The modified Koyanagi technique versus two-staged urethroplasty using buccal mucosal graft in managing proximal hypospadias: a randomized clinical trial

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Background
One of the most challenging cases in correction is proximal hypospadias. There are many techniques used, but no technique has shown success or acceptance universally. The purpose of our study is to compare the modified Koyanagi (MK) technique and two-staged urethroplasty by buccal mucosal graft techniques in managing proximal hypospadias types regarding rate of success, postoperative complications, and cosmesis.
Patients and methods
A total of 40 patients with proximal hypospadias types were enrolled, and these patients underwent surgical repair using MK technique or two-stage urethroplasty using buccal mucosal graft techniques. Patients were randomized into two equal groups (n=20): group A underwent MK technique, and group B underwent two-staged urethroplasty using buccal mucosal graft techniques. The follow-up ranged from 6 to 18 months.
Results
The rate of success was 60% in group A compared with 75% in group B. Higher incidence of fistula was in group A (six cases) than group B (two cases), urethral stricture was the same (two cases in each group), meatal stenosis was less in group A (two cases) than group B (eight cases), and residual chordee was more in group A (two) than B (one), with no penile rotation in both groups.
Conclusions
The MK for repair of proximal hypospadias is a good technique and gives successful surgical results but requires meticulous technique and tedious preservation of blood supply.
Two-staged urethroplasty is a technically straightforward and feasible technique, with less fistula rate, but requires more time, as a two-session operation, with good results in severe chordee and success rate.

Keywords:
hypospadias, modified Koyanagi, two-staged urethroplasty

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Background

In 10–20% of all hypospadias, proximal hypospadias with chordee occur with their complex nature. Penoscrotal transposition occurs in few cases. There are many techniques (ranging from single-stage 'tubes' to staged repairs), as most techniques have no good outcome [1].

In severe hypospadias, modified Koyanagi (MK) repair is a two-staged repair done in one setting and had an extra-benefit of associated transposition correction. Preoperatively, one of the essential prerequisites is the hormonal stimulation. It is the recommended technique despite its high rate of reoperativity, as it contributes to a pleasant cosmetic outcome while also minimizing the average operations' number most children would need [2].

Therefore, techniques of Yoke for repairing hypospadias are deemed a secure and efficient technique for repairing severe proximal hypospadias owing to the continuity of skin flap of the prepuce and ventral urethral plate with vascular pedicle blood supply [3].

The typical two-staged technique includes first, penile curvature correction with ventral bed of tissue preparation (buccal mucosa, preputial skin grafts, or transposed flaps of prepuce), and second, the neourethral plate is tubularized. There are several tissues that can be harvested easily from the inner cheeks: harvesting two strips (one from each cheek) if there is a need for a long strip, and Harvesting long graft of the buccal mucosa (from inner cheek to lower

lip) may result in scarring and deformity of mouth angle. However, the buccal mucosa basement tissue has an elastin-rich connective tissue which is stiff and can provide a good scaffolding preventing a diffuse diverticulum. The durability and easiness of suturing and harvesting may be explained by high elastin in the buccal mucosa. The neo meatus persists as a vertical slit, offering a good aesthetic look with no urinary flux issues [4].

The aim of this study is to compare the MK technique and two-staged urethroplasty by buccal mucosal graft techniques in managing proximal hypospadias types regarding rate of success, postoperative complications, and cosmesis.

Patients and methods

This is a prospective randomized parallel clinical study on 40 children aged from 6 to 24 months diagnosed as proximal hypospadias from May 2017 to May 2019. The opening of urethra was at or just distal to the penoscrotal junction in all children, with no previous history of any hypospadias surgeries. Prophylactic antibiotics were administered intraoperatively and during the whole hospital stay in the form of intravenous injection antibiotics.

All patients were followed up for 6 months to 1.5 years. Informed written consents were obtained from the parent and/or legal guardian of the child, and the study was approved by the local ethics committee.

The children were classified equally (n=20; group ratio 1 : 1) into two groups: group A included children undergoing repair with MK technique, and group B included children undergoing repair with two-staged urethroplasty using buccal graft. Group allocation was done by the sealed envelope technique by a doctor who did not participate in the study.

All children were subjected to the following:

(1) Clinical evaluation:
   (a) History taking: personal, family, past history of medical diseases, and history of surgical operations.
   (b) Clinical examination.
(2) Investigations:
   (a) Complete blood count.
   (b) Bleeding profile (prothrombin concentration time and international normalized ratio).
   (c) Renal ultrasound to exclude other congenital urological anomalies.

Karyotyping was done for children with penoscrotal hypospadias or in cases with bifid scrotum.

Patients with distal hypospadias, circumcised penis, undiagnosed ambiguous genitalia, and previously repaired hypospadias were excluded. Local examination inspected the size of meatus (narrow or wide), surrounding around, size of urethral plate (narrow or wide), any scarring, presence of prepuce (its shape), penis size, skin deficiency on the ventral aspect of the penile shaft and/or torsion, presence of penile rotation or chordee, penoscrotal transposition presence, urine stream nature, and associated local anomalies.

Operative technique

In group A

Before starting the operation, skin incisions were marked. The outer skin incision enclosed the hypospadias meatus proximally and spread laterally and dorsally to the penile foreskin until it reached at 12 o'clock position (Fig. 1).

Outlining of the inner circum-coronal incision of the dorsal foreskin was done and then circumferential incision less than 5 mm proximal to the corona.

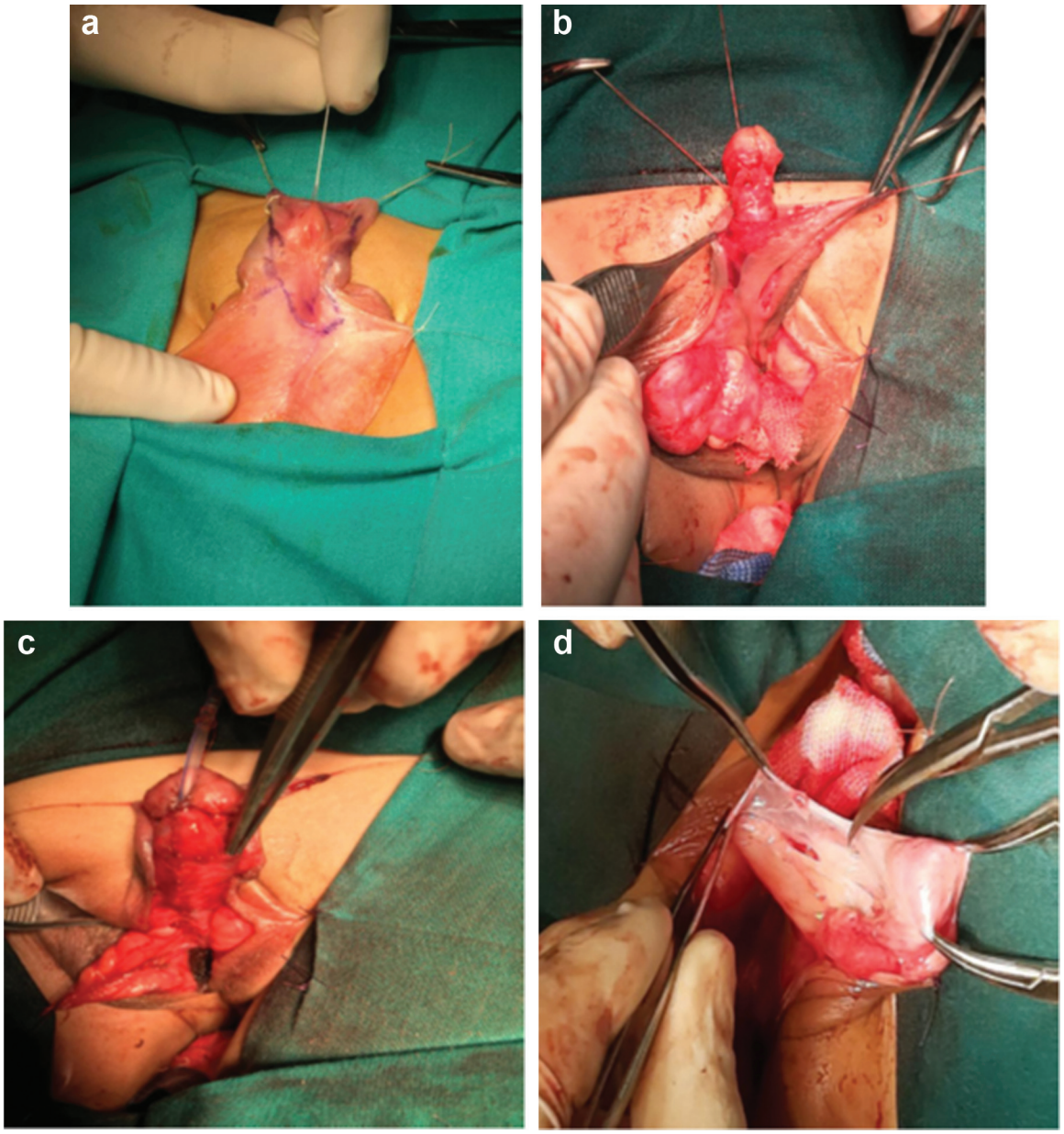
An appropriately sized silicon Foley catheter (mostly 6 or 8 F) was inserted. The inner incision is made first along the full circumference of the previous-defined skin marking. Dartos mobilization and orthoplasty are needed with harvesting of the flap. When it was completed, the penile shaft was almost degloved. An artificial erection test was done to assess the presence and extent of chordee. Classic orthoplasty was also done when the urethra was mobilized enough and chordee removed completely. Chordees were usually corrected, and this was confirmed by another artificial erection. Glans cleavage and creation of glanular wings is done by a vertical midline incision. Formation of the urethra was as follows: the inner edges of the flaps are sewn together with fine absorbable suture (6–0).

Once this has been accomplished, one has essentially created a neourethral plate. The outer edges of the skin flaps can then be sutured together to create the neo urethra. The dartos wrap is easier to harvest, but the tunica vaginalis wrap seemed more reliable.

Glanuloplasty is done by an approximation of the glanular wings using 6-0 mattress sutures.

Byars flaps of dorsal foreskin and its subcutaneous tissue can be used to cover the new urethra.

Figure 1



Group A (a) outlining of skin incision; (b) centralization of the flap; (c) neo urethra tubularization; (d) tunica vaginalis flap.

Skin closure and dressing by dressing of light gauze was applied to the wound, and the penis held in dorsiflexion against the suprapubic area.

Postoperative care and follow-up

An appropriate intravenous fluid is taken until tolerating oral feeding. To prevent postoperative urinary tract infection, cefalexin was administered immediately postoperative till 2 days after removal of urinary catheter. Gentamicin ointment was put every day at the site of catheter emergency.

Clinical assessment of the procedure was done regarding the following: condition of the skin, glans shape, meatal final position, urinary stream, and direction and size of neourethral meatus. The functional, anatomical, and cosmetic results were used to assess the outcome, and excellent outcome was 'cosmetically and anatomically normally looking penis able to direct a forceful urine stream.' A minor defect that would require no further management is considered a satisfactory outcome. A complication is anatomical or functional defect that requires surgical intervention. The management is considered to be failed where there is complication that requires complete reconstruction.

In patients of group B

First stage

The first phase is critical, as it lays the groundwork for the success in the second stage for a straight, aesthetic,

and ordinarily working penis. It consists of correction of chordee and graft harvest (Fig. 2).

Laying the graft to the graft bed, the glans is divided in midline with creation of two glanular wings by lateral stay sutures, and the graft is specifically laid down with a V-shaped inset of the graft onto the back wall of the meatus of urethra to decrease the risk of eventual anastomotic stricture.

Then suturing the graft is done to the graft bed margins by interrupted 7-0 polydioxanone monofilament absorbable suture with immobilization of the graft.

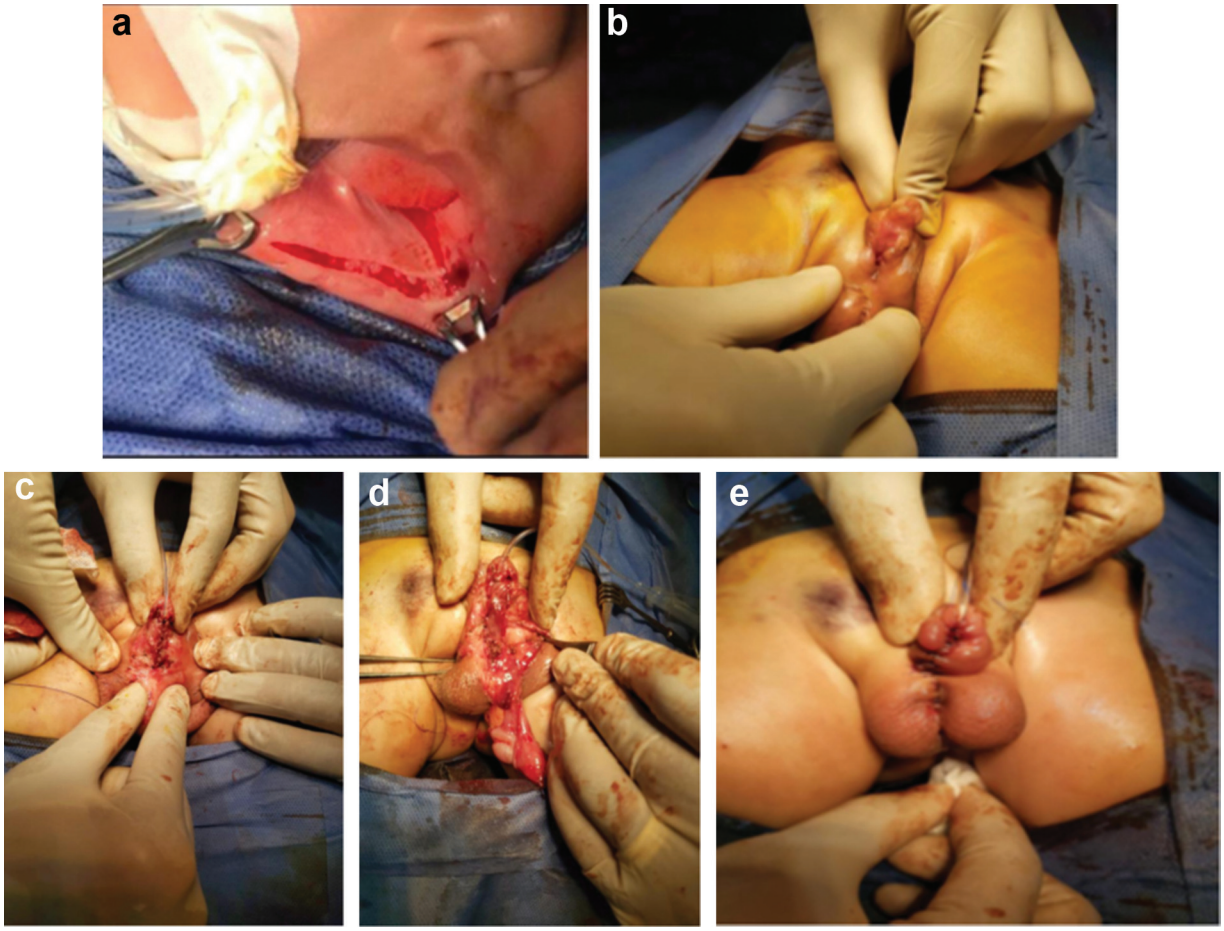
In urethra, passing an 8- or 10-catheter into the bladder was done. A roll of grass or Vaseline gauze of appropriate width and thickness is wrapped across the catheter to ensure the glans' edges are well apart. Two lateral sutures are used to create the first 'tie-over,' and many looped 4-0 nylon sutures pick up the shaft's graft and skin margins together with the shaft's tunica and are connected in the midline with knots. This strong 'tie-over' dressing ties the graft up and avoids hematoma development.

Second stage

A successful graft is smooth and well vascularized, and the glans is sharply delineated. A U-shaped strip of the grafted buccal mucosa is marked from the ventral limit of the neo-external urethral glanular meatus with the lower limits of the U skirting closely around the margin of the proximal urethral meatus U-shaped incision over the graft strip. If graft taken is successful, it looks shiny pink as matured mucosa. Shaft skin is mobilized before tubing of the neo urethra.

Harvesting of the subcutaneous tissue on a vascularized pedicle is done for 'waterproofing' (subcutaneous tissue harvested from the proximal penile shaft and scrotum). Subcutaneous tissue is harvested on its vascular pedicle from the penile shaft skin. The glans wings are mobilized, and a triangular wedge of glans tissue is excised to obtain a secure glanular approximation. Glans closure is performed by interrupted stitches

Figure 2



Group B (two stage): (a) buccal graft is harvested from the inner check. (b) Graft after complete healing and good area from proximal meatus to the tip of the gland. (c) Formation of the neo tube by two layers: inner interrupted and outer continuous using Vicryl 6.0 and 5.0, respectively. (d) Covering of the neo tube with tunica vaginalis. (e) Closure of the skin around the shaft of the penis and correction of the prepenile scrotum.

using 7-0 PDS, or it can be done in two layers. It is desirable to remove all subcutaneous tissue and excess skin to prevent a bulky penis. The skin is approximated, and compressive dressing completes the second stage.

In the 10th postoperative day on the ward, the catheter and dressing were removed. Penile skin is transposed, followed by completion of repair of a circumcised penis. Reviewing of the child was done at the second month in the outpatient clinic.

Statistical analysis

All data were statistically analyzed using Statistical Package of Social Science (SPSS version 22) (Statistical analysis was done using IBM SPSS statistics for windows, Version 23.0, Armonk, NY: IBM Corp). Quantitative data were expressed as a mean±SD, whereas qualitative data were expressed as frequency and percentages. Qualitative variables were compared using a χ^2 test, whereas quantitative continuous data were compared using the analysis of variance test.

A *P* value less than 0.05 was considered statistically significant. A univariate analysis with linear Pearson correlation (cubic spline functions) was used to evaluate the shape of the relationship between the continuous variables and outcome.

Results

The age of children ranged from 6 to 24 months, with a mean of 18 months.

The percentage of chordee was 65% in Koyanagi group (13 patients) and 50% in two-staged group (10 patients) (*P*=0.262).

Fistula occurred in six cases in group A and two cases in group B, temporary fistula occurred in five cases four in group A and one in group B, and big fistula occurred in three cases (two in group A and one in group B). Temporary fistulae were noticed on the seventh postoperative day, and spontaneous closure occurred in 3 weeks. The big fistulae have failed conservative treatment and were closed surgically. The meatal stenosis developed in 10 cases within the first month postoperatively and all improved by regular urethral dilatation The meatal stenosis was more observed in group B (eight cases) than group A (two cases). In all cases, no penile torsion or rotation was observed following flap reflection toward the neo urethra (Table 1).

Table 1 Complications and success rate in both groups

	Koyanagi (*N*=20)		Two staged (*N*=20)		*P* value
	Number	%	Number	%	
Disruption	2	10	1	5	1
Infection	4	20	3	15	1
Urethral stricture	2	10	2	10	1
Residual chordee	2	10	1	5	1
Meatal stenosis	2	10	8	40	0.065
Fistula	6	30	2	10	0.235
Success rate	12	60	15	75	0.311
Penile rotation	0	0	0	0	–

Four cases (two from each group) had a failure by complete disruption owing to severe infection, which appeared earlier postoperatively. The success rate in group A was 60.0% compared with 75.0% in group B. The success result was defined as good cosmetic and anatomic outcome, with a direct forceful urinary stream at the end of the follow-up in one-and-a-half year.

A complication was an anatomical or functional defect that required surgical intervention (Table 1).

Discussion

One of the most challenging cases in correction is proximal hypospadias. There are many techniques used, but no technique has shown success or acceptance universally. Many techniques are multistaged which is a big disadvantage but they have the advantage of fixing different anatomical problems step by step providing a time for solving its different aspects [2].

For proximal hypospadias, Koyanagi *et al.* [5] demonstrated a meatal-based foreskin flap repair in 1984. They used the preputial skin inner layer for constructing a neo urethra [2].

This operation had a comparatively high complication rate, as no significant effort was made to maintain skin flaps vascularity. Modifying the procedure (yoke repair) with preserving flap blood supply resulted in a decreased complication rate [6].

The MK technique had a higher rate of success owing to preserving the skin flaps' lateral vascularity without depending on the emerging microvasculature from the urethral meatus and corpus spongiosum [6].

Two-staged repair is used to correct proximal hypospadias with ventral curvature more than 30° present after dissecting the ventral dartos and scrotal

attachment of the penis transecting the urethral plate. In 2008, Snodgrass began to replace the entire urethral plate from the native urethra to the tip of the glans with wider graft taken from the oral mucosa, and after 6 months, the graft is vascularized and is ready for tubularization [7,8].

In our study in group A, six (30%) of 20 patients developed urethra cutaneous fistula. Four of them closed spontaneously within 1 month and two patients needed a second operation for repair of the fistula after 6 months.

Hayashi *et al*. [9] operated on 24 patients using the MK technique for the one-stage repair and the correction of the penoscrotal transposition. Complications occurred in five patients (four patients had fistula).

In our study, 20 patients with age ranged 6–24 months underwent the one-stage MK repair for severe proximal hypospadias, and six (30%) patients developed urethra-cutaneous fistulae.

Elsaied *et al*. [10] operated on proximal hypospadias. Rate of success was 90% with good cosmesis and adequately sized glanular meatus. Incidence of complications was 10%, that is, 6.7% urethrocutaneous fistula and 3.3% urethrocutaneous fistula, which closed postoperatively within 3 weeks without surgery, and the second child was operated 6 months later for closure of fistula.

Vepakomma *et al*. [1] operated on 24 patients, and a urethra cutaneous fistula resulted in five (20.8%) patients.

As we operated also on 20 patients with two-staged procedure, and the fistula rate was very low (two patients) (10%), and the *P* value was significant (0.032).

Snodgrass and Bush [7] operated on 22 patients with proximal hypospadias, and complication resulted in 50%, which included one fistula and glans dehiscence and one recurrent ventral curvature, and on serious cases (33%), they used extended wing dissection, and less complication resulted, including one fistula and three glans dehiscence.

In our results, glans dehiscence resulted in six cases after two-staged repair. This is attributed to using the technique of extended wing dissection as described by Snodgrass and Bush [7] in proximal hypospadias cases, which is associated in most of cases with small glans penis.

Nerli *et al*. [12] operated on 14 patients with proximal hypospadias. Complication occurred in five patients, where one (7%) patient had complete breakdown of the repair within 2 weeks postoperatively. Three (21.6%) patients had urethrocutaneous fistula. All of these three children underwent repair of the fistula and had a successful outcome. Stenosis of the meatus occurred in one (7%) patient, with poor stream, and this child was taught self-meatal dilatation.

Elkassaby *et al*. [13] showed that 8% of the patients developed infection, which led to complete failure on the fifth postoperative day, and from the start, it was severe.

We encountered a meatal stenosis in eight (40%) patients in the two-stage technique and only one (5%) case with MK technique. All cases showed improvement by regular dilatation twice weekly for 3 months by a 6–8-Fr urethral catheter.

Elsaied *et al*. [10] used MK technique on 30 cases with proximal hypospadias. No cases developed meatal stenosis. The postoperative follow-up was mainly clinical. Dilatation was not required in any case, but to ensure patency, meatal probing gently was done for the first month.

No cases developed urethral stricture, complete necrosis, or residual chordee, and they stated that their results are better than other studies such as Emir *et al*. [6].

Vepakomma *et al*. [11] have operated on 24 patients using Koyanagi technique and showed major disruption in one patient, stenosis of the meatus and distal neo urethra (which required laying open of distal urethra) in one patient, and break down of the glans in one patient.

In two cases, complete disruption of the repair occurred and two cases of urethral stenosis by using Koyanagi technique but by using two-stage technique one case has developed urethral stricture and same two cases developed major breakdown of the repair after the second stage.Hayashi *et al*. [9] operated 20 patients with one-stage MK for proximal hypospadias. Success rate was 70%. However, 15% of the patients developed urethra cutaneous fistulae and 15% of the patients developed stenosis in the meatus.

A retrospective review [14] of 34 patients with proximal shaft to perineal hypospadias operated by two-stage technique showed that there were

complications, comprising four glans dehiscence, two fistula, one diverticulum, and one urethral stricture.

To our knowledge, the cause of complications in group A might be inadequacy of blood supply to the neourethral flaps; vascular nourishment to the neourethral flaps, which may each be several cm. long, will thus depend entirely on the blood supply coming from the region of the urethral meatus and its surrounding corpus spongiosum (modification of the Koyanagi technique for the single-stage repair of proximal hypospadias [6].

Conclusions

The MK for repair of proximal hypospadias is a good technique and gives successful surgical result but requires meticulous technique and tedious preservation of blood supply.

Two-staged urethroplasty is a technically straightforward and feasible technique, with less fistula rate, but requires more time, as a two-session operation, with good results in severe chordee and success rate.

Pediatric urologists, should continue with the new procedures of one stage that can decrease the number of operative procedures to repair these anomalies, reaching an esthetic, safety, and economic perspective, especially in the era of cost containment.

Follow-up of 6–18 months in our study is not enough to evaluate long-term results, as we still have the occasional patient who presents with a severe long-segment stricture or even lichen sclerosis of the constructed anterior urethra.

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Conflicts of interest
There are no conflicts of interest.

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