

### Basic information

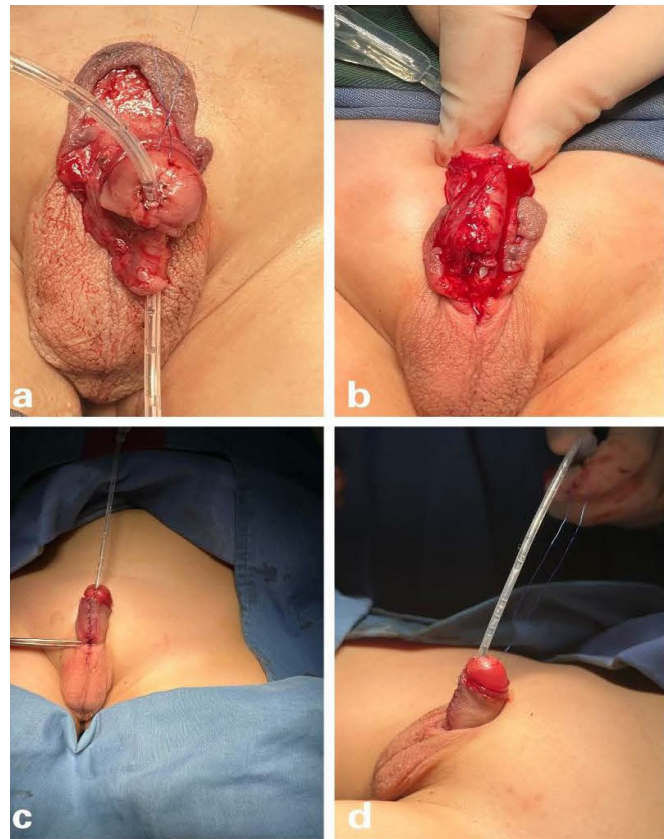
The research group consisted of patients with an age range of 1 to 6 years old, with a mean age of ( $3.61 \pm 1.08$ ) years; The post-operation penis length ranged from 2 to 4 cm, with a mean length of ( $2.13 \pm 1.07$ ) cm. In the control group, the ages ranged from 1 to 5 years old, with a mean age of ( $3.57 \pm 1.09$ ) years, and the post-operation penis length ranged from 2 to 5 cm, with a mean length of ( $2.16 \pm 1.08$ ) cm. There was no statistically significant difference between the basic data of the two groups ( $P > 0.05$ ).

### Postoperative follow-up results

The postoperative follow-up period for children in both groups ranged from 12 to 60 months, with a mean duration of 33 months. In the research group, there were 6 cases of postoperative complications after the second stage operation, including 3 cases of urinary fistula and 2 cases of urethral stricture, while in the control group, there were 13 cases of postoperative complications, including 5 cases of urinary fistula, 4 cases of urethral stricture, and 1 case of glans dehiscence. Comparing the incidence of urethral fistula, urethral stricture, and total complications between the two groups, the research group had a statistically significant lower rate ( $P < 0.05$ ) than the control group, and there was no statistically significant difference in the incidence of glans dehiscence, urethral diverticulum, and recurrent penile



**Figure 3.** One-stage urethroplasty: **a-b** Transverse island flaps approximately  $40 \times 11$  mm; **c-d** make the skin at the junction of the inner and outer prepuce plates on the dorsal side of the penis to island pedicled flaps, then suturing it into a tube.



**Figure 4.** One-stage urethroplasty: **a-b** Poke the end of the tube out from the subcutaneous tunnel of the glans to fossa navicularis of the glans to form a proper external urethral orifice. **c-d** Postoperative appearance of hypospadias.

curvature between the two groups ( $P > 0.05$ ), as shown in **Table 1**.

#### **Comparison of PPPS scores on penile appearance between the two groups**

We distributed PPPS questionnaires among patients' parents at the end of postoperative follow-up. A total of 67 questionnaires were collected, and the response rate was 100%. The results showed that compared with the control group, there was no difference in parental satisfaction between the children in the research group in terms of penile length ( $p = 0.26$ ), the shape of the glans ( $P = 0.087$ ), and penile curvature ( $P = 0.38$ ). However, in terms of urethral meatus position and shape ( $P = 0.034$ ), the shape of the penile skin ( $P = 0.002$ ), and overall appearance of the penis ( $P = 0.015$ ), the research group exhibited a higher level of parental satisfaction than the control group ( $P < 0.05$ ). Details are presented in **Table 2**.

#### **DISCUSSION**

Hypospadias is a common congenital malformation in the pediatric genitourinary system, which has undergone several advances and evolutions in treatment.<sup>(4)</sup> Surgery remains the only effective treatment for addressing hypospadias. However, the choice of surgical approach remains highly controversial.<sup>(5)</sup> Proximal hypospadias is not only considered as the ectopic urethral meatus but also frequently associated with a small glan, inadequate penile skin, severe penile curvature, etc. These factors make the complication rate of proximal

hypospadias surgery much higher than that of distal hypospadias. The pertinent literature reports the complication rate of proximal hypospadias ranging from 45% to 68% for proximal hypospadias.<sup>(6)</sup>

Urethroplasty of proximal hypospadias can be performed in two principal approaches, namely, one-stage and two-staged repairs, with the choice of procedures closely related to the transection of the urethral plate. In the one-stage procedure, the most commonly used techniques to preserve the urethral plate include TIP and Onlay, while the most commonly used techniques without preserving the urethral plate include Duckett's procedure, Duckett+Duplay, and Urethroplasty using a pedicled foreskin flap based on the urethral orifice (Koyanagi's procedure).

One-stage surgery has many advantages, such as reduced hospitalization duration, lower hospitalization costs, and diminished anesthesia-related risks. However, it asks for the execution of a one-time complex procedure, the operator of which has to master multiple techniques. What's more, it has a high complication rate. One-stage transverse preputial Island flap urethroplasty (Duckett's procedure) is the classic procedure for the treatment of proximal hypospadias, which was reported by Dr. Duckett in 1980, based on the vascularized flap coiling procedure of Asopa and Hodgson.<sup>(7)</sup> The foreskin is a good alternative material to the urethra with accessibility, resistance to urinary irritation, absence of hair, and the potential for more satisfactory penile appearance after the Duckett procedure. However, the disadvantages of the Duckett procedure are also

more obvious; the whole procedure is more complicated, requires the surgeon's higher surgical skills, and has a longer learning curve. The complication rate after the one-stage Duckett procedure is high, and the overall complication rate after the Duckett procedure reported in the literature ranged from 24% to 67%.<sup>(8)</sup>

In recent years there has been a gradual increase in the number of surgeons choosing two-stage repair for the treatment of proximal hypospadias. Results of an online survey of 377 participants from 68 countries show that 76.6% of surgeons prefer two-stage repair of proximal hypospadias.<sup>(8)</sup> The two-stage surgery allows a complex surgical procedure to be split into two relatively simple surgeries. Surgeons remove the contracted urethral plate and correct the penile curvature during the first surgery. Some of them concurrently reconstruct a new urethral plate using free graft or pedicled flaps. In the second operation, surgeons shape the new urethra, employing pedicled flaps, free graft, or a urethral plate that has already been reconstructed during the first surgery. Common two-stage procedures include the Byars procedure, Bracka procedure, and so on. However, some scholars believe that the lack of blood supply to the free graft increases the risk of avascular necrosis, which can significantly impact subsequent surgery.<sup>(9)</sup> In 2016, Chen et al. introduced a new two-stage surgical method, which performs penile straightening and tube pedicled preputial flap to form the new urethra at the first surgery, and this step is the same as that of one-stage Duckett's surgery.<sup>(10)</sup> However, the difference is that a about 0.5 cm-long fistula is actively formed between the new proximal urethral meatus and the original meatus. A substantial portion of the child's urine is drained from this fistula after the procedure, which is then repaired at the second procedure after 6-12 months. The emergence of the two-stage Duckett procedure of active fistulization has provided a novel approach for hypospadias repair. We have been using the Duckett procedure with active fistulation to repair proximal hypospadias since 2017, and the overall complication rate in the research group is 13.9%, which is significantly lower than that of the control group, which is 38.7%, and the difference is statistically significant ( $P < 0.05$ ).

The incidence of glans dehiscence reported in the literature ranged from 0% to 8%.<sup>(11)</sup> Glans dehiscence significantly affects the overall appearance of the penis and decreases patient satisfaction after surgery. In this study, no glans dehiscence occurred in the research group, and one case of glans dehiscence occurred in the control group, with no statistically significant difference between the two. This outcome in the two groups aligns with the same procedure they underwent, involving freeing the glans wings and wrapping and shaping the glans again. We used conservative treatment in this case of a glans dehiscence patient, and the urethral meatus was located in the coronary groove at last.

Urinary fistula is the most common complication of proximal hypospadias. The literature reports an incidence rate of urinary fistula after one-stage Duckett's ranging from 10% to 23%.<sup>(12)</sup> In this study, the incidence of urinary fistula in the research group was 8.3%, which was much lower than that of 16.1% in the control group, and the difference was statistically significant ( $P < 0.05$ ). Zhang et al. reported the incidence of urinary fistula in active fistulation two-stage Duckett opera-

tion to be 7.3%, which is consistent with our results.<sup>(13)</sup> The reasons for the occurrence of urinary fistula may be multifactorial, including factors such as poor blood supply, scarring, urinary extravasation, poor suturing technique, and postoperative infection.<sup>(14)</sup> The long urethral defect in the proximal hypospadias hampers the blood supply to the ends of the new urethra formed by pedicled preputial. In the two-stage Duckett procedure, the length of the neourethra formed by the coiled tube is shorter than the length of the defective urethra because of the active fistulation for proximal hypospadias. Therefore, when selecting a foreskin pedicled flap, flaps' blood supply can be more adequately ensured and the effects of inadequate blood supply can be reduced. In addition, because of the presence of the fistula, secretion drainage in the urethra is more fluid, reducing the potential for local infection. The combination of these factors may account for the eventual reduction in the incidence of urinary fistula.

Urethral stricture, particularly anastomotic stricture, is a common complication after Duckett procedure. The incidence of urethral stricture after Duckett procedure has been reported to be 5%-13% in previous literature.<sup>(8,12)</sup> The occurrence of stricture may be associated with several factors, including inadequate blood supply, a narrow anastomotic circumference, scarring constitution, significant inflammation and suture technique. In addition, compression of the fascia skin flap and twisted urethra may also be responsible for stricture.<sup>(14,15)</sup> Because of painful urination and difficult management, urethral stricture is a postoperative complication that surgeons try to avoid. In our study, the incidence of urethral stricture in the research group is 5.6%, which was lower than the incidence of 12.9% in the control group, and the difference is statistically significant ( $P < 0.05$ ). In fact, we can consider the first operation as the healing of the posterior wall of the anastomosis and the second operation as the healing of the anterior wall of the anastomosis. Staged management of the anastomosis reduces the risk of anastomotic stenosis. In addition, active fistulation allows most of the urine to pass through the stoma, allowing the new urethra to grow and heal adequately with the surrounding tissue, reducing the possibility of urethral stricture due to urethral distortion. Similar findings were reported by Chen and other studies, demonstrating that the incidence of urethral stricture after two-stage Duckett's procedure is significantly lower than that of one-stage Duckett's procedure.<sup>(10)</sup>

Urethral diverticulum is one of the major complications after hypospadias, particularly in proximal hypospadias. The literature has reported an incidence of urethral diverticulum after hypospadias ranging from 0% to 21%.<sup>(16)</sup> The formation of urethral diverticulum may be closely related to distal urethral stricture and urethral distortion.<sup>(17)</sup> However, in this study, there were 2 cases of urethral diverticulum in the control group that was not combined with urethral stricture, and there were no cases of urethral diverticula in the research group. The data showed a significant difference between the two groups ( $P < 0.05$ ). Charles et al. also reported that only 1 out of 13 cases of postoperative urethral diverticulum after hypospadias had a urethral stricture.<sup>(5)</sup> Therefore, we speculate that the occurrence of urethral diverticula in the two cases of the control group may be related to simple urethral distortion. In the early postoperative

period, the urethral wall lacks strong support, and the pressure of urine flow on the urethral wall causes the weak urethral wall to bulge out, eventually forming urethral diverticulum. Most of the urine is discharged from the fistula after the active fistula of Duckett procedure and reduces the impact on the new urethra. As a result, the newly formed urethra grows and heals fully with the surrounding tissues, which increases the stability of the urethra and minimizes urethral twisting, ultimately reducing the occurrence of urethral diverticulum.

In the treatment of hypospadias, the objective of surgery is not only to restore normal penile function but the improvement of postoperative penile appearance should also be emphasized. Unsatisfactory penile appearance may have long-term implications for a child's quality of life.<sup>(18)</sup> Several follow-up studies have focused on post-operative penile appearance. For example, Thiry et al studied the penile appearance of post-pubertal children after hypospadias surgery and found that the children's satisfaction with penile appearance was 87% and 83%, respectively.<sup>(19)</sup> Ceccarelli et al followed up on the penile appearance of the study population including 187 children after hypospadias surgery and found that the children's and their parent's satisfaction with penile appearance was 83% and 87%.<sup>(6)</sup> Because of the young age of the patients in this study, we used the PPPS scale to assess the satisfaction of the parents of the children. The results showed that after two-stage active fistula urethroplasty, the parents were more satisfied with the penis skin shape as well as the overall appearance of the penis compared to the one-stage Duckett procedure. The second procedure of our two-stage Duckett procedure with active fistula not only performed urinary fistula repair or proximal urethroplasty but also shaped the distal penile skin for cosmetic secondary repair, resulting in an improvement in the overall appearance of the penis. However, both procedures, whether one-stage or two-stage, had the same management of the external urethral orifice, glans, and penile curvature correction, which is consistent with the PPPS evaluation results. However, this study still has some limitations, including its relatively small sample size and a single-center retrospective study. Additionally, nutritional status was not excluded as a confounding factor. And the statistical data of long-term complications such as recurrent penile curvature were insufficient. Further clinical studies with larger sample sizes and longer-term follow-up are needed to advance our understanding of this procedure and its outcomes.

## CONCLUSIONS

Compared with the one-stage Duckett procedure, the two-staged procedure with active fistulation significantly reduces the overall complication rate of proximal hypospadias, especially the incidence of urinary fistula, urethral strictures, and urethral diverticulum, and to a certain extent, improving the parents' satisfaction with the postoperative penile appearance. Therefore, we believe that the staged Duckett procedure with active fistulation is a very effective method for the treatment of proximal hypospadias.

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## CONFLICT OF INTEREST

All authors acknowledge that there is no conflict of interest.

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