Single vs. double dartos layers for preventing fistula in a tubularised incised-plate repair of distal hypospadias

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ABBREVIATION
TIP, tubularised incised-plate

Abstract  Objective: To compare the outcome of a single vs. a double-layer dartos interposition for preventing a fistula after tubularised incised-plate (TIP) distal hypospadias repair.

Patients and methods: We retrospectively reviewed the records of patients with primary distal hypospadias who had the hypospadias repaired between February 2009 and June 2011, operated by one surgeon (S.A.K.). In all of the children a standard TIP urethroplasty was performed, which was covered by a dartos fascial flap fashioned using one of two techniques, i.e. in Group I (48 patients) double dartos preputial flaps were used, and in Group II (52 patients) a single dorsal dartos flap was used and transposed ventrally via a ‘buttonhole’. The fistula rate and other complications related to each group were recorded.

Results: The mean (range) follow-up was 12 (6–22) months for Group I and 14 (6–24) months for Group II. The result was considered a success in 96% of Group I and 92% of Group II. In Group I there were no fistulae, while in Group II there were four fistulae (8%) detected; this difference was statistically insignificant ($P = 0.1$). Meatal stenosis was associated with a fistula in one patient in Group II but not in the other three. In Group I a meatal stenosis developed late after complete
healing of the urethroplasty, with no associated fistula. The repair broke down in one patient in Group I (2%).

**Conclusion:** A double-dartos neourethral cover in TIP hypospadias repair seems to be more effective than a single layer for preventing a fistula, despite there being no statistically significant difference between the groups. However, the protective effect of double-dartos flaps must be appropriately evaluated in a prospective, randomised and controlled study in more patients.

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**Introduction**

Urethrocutaneous fistula remains the most frustrating complication of hypospadias repair, with a frequency of 5–23% [1,2]. The more proximal the hypospadiac orifice the greater is the rate of postoperative urethrocutaneous fistula formation [3]. After a tubularised incised-plate (TIP) repair, fistulae are reported in up to 17% of cases [4]. The reasons why fistulae do or do not develop are not fully understood [3]. Deficiencies in local growth factors in hypospadiac skin might contribute to the high rate of healing complications after hypospadias surgery [5]. Mechanical factors could be responsible for poor healing after hypospadias repair, such as epithelial interposition between the edges of the neourethra, a high intraurethral pressure secondary to meatal stenosis, or an obstructed catheter, resulting in the disruption of the suture line, urinary leakage and fistula [6]. Also, local ischaemia was reported by Elbakry [6] as a humoral factor impairing or even suppressing the healing process of the neourethra in hypospadias surgery. Ischaemic changes can be attributed to an inadequate blood supply to hypospadiac penile skin, extensive dissection, hostile tissue manipulation, prolonged use of a tourniquet, massive postoperative oedema, haematoma with a pressure effect and finally, a tight dressing [6,7]. In an effort to reduce fistula formation and the need for repeat surgery, many strategies have been proposed, and these include the use of optical magnification, fine suture material, soft-tissue interposition, small-calibre stents, antibiotics, and new surgical approaches [3]. In the present study we compared single vs. a double-layer dartos fascia for neourethral covering as a method for preventing fistula after TIP urethroplasty.

**Patients and methods**

Between February 2009 and June 2011 all TIP urethroplasties for primary distal hypospadias, operated by, or under the direct supervision of, a senior paediatric urologist (S.A.K.), were retrieved retrospectively from a departmental database. We report only repairs covered by preputial interpositional flaps transposed ventrally via a buttonhole manoeuvre, or by double-layered flaps after splitting the midline. Local or systemic preoperative androgen therapy was not used. Circumcised patients and those with previous hypospadias repair were excluded from the study. All of the patients were followed up by the same surgeon, and their complications were assessed based on the patients’ medical records, focusing on healing problems, particularly the rate of fistula formation, repair breakdown and fibrotic stenosis.

**Surgical technique**

Under general anaesthesia, with or without a caudal block, and using a magnifying loupe, a glansular stay suture was placed in the midline along the long axis of the penis, and used for traction. A tourniquet was applied to the base of the penis to obtain a bloodless operative field. A circumferential, subcoronal incision was started dorsally and extended ventrally to join the limbs of the U-shaped incision surrounding the hypospadiac meatus. The penis was degloved, with the creation of a well-vascularised subcutaneous dartos tissue flap extending proximally to the root of the penis. The flap was then separated from the overlying preputial and penile skin. An artificial erection was induced to assess any residual chordee. The urethral plate was then incised, starting from within the hypospadiac orifice to terminate just proximal to the glans tip. The depth of incision depended on the width and grooving of the urethral plate. The incised plate was then tubularised over a 6–8-F stent, with no tension and with a one-layer running subcuticular suture (6–0 polyglactin). Tubularisation was extended to the mid-glands only, to obtain a wide meatus, thus avoiding late meatal stenosis. The glands wings were deeply dissected laterally to ensure a tension-free closure over the interposed dartos flaps. In the present study we evaluated two groups of patients, based on the techniques of neourethral coverage.

Group I included 48 patients in whom the repair was covered with double-dartos flaps. The preputial flap was split vertically into right and left sections of equal size. After visibly assessing the vascularity of the split, the preputial flap on each side was transposed ventrally and fanned out over the neourethra to reduce its bulk. The left flap was sutured to the right and left glans recession, and to the periurethral tissue, with interrupted 6/
0 polyglactin sutures. The right flap was then rotated to overlap the left one and was fixed similarly.

Group II included 52 patients in whom the dorsal preputial flap was used to cover the neourethra after being transposed ventrally with a buttonhole manoeuvre. The flap was then sutured to the glans wings over the neourethra and to the corpora cavernosa as a single layer.

The glans wings were approximated without tension. A urethral stent was secured and left for 5–7 days in all cases. A non-adhesive dressing was applied. Oral antibiotics and oxybutynin were administered until the catheter was removed, to protect against infection and bladder irritability.

**Follow-up**

The first follow-up visit was at 1 week after surgery for catheter removal and to evaluate the repair. The evaluation included a local examination and visual assessment of the urine stream to detect any fistula formation. The second follow-up visit was 2 weeks later, and a detailed history was obtained, focusing mainly on the presence of a double stream or voiding from a fistula, and any other complications. The meatus was examined physically and any obviously stenotic meatus was calibrated. The two patients with obstructive symptoms were too young for objective uroflowmetry, so we depended on a visual evaluation of the urine stream. Further follow-up visits were planned after 1 month, and then every 3 months for ≥6 months.

Success was defined as healing with no fistula, with a normal-looking meatus at the tip of the penis, and with a normal voiding force and calibre. The success rate and any complications related to each technique were recorded. Data were compared using Fisher’s exact test, with differences considered significant at \( P < 0.05 \).

**Results**

The two groups were similar in their age at surgery. The procedure was completed successfully in all of the patients, with no intraoperative complications. The mean (range) follow-up was 12 (6–22) months for Group I and 14 (6–24) months for Group II. The results were considered successful in 96% of Group I and 92% of Group II. In Group I no fistulae were reported, while in Group II four fistulae (8%) were recorded. The difference in fistula rate between the groups was not statistically significant (\(P = 0.1\)).

In Group I a meatal stenosis developed late, after full healing of the urethroplasty with no associated fistulae, and it responded to regular meatal dilatation for 8 weeks.

In Group II a urethrocutaneous fistula was associated with meatal stenosis in one patient but not in the other three. The fistula associated with stenosis healed with frequent meatal dilatation. Of the other three fistulae, one healed spontaneously while the other two were surgically closed after a 6-month interval. No cases of repair breakdown were reported in Group II, but in Group I there was one breakdown that was repaired after a 6-month interval; that was covered with a tunica vaginalis flap, with successful outcome (Table 1).

**Discussion**

The present study indicates that covering the neourethra in a TIP hypospadias repair with a vascularised fascial flap decreases the possibility of fistula development and other healing problems. A urethrocutaneous fistula is an inherent complication of hypospadias repair, and represents the most common problem after such surgery, occurring at various rates [6,8–11]. Well-vascularised interposition tissue between the penile skin and the neourethra is essential for preventing a urethrocutaneous fistula [6,12–14]. Without dartos flaps fistulae were reported in 15–29% of cases after TIP urethroplasty [15,16].

The present series is our experience with TIP repair of distal hypospadias, covering the neourethra with a dartos flap fashioned as a double- (Group I) or single-layer (Group II) cover. Our results showed that the fistula rate was higher among urethroplasties covered with a single layer (8%) than with a double layer (none), although the difference was not statistically significant (\(P = 0.1\)). Many other studies have compared a single and double dartos interposition flap after TIP urethroplasty (Table 2) [15–21].

In almost all of these studies the double-dartos flaps resulted in a better outcome for fistula formation, but a statistically significant difference was reported only by Appignani et al. [15], and not by Yigiter et al. [16], Elsayed et al. [17] nor Erol et al. [18]. Bertozzi et al. [22], in a multicentre review of 394 repairs covered with double-dartos flaps, reported fistulae in only four cases (1.01%). All of the fistulae were small and healed spontaneously after a few weeks. By contrast with the present results for the fistula rate in repairs covered with single dartos flaps (8%), Djordjevic et al. [13,14] reported no fistula formation with single dartos flaps, but such an outcome was not the case with others using single dartos flaps, who reported fistula rates of 13% [20] and 26% [17]. In the present study a meatal stenosis was reported in one patient who received a single dartos flap (2%), and this case was associated with a fistula. Another case of meatal stenosis was reported with a double-dartos flap (2%) and was detected late in the follow-up (at 3 months) after complete healing of the urethroplasty.

Others have reported meatal stenosis in 0.7% and 17% of patients after a TIP repair [2,23]. Bertozzi et al. [22], in their multicentre analysis of double-dartos flaps, reported a meatal stenosis rate of 2.8% of cases. In Group I there was one case (2%) of repair breakdown and wound dehiscence. This failure of repair was
reported early in the study and was associated with a difficult approximation of the glans wings, which might have caused pressure ischaemia of both the urethroplasty and the glans edges. Elbakry [24] argued against using dartos flaps because they hinder a tension-free closure of the glans and increase the risk of glans dehiscence, and these complications are more likely to occur with double-dartos flaps. We anticipated such complications in further cases by using a generous glans dissection, and fanning out the distal ends of the two halves of the dartos flap to reduce its bulk, and we detected no further cases of glans dehiscence or repair breakdown. Our result approached those of Bertozzi et al. [22] for double-dartos flaps, in which no cases of glans dehiscence were reported in 394 patients.

Despite many studies there are still heterogeneous and conflicting data on the superiority of double vs. single dartos neourethral covers [6]. Most of these studies [15–17,23] were retrospective, as was the present study. The only prospective, randomised study was by Erol et al. [18], but this study had no control group (i.e. a group with no dartos interposition).

Another point that might contribute to the heterogeneity of the results is that most of these studies [15–17,23] enrolled cases with distal, mid-penile and proximal hypospadias, and because there is evidence of a high fistula rate with more proximal hypospadias [3], the present study included only cases of primary distal hypospadias. Patients with mid- or proximal hypospadias were excluded, to allow an appropriate evaluation of dartos interposition flaps as a method for preventing fistula formation. Erol et al. [18] similarly only included patients with distal hypospadias. However, despite including different hypospadias defects, all of these studies showed overall excellent results with double-dartos flaps, regardless of the proximity of the defect, and if double-dartos flaps achieved good results with proximal defects, it is more logical to achieve the same or better results with distal defects. Thus the present study, having been limited to distal lesions, might not have added very much to the study design.

Table 1  Postoperative complications in two groups.

| Complications, n (%) | Group I (double) | Group II (single) | Total | $P$ |
|---------------------|------------------|------------------|-------|----|
| n patients          | 48               | 52               | 100   |    |
| Fistulas            | 0                | 4(8)             | 4(4)  | 0.12|
| Repair breakdown    | 1(2)             | 0                | 1(1)  | 0.48|
| Meatal stenosis     | 1(2)$^a$         | 1(2)$^b$         | 2(2)  | >0.99|
| Total               | 2(4)             | 4(8)             | 6(6)  | 0.44|

$^a$ Meatal stenosis in Group I developed late after full healing of urethroplasty, with no associated fistula.

$^b$ Meatal stenosis was associated with a fistula in one patient from Group II.

Table 2  Studies comparing single and double dartos interpositional flap after TIP urethroplasty.

| Study | No. of cases according to urethral cover | Fistula rate (%) |
|-------|------------------------------------------|------------------|
| [19]  | Double 42 | 0 | 3.7 |
|       | Single 54 | 0 | 13.7 |
| [20]  | Double 45 | 0 | 0.7 |
|       | Single 29 | 0 | 8.1 |
| [21]  | Double 28 | 0 | 6.3 |
|       | No cover 10 | 0 | 15 |
| [18]  | Double 40 | 0 | 0.7 |
|       | Single 37 | 0 | 10 |
| [15]  | Double 57 | 0 | 29.4 |
|       | Single 40 | 0 | 26 |
|       | No cover 40 | 0 | 26 |
| [16]  | Double 132 | 0 | 29.4 |
|       | Single 23 | 0 | 26 |
|       | No cover 17 | 0 | 26 |
| [17]  | Double 40 | 0 | 6.3 |
|       | Single 37 | 0 | 15 |
| Present | Double 48 | 0 | 7.7 |
|        | Single 52 | 0 | 15 |
Elbakry [6] stated that successful healing after hypospadias repair is the end result of perfecting all of the technical steps. We agree with this statement, because if a second-layer cover were protective against fistula formation, then fistulae would still not develop despite the use of these flaps. Hafez and Helmy [23], assessing penoscrotal hypospadias repaired with TIP, recently reported that the use of a dartos flap cover during repair showed no statistically significantly better success rates for a surgeon after 2 years of fellowship training than for a surgeon performing the operation early in fellowship training.

Also, it is unclear why the fistula rate was not affected when Snodgrass et al. [26] did not use a second-layer cover after TIP repair for distal hypospadias. This finding could be explained by some surgeons reaching a level of precision with the surgical technique at which they are able to compensate for the healing and promoting effects of the neourethral cover.

The belief that the neourethral cover acts only as a mechanical barrier that stops urine leakage might not be true, because no barrier can stop urine from leaking, even if the cover is in two layers. Therefore, the lower fistula rate with a double- vs. a single-layer dartos cover might be related to the higher vascularity and the second layer ‘backup’ of the double-dartos compared to the single dartos.

One limitation of the present study was that it was retrospective, so it might have been difficult to control selection bias. Also, there was no control group in which no cover was used for the urethroplasty, but in our department we are not permitted, for ethical purposes, to leave a hypospadias repair with no cover. Also, the number of patients in each group was insufficient for a valid recommendation. Another limitation was the lack of an intraoperative consideration of the preputial vascular anatomy, as described by Perovic and Radojcic [27], in which not all preputial dartos flaps can be divided into right and left halves with equally good blood supplies.

Because there have been promising results with a double-dartos cover, and because the surgical technique is not very different from the classical single layer, we recommend that this technique should be assessed in a prospective, controlled trial on many patients, to facilitate the standardisation of the appropriate method for neourethral protection.

In conclusion, a double-dartos neourethral cover in TIP hypospadias repair seems to be more effective than a single layer for preventing a fistula, despite the present results not being statistically significant, and it was technically easy and not time-consuming. However, the protective effect of double-dartos flaps must be evaluated appropriately in a prospective, randomised and controlled study in a large number of patients.

Conflict of interest

No conflict of interest to declare.

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